

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, 2023  
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 85-3681132  
(State or other jurisdiction of  
incorporation or organization) (I.R.S. Employer  
Identification No.)  
3513 Brighton Blvd.,  
Suite 410  
Denver,  
CO 80216  
(Address of principal executive offices) (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 \$11.50 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 ☐

☒

Smaller reporting company

Non-accelerated filer

☒

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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on Nasdaq Capital Market on January 5, 2024 was approximately \$

24,232,239

.

The number of shares of Registrant's Common Stock outstanding as of March 31, 2024, was

75,419,458

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#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2024 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 2024 proxy statement on or before April 29, 2024.

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## Table of Contents

	Page
<a href="#"><u>Cautionary Note Regarding Forward-Looking Statements</u></a>	1
<b>PART I</b>	
Item 1. <a href="#"><u>Business</u></a>	3
Item 1A. <a href="#"><u>Risk Factors</u></a>	30
Item 1B. <a href="#"><u>Unresolved Staff Comments</u></a>	63
Item 1C. <a href="#"><u>Cybersecurity</u></a>	63
Item 2. <a href="#"><u>Properties</u></a>	63
Item 3. <a href="#"><u>Legal Proceedings</u></a>	63
Item 4. <a href="#"><u>Mine Safety Disclosures</u></a>	63
<b>PART II</b>	
Item 5. <a href="#"><u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u></a>	64
Item 6. <a href="#"><u>[Reserved]</u></a>	66
Item 7. <a href="#"><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	67
Item 7A. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	81
Item 8. <a href="#"><u>Financial Statements and Supplementary Data</u></a>	86
Item 9. <a href="#"><u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u></a>	141
Item 9A. <a href="#"><u>Controls and Procedures</u></a>	141
Item 9B. <a href="#"><u>Other Information</u></a>	142
Item 9C. <a href="#"><u>Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</u></a>	142
<b>PART III</b>	
Item 10. <a href="#"><u>Directors, Executive Officers and Corporate Governance</u></a>	143
Item 11. <a href="#"><u>Executive Compensation</u></a>	143
Item 12. <a href="#"><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></a>	143
Item 13. <a href="#"><u>Certain Relationships and Related Transactions, and Director Independence</u></a>	143
Item 14. <a href="#"><u>Principal Accounting Fees and Services</u></a>	143
<b>PART IV</b>	
Item 15. <a href="#"><u>Exhibits, Financial Statement Schedules</u></a>	144
Item 16. <a href="#"><u>Form 10-K Summary</u></a>	148

## 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 the Company believes that its plans, intentions, and expectations reflected in or suggested by these forward-looking statements are reasonable, the Company cannot assure you that it 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 Company’s 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 the Company’s future results and could cause those results or other outcomes to differ materially from those expressed or implied in the Company’s forward-looking statements:

- our plans to conduct further clinical trials and anticipated enrollment, clinical sites, 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 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; and
- our intended use of net proceeds from our public offerings.

You should understand that the following important factors, among others, could affect the Company's future results and could cause those results or other outcomes to differ materially from those expressed or implied in the Company's forward-looking statements:

- the Company's future capital requirements and sources and uses of cash;
- the Company's ability to obtain funding or raise capital for its operations and future growth;
- any delays or challenges in obtaining FDA approval of the Company's SCD product candidates;
- economic downturns and the possibility of rapid change in the highly competitive industry in which the Company operates;
- the ability to develop and commercialize its products or services following regulatory approval of the Company's product candidates;
- the failure of third-party suppliers and manufacturers to fully and timely meet their obligations;
- product liability or regulatory lawsuits or proceedings relating to the Company's products and services;
- inability to secure or protect its intellectual property;
- dispute or deterioration of relationship with the Company's major partners and collaborators;
- the ability to maintain the listing of its Common Stock on Nasdaq;
- the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition, and the ability of the Company to grow and manage growth profitably; and
- 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 the Company assess the impact of all such risk factors on its 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 the Company or persons acting on its behalf are expressly qualified in their entirety by the foregoing cautionary statements. The Company undertakes 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.

#### EXPLANATORY NOTE

*Restatement of Consolidated Financial Results for the fiscal year-ended December 31, 2022, and interim periods for the fiscal year-ended December 31, 2023.*

As previously disclosed in the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on March 27, 2024, certain of the Company's previously filed interim unaudited and annual audited consolidated financial statements should no longer be relied upon and a restatement is required for these previously issued consolidated financial statements. The Company has restated herein its consolidated financial statements as of and for the year ended December 31, 2022 (see Notes 3 and 19). In addition, the Company has restated its unaudited quarterly financial data for the first three quarters of the year ended December 31, 2023 as presented in Note 19, Restatement of Unaudited Quarterly Results.

## 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 its 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 clinical stage medical technology company developing a proprietary platform therapy, our Selective Cytopheretic Device ("SCD"), to reduce the consequences of hyperinflammation on vital organs. The inflammatory response is critical to fend off infections and repair damaged tissue in the body. Central to inflammation are the cells within blood and lymph circulatory systems, called white blood cells (primarily neutrophils and monocytes), also referred to commonly as "pus" cells.

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 the foreign pathogens or damaged tissue, enhancing the immune response.

If the inflammatory response becomes excessive and dysregulated (referred as proinflammatory), normal neutrophil cells die off ("apoptosis"), allowing the inflammatory cells to continue to produce cytokines, 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 heart, lung, kidney and liver diseases. 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. The cytokine storm, when left uncontrolled, can lead to organ damage and even death.

Based on clinical and preclinical studies conducted over the last 15 years, the Company's technology has shown promise in modulating the degree of activity of proinflammatory cells to help reduce tissue damage and speed the repair and recovery of organ function. We believe this approach, if successful, will transform the ability of clinicians to treat acute organ failure in the intensive care unit ("ICU") and to improve organ function in hospitalized patients.

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 is an extracorporeal synthetic membrane device designed to be easily integrated into existing continuous renal replacement therapy ("CRRT") systems that are commonly installed in hospitals, including in ICUs throughout the United States. Once approved and commercialized, our SCD would initially target acute kidney injury in both the pediatric CRRT population as well as adults on CRRT. In addition, we are developing our SCD to address inflammation associated with chronic dialysis and chronic heart failure.

There is substantial clinical demand for safe and effective control of hyperinflammation. The use of our SCD to reverse the cytokine storm in pediatric and adult patients with acute kidney injury on CRRT in clinical studies with more than 140 patients reduced mortality rates by 50%, and, of those patients who survive 60 days, none have required dialysis.

## **Pediatrics**

In June 2022, we submitted a humanitarian device exemption ("HDE") application with the U.S. Food & Drug Administration ("FDA") for pediatric patients with acute kidney injury ("AKI") on CRRT. On February 22, 2024, we received the FDA HDE Approval Order, which allows sales to qualified healthcare facilities.

We intend to continue to shape our commercial and distribution strategy by expanding indications and pursue collaborations with partners in markets where such partners provide strategic capabilities in commercializing our product candidates and enabling access to specific patient populations. On December 27, 2022, we entered into a license and distribution agreement (the "Distribution Agreement") with Nuwellis, Inc. ("Nuwellis"), pursuant to which we appointed Nuwellis as our exclusive distributor for the sale and distribution of our pediatric SCD product throughout the United States once we receive from the FDA a written authorization to market such product for pediatric use pursuant to our HDE application. Pursuant to the Distribution Agreement, we received an upfront payment, and will receive milestone payments upon achievement of certain milestones and royalties on gross sales of the SCD product. The Distribution Agreement has an initial term commencing on December 27, 2022 and shall end on the three (3) year anniversary from the date that is the earlier of (a) ninety (90) days after we receive FDA authorization to market such SCD product for pediatric use and (b) the first commercial sale of the SCD product. The term of the Distribution Agreement may be automatically extended for additional terms of one (1) year and for a total of two (2) consecutive extensions. Each party has the right to terminate the Distribution Agreement for material breach if such breach is not cured within ninety (90) days after written notice and we have additional rights to terminate the Distribution Agreement in accordance with other terms set forth in the Distribution Agreement. On December 29, 2023, the Distribution Agreement was amended and the Distributor shall pay Supplier the following milestone payments set forth below on the later to occur of (i) 30 days after achievement of the corresponding milestone events or April 1, 2024, and the Distributor has waived the repayment of the upfront payment from Supplier.

## **Adults**

In addition, on February 9, 2023, we received approval from the FDA of our investigational device exemption ("IDE") application to conduct a pivotal study evaluating the effectiveness of SCD in reducing hyperinflammation in adults with AKI requiring CRRT. The Company began enrollment in Q2 2023 and expect to generate interim study results during the second half of 2024 and topline study results and submission of a Pre-market Approval ("PMA") application in the first half of 2025. There is no guarantee that we will complete the AKI adult trial in a timely manner, or at all, nor will there be any assurance that positive data will be generated from such trial. Even if we are able to generate positive results from these trials, the FDA may require us to conduct additional trials to support the study, or disagree with the design of the trials and request changes or improvements to such design.

We have received two additional Breakthrough Device Designations ("BDD") in 2023, totaling three. On April 29, 2022, we received a Breakthrough Device Designation ("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 such trial.

On September 28, 2023, we received Breakthrough Device Designation for our patented and cell-directed SCD 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 Breakthrough Device Designation for our patented and cell-directed SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure. We have been granted three

Breakthrough Device Designations from the FDA for the SCD device, each of which is expected to expedite the clinical development and regulatory review of the SCD for use in the designated patient population.

We believe that our novel therapeutic device is readily applicable for use in other indications, which will require additional clinical studies and FDA approval and increase the addressable market for our SCD technology. As we continue our work to expand indications, we believe we will have the ability to take advantage of economies of scale to reduce costs of production. We believe our scalable manufacturing process demonstrates a significant competitive advantage in the hyperinflammatory market.

We have pursued patent protection for our SCD technology as well as other technologies. Our patent portfolio consists of 40 patents and 8 pending patent applications in the U.S. and certain foreign jurisdictions. Of these patents and patent applications 33 are owned exclusively by us, and 15 are co-owned with the University of Michigan ("UOM"). UOM has granted to us an exclusive worldwide, royalty bearing license to UOM's interest in all of the co-owned patents and applications. This license permits the Company to commercialize our SCD in all human therapeutic indications. For more information, see " — Intellectual Property" below.

Our senior management team and Board have an average of more than 19 years of experience in the healthcare industry, including expertise in medical affairs, commercialization and distribution in our initial therapeutic priority areas. We are also supported by a group of well-respected scientific advisors who are experts in the development of our technology and products.

### ***Our Approach***

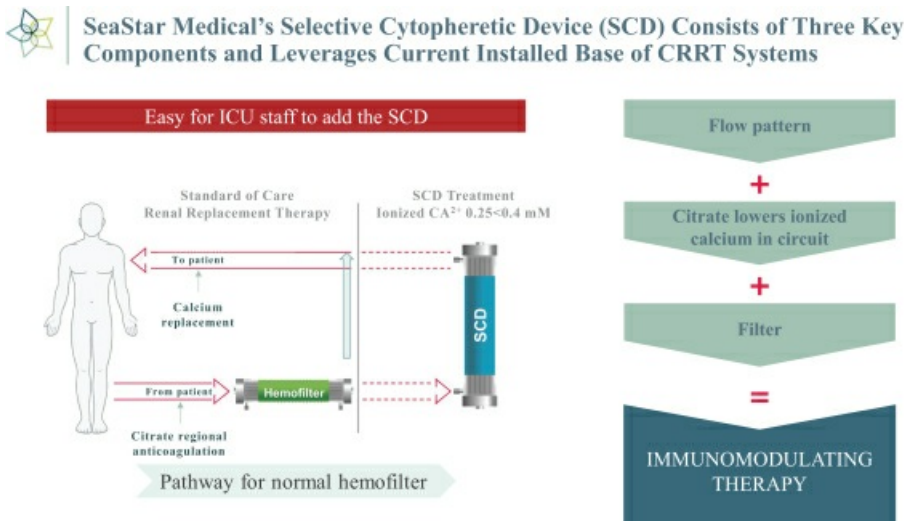
The acute inflammatory response occurs in a well-defined coordinated sequential response. Neutrophils are the first responders followed by monocytes. The monocytes, as they egress into tissue also follow another sequence of differentiation into tissue macrophages. The first are proinflammatory macrophages, followed by patrolling, reparative macrophages.

This complex tightly 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 not, further tissue destruction may occur when uncontrolled hyperinflammation leads to degradative reparative processes with worsening tissue or organ function. If this excessive systemic inflammation is severe and prolonged, multi-organ failure, including cardiovascular, respiratory, kidney, liver 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 activated cells, is a potentially transformative, if not disruptive, therapeutic approach to a range of acute and chronic inflammatory disorders.

Our SCD is an extracorporeal synthetic membrane device designed to bind activated leukocytes (neutrophils and monocytes) as part of a CRRT extracorporeal circuit. When added to the circuit and release of a standard CRRT system (using regional citrate anticoagulation) immediately following a standard hemofilter cartridge, blood within



the standard hemofilter cartridge enters our SCD and disperses among the fibers of the device. Upon exiting our SCD under a low calcium environment, the blood is returned to the patient's body.

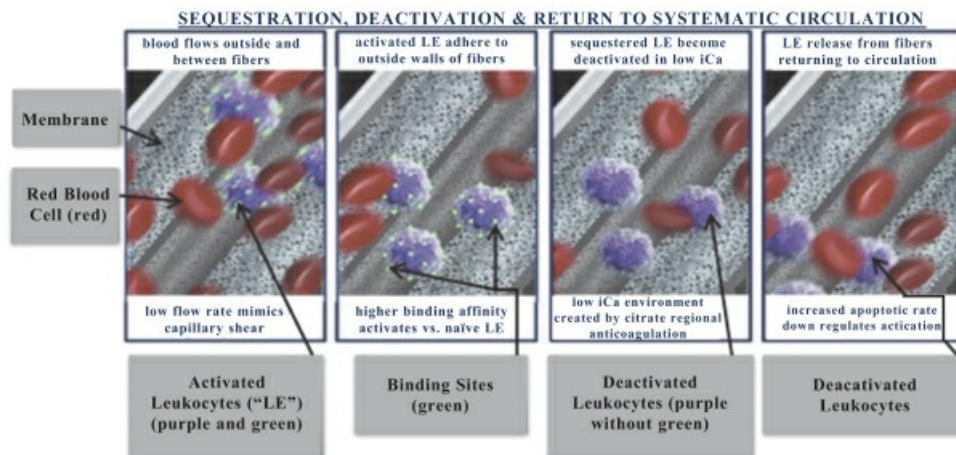


Our SCD delivers its therapeutic benefit by attenuating the excessive inflammatory response of activated neutrophils and monocytes. Uninterrupted, the excessive inflammatory response progresses to multi-organ failure ("MOF"), with documented increases in both morbidity and mortality in critically ill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

### Mechanism of Action

The mechanism of action of our SCD consists of two steps: 1) binding activated neutrophils and monocytes on our SCD biomimetic membrane and 2) deactivating the activated neutrophils by maintaining a specified ionized calcium level within our SCD. Our SCD utilizes clinically approved regional citrate anticoagulation protocols to lower the ionized calcium level, which prevents blood clogging within the circuit and immuno-modulates the activated

neutrophils, which are then returned to the patient. Calcium is then infused into the blood returning to the patient from the SCD, thereby maintaining normal calcium levels in the patient throughout the process.



#### Our SCD and Neutrophils

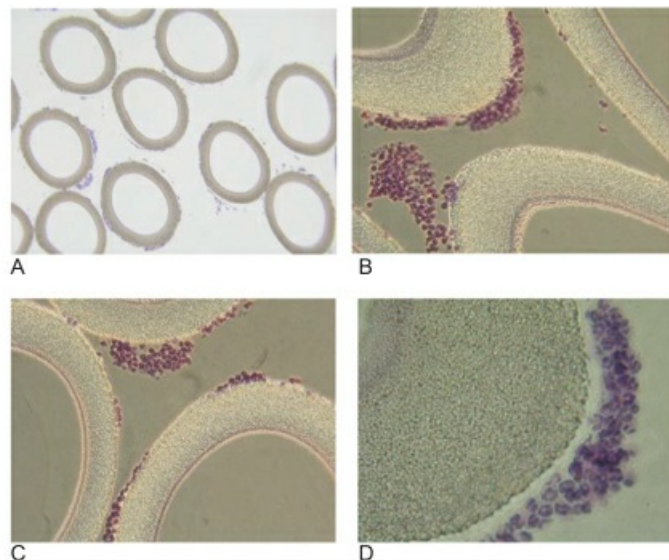
Calcium plays a critical role in many biological processes. In the case of neutrophils, calcium can have a profound effect on their activity. It has been shown that lowering calcium levels in neutrophils can lead to higher levels of neutrophil apoptosis (deactivation). Our SCD is designed to selectively bind the most highly activated neutrophils (associated with hyperinflammation) and in a low iCa environment, the activated neutrophils are deactivated, which has the effect of reducing hyperinflammation. 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. Calcium also has an important influence on monocyte activity. A high percentage of the circulating monocyte subtypes (M1 proinflammatory versus M2 patrolling, reparative) has been shown to influence the degree of acute organ injury and chronic organ dysfunction. In vitro, our SCD membranes in a low iCa perfusion circuit binds the proinflammatory monocytes within the blood more selectively. This selective binding has been shown in clinical trials and results in less proinflammatory circulating monocytes in inflammatory disorders. It is important to note that our SCD does not sequester 100% of these monocytes as they are important to maintaining immune homeostasis.

#### Histological evaluation of our SCD

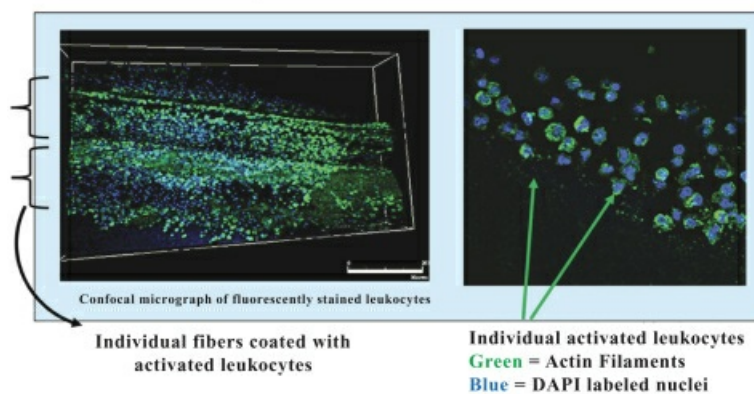
Microscopy of our SCD after being used for patient treatment demonstrated the binding of leukocytes on the outer surface of the membranes of the cartridge along the blood flow path within the extracorporeal circuit. The bound leukocytes were dominated by neutrophils and monocytes (see Figure 1 below).



**Figure 1:** Activated Leukocytes adherence to the membrane. Light micrograph stained with Hematoxylin and Eosin (H&E). Panel A: Low-power micrograph showing adherent cells around each fiber (160x). Panel B and 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 ability of neutrophils and monocytes to bind to the outer walls of the hollow fiber membranes (figure below) rather than the inner walls, which is the conventional blood flow path, is due to the difference in shear forces of blood flow. The shear force of our SCD is similar to capillary flow providing a microenvironment for the neutrophils and monocytes, enabling the cells to catch and release.

#### Activated Leukocytes Adhere To Surface of Fibers In SCD



### ***Our Market Opportunity***

We are a therapeutic medical device company. Our clinical data was 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 PMA study in adult AKI. In the long term, we intend to pursue the application of our SCD technology to additional indications, including acute respiratory distress syndrome, chronic dialysis, cardiorenal syndrome and hepatorenal syndrome and others.

### ***Our Initial Market Opportunity in Acute Kidney Injury***

We believe AKI has increasingly received the attention of healthcare professionals and academic publications that reveal the devastating clinical and financial impact of what is most-often a multi-organ syndrome. 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 Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease ("RIFLE"), an international consensus classification for AKI staging and diagnosing guidelines introduced in 2004, the Acute Kidney Injury Network ("AKIN") 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 both 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 of 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 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, complimentary therapies, and pharmacologics. As hospital administrators and government officials gain understanding of the impact and burden of AKI increases, 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 approximately 50%, treating AKI is increasingly of 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 sub-set of the 6 million AKI patient population.

The AKI market needs 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 expand 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 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. In addition, we have submitted the HDE for the pediatric AKI indication in June 2022. On February 22, 2024, we received the FDA HDE Approval Order, which allows sales to qualified healthcare facilities. In February 2023, the Company received FDA IDE approval for the adult AKI indication. This indication has received the FDA BDD for our SCD therapy targeting AKI adult patients, 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 Breakthrough Device Designation for our patented and cell-directed SCD 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 Breakthrough Device Designation for our patented and cell-directed SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure. We have been granted three Breakthrough Device Designations from the FDA for the SCD device, each of which is expected to expedite the clinical development and regulatory review of the SCD 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 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 product candidates 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 in 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 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 anticipate the potential commercial launch of our SCD product candidates 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 filters, 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 Stage Product Candidates

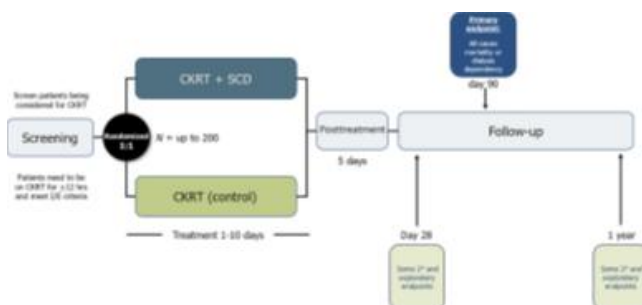
The following disclosure summarizes the key clinical studies in which our SCD product candidates (Quelimmune for pediatrics) have been evaluated. All trials and studies below are conducted under IDEs approved by the FDA.

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 23, 2024, we announced a final Approval Order for the HDE.

### Clinical Progression

#### SCD 006 Pivotal Study ("SCD 006") Design

We are actively enrolling and treating patients in a pivotal clinical trial of the SCD for the treatment of AKI in adults under a granted Breakthrough Device Designation (BDD) (April 2022) by the FDA. This trial ("SCD-006"; NCT05758077) is a 200 subject, prospective, multi-center, open label, randomized, two-arm comparative pivotal study conducted in the United States. SCD-006 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 recently 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 SCD-006 IDE Protocol to the FDA on January 6, 2023 and attained approval in March 2023. We began enrollment in the second quarter of 2023 and we anticipate the enrollment period to last 15 to 18 months. 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 approval process for SCD-006.

We currently anticipate generating interim results from this trial in late 2024 and topline study results and submission of a PMA application by early 2026. Additional clinical studies under IDEs include cardiorenal syndrome and hepatorenal syndrome. We are also conducting exploratory clinical research at 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**

*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, doi: <a href="https://doi.org/10.1016/j.xkme.2024.100">https://doi.org/10.1016/j.xkme.2024.100</a> ). See additional details below on the SCD-PED studies.
SCD-PED-02	To assess the safety of SCD in children with AKI weighing $\geq 10$ kg and $\leq 20$ 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, doi: <a href="https://doi.org/10.1016/j.xkme.2024.100">https://doi.org/10.1016/j.xkme.2024.100</a> ). See additional details below on the SCD-PED studies.



<b>SCD-005</b>	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).
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#### 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 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.

A total of 134 patients were enrolled in 21 United States medical centers. 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 0.4 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. 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.

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. Due to the reliance of the SCD on a narrow intra-circuit iCal range for functional efficacy and the concern that patients randomized to the SCD were not receiving effective therapy due to insufficient iCal levels, the interim analysis was performed early, after enrollment of 134 patients. Enrollment was paused on May 24, 2013, to assess the clinical impact of the calcium shortage on study endpoints. 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. Furthermore, none of the SAEs were considered 'definitely' device related per the principal investigator. The amount of time patients in both the control and treatment group 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. Furthermore, 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% of SCD treated subjects versus 58% 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). 5/6 (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.

#### ***Chronic Applications in Inflammatory Disorders and Corresponding Studies at the University of Michigan ("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 phenotype. 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.

##### *Cardiorenal Syndrome*

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 present with this disorder; this condition is increasing in incidence with an estimated one million hospital admissions annually in the United States. 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.

The CRS clinical trial at the UoM is a safety and efficacy dose escalation study in 10 patients that was designed to evaluate whether ultrafiltration therapy in CRS, a disease with a dismal prognosis and currently ineffective therapy, with SCD therapy will improve cardiac and renal (production of urine) functions. 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. One patient has been successfully treated with the SCD thus far in this study. 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.

#### *Hepatorenal Syndrome (HRS)*

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.

#### *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 source critical components from vendors that have been approved and qualified through our vendor management program. Fresenius Medical Care North America ("FMCNA") is the current supplier of the filter used in our pediatric acute kidney injury indication. In March 2022, we entered into a supply agreement (the "Supply Agreement") with an FMCNA affiliate, Fresenius USA Marketing, Inc. ("FUSA"), to supply certain filters at an agreed amount per case for use in our SCD product in our upcoming clinical trial and any additional clinical trials. We may resell the filters as part of the SCD system in both an Emergency Use Authorization application as well as a future PMA-approved product. The initial term of the Supply Agreement is for three years commencing on March 31, 2022. 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.

We are in the process of developing a second source for the adult and pediatric filters, which will enable us to better manage any supply disruptions. In addition, we have secured a supplier to provide the tubing set required to assemble the SCD device, although we are able to identify and secure additional sources of supplies for the tubing set as it is readily available in the market.

### **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 pediatric and adult products in the United States. If during such period, SeaStar Medical elects to promote and sell the SCD through distributors, SeaStar Medical will be required to provide FUSA with a right of first refusal to be SeaStar Medical's 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 receive written authorization from the FDA to market our SCD for pediatric use pursuant to our HDE application. On December 29, 2023, the Distribution Agreement was amended and the Distributor shall pay Supplier the following milestone payments set forth below on the later to occur of (i) 30 days after achievement of the corresponding milestone events or April 1, 2024, and the Distributor has waived the repayment of the upfront payment from Supplier.

### **Third-Party Reimbursement**

We anticipate that coverage and reimbursement by Centers for Medicare and Medicaid Services ("CMS") and private payors will be essential for most 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 the Company's Business Operations — Should the Company's*

products be approved for commercialization, lack of third-party coverage and reimbursement for the Company's devices could delay or limit their adoption."

## Intellectual Property

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 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. A U.S. patent term may be shortened, if a patent is terminally disclaimed by its owner, over another patent.

The Company currently has 18 issued U.S. patents and 3 pending U.S. patent applications. The Company also has 22 issued foreign patents and has 3 pending foreign patent applications. The Company's issued patents begin to expire in 2028, with the last of these patents expiring in 2034, 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, 2023:

	US	Foreign	US	Foreign
SCD Technology (Patent Families 1-5)	16	22	2	3
Other Technology (Patent Families 6-10)	2	—	3	—
Total	18	22	5	5

With respect to our SCD technologies, we own patents and patent applications in five patent families. The patents and applications in Patent Family 1 are co-owned by the Company and UOM. The patents and applications in Patent Families 2-5 are solely owned by the Company. 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 and one pending U.S. patent application 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, and the pending application, if granted, will expire in 2028, assuming that the required maintenance fees are paid. We also co-own with UOM counterpart patents granted in Canada, Japan and New Zealand. 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 subject 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
United States	Pending	2028*	Systems for treating leukocytes and platelets and methods for treating subject having inflammatory conditions by processing leukocytes or platelets
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

\* 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.

Pursuant to a license agreement with UOM (as amended, 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 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 UOM a royalty fee equal to 1% of net sales and reimbursement of patent costs. To date, we have not paid and do not owe any royalty payments under the UOM License Agreement. We have paid approximately \$124 thousand in patent costs reimbursement since January 1, 2020. The UOM License Agreement also imposes certain diligence obligations on us and requires us to achieve specified milestone events by a certain date. Under the UOM License Agreement, UOM's liability is limited and we agreed to indemnify and hold 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.

The UOM License Agreement will remain in effect, unless earlier terminated, until all licensed patents have expired. If we materially breach the terms of the UOM License Agreement, 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 UOM may terminate the agreement immediately upon our breach. We may also terminate the agreement by giving UOM 90-day advanced notice provided certain conditions are met.

In addition to the co-owned patents and patent applications in Family 1, we also solely own four additional patent families (Families 2-5) directed to the SCD technology. Patent Family 2 includes one U.S. patent and one pending U.S. patent application directed to a second generation of the SCD cartridge and methods for using our SCD cartridge to process leukocytes. The patent will expire in 2031, and the application, if granted, will expire in 2031, assuming that the required maintenance fees are paid. Counterpart patents have been granted in Australia, Europe, and Japan with the European patent having been validated in France, Germany, Italy, Spain, and the United Kingdom, and a patent application is pending in Canada. These patents, and the application, if granted, 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	2031	Cartridge for treating leukocytes or platelets
United States	Pending	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, & UK	Granted	2031	Cartridge for sequestering leukocytes or platelets
Canada	Pending	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

\* 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.

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 patent applications are pending in Canada and Europe. These patents, and patent applications, 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	Pending	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.

Patent Family 5 includes three U.S. design patents, three European Community design patents, and three United Kingdom design patents directed to a medical device connector as follows:



#### Patent Family 5

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2025	Design patent directed to a medical device connector
United States	Granted	2024	Design patent directed to a medical device connector
United States	Granted	2025	Design patent directed to a medical device connector
United Kingdom	Granted	2034	Design patent directed to a medical device connector
United Kingdom	Granted	2034	Design patent directed to a medical device connector
United Kingdom	Granted	2034	Design patent directed to a medical device connector
European Community	Granted	2034	Design patent directed to a medical device connector
European Community	Granted	2034	Design patent directed to a medical device connector
European Community	Granted	2034	Design patent directed to a medical device connector

With respect to our other technologies, we solely own patents and patent applications in five additional patent families (Patent Families 6-10) which are summarized as follows:

#### Patent Family 6

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Pending	2040*	Devices and methods for preparing a donor organ for transplantation

\* Expiration date if application is granted.

#### Patent Family 7

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Pending	2040*	Device and methods for reducing rejection of a transplanted organ in a recipient

\* Expiration date if application is granted.

#### Patent Family 8

	Jurisdiction	Status	Expiration Date	Subject Matter
	PCT	Pending	2041*	Devices and methods for treating cytokine release syndrome and tumor lysis syndrome

\* Expiration date if application is granted.

#### Patent Family 9

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

#### Patent Family 10

	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, we have the additional challenge of establishing medical industry support, which will be driven by treatment data resulting from human clinical studies. Should our device become market cleared by the FDA or the 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 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. Lack of third-party coverage and reimbursement for the Company's devices could delay or limit their adoption, and as such harm our competitive advantage in the market.

#### Sales and Marketing

While currently we do not have a significant sales and marketing capability, we are actively pursuing resources and support for commercialization efforts in light of obtaining FDA HDE approval for pediatrics with AKI on February. On December 27, 2022, we entered into a U.S. License and Distribution Agreement with Nuwellis, for the pediatric SCD that received approval on February 23, 2024. On December 29, 2023, we amended the distribution and license agreement with Nuwellis. We will leverage their existing sales team that has similar call points to those needed for the pediatric SCD. We intend to build or contract for medical education as well as clinical training and support.

## Government Regulation

Our SCD product is subject to regulation by numerous regulatory bodies, primarily the FDA, and comparable international regulatory agencies. 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 includes a system of cartridges to interact with the patient's hyperinflammatory cells to allow them to become deactivated 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 its premarket development, review and approval of our 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, or recalls, 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 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 or PMA 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 pre-market 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 may include performance standards, post market surveillance, patient registries, and/or guidance documents. Most Class II devices require the manufacturer to submit to the FDA a pre-market 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 placed in Class III. In addition, novel devices that have not been previously classified by the FDA or that have 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. 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 assure that they are used in a safe and effective manner. We believe that SCD will be classified as a Class III device and as such will be subject to PMA submission and approval.

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 this challenge, 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 Human 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.

The HDE is a marketing application for an HUD under Section 520(m) of the FD&C Act. 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 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.

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 8000. 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 x 8000).

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.

The SCD (Quelimmune pediatrics) is eligible to sell for a profit as per the Final Approval Order issued to Company on February 23, 2024.

#### *Pre-market Approval Pathway*

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

After a pre-market approval 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 pre-market approval 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 ("QSR"). The agency also may inspect one or more clinical sites to assure 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.

#### *Clinical Trials*

Clinical trials are almost always required to support pre-market approval 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 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 the FDA's IDE requirements for investigator selection, trial monitoring, reporting and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, 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 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 apply. These include:

- establishment registration and device listing;
- the QSR, 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;
- 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;
- medical device reporting regulations, which require that manufactures 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
- corrections and removal reporting regulations, which require that manufactures 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 device, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new PMA or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and

actions in reviewing PMA supplements as it does in reviewing original PMAs. 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, 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 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 will 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, 2023, we had 12 full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

#### **Corporate History**

The Company was initially incorporated as the Predecessor under the name Nephron, Inc. on June 6, 2007. On August 3, 2007, we amended our corporate name to CytoPhex, Inc. On June 19, 2019, we amended our corporate name to SeaStar Medical, Inc., herein the Predecessor as previously 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](http://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**

- The Company has incurred significant losses since its inception and may continue to incur significant losses for the foreseeable future.
- The Company has not generated any significant revenue and may never be profitable.
- The Company has a limited operating history.
- If the Company fails to obtain additional financing, it would be forced to delay, reduce or eliminate its product development program.
- The Company may not use its net operating losses to offset future taxable income Risks Related to the Company's Business Operations.
- The Company may not receive approval from the FDA to market its product.
- The Company is subject to certain risks relating to pursuing an FDA approval process.
- The Company may not be able to manage its growth effectively.
- The Company will initially depend on revenue generated from a single product.
- The Company may fail to comply with extensive regulations of United States and foreign regulatory agencies.
- Delays in successfully completing the Company's planned clinical trials could jeopardize its ability to obtain regulatory approval.
- The Company has limited experience in identifying and working with large-scale contracts with medical device manufacturers.
- Difficulties in manufacturing the Company's SCD could have an adverse effect upon its revenue and expenses.
- The Company faces intense competition in the medical device industry.
- The Company outsources many of its operational and development activities for which it may not have full control.
- The Company may be subject to enforcement action if it engages in improper marketing or promotion of its products.
- The Company is subject to stringent and changing privacy laws, regulations and standards
- The Company depends on key personnel and its inability to attract and retain qualified personnel could impede its ability to achieve its business objectives.
- The Company's products may in the future be subject to product recalls.
- The Company's business is subject to risks arising from future pandemics.

- The Company's forecasted operating and financial results may not be accurate
- The Company's estimates of market opportunity, industry projections and forecasts of market growth may prove to be inaccurate.
- The Company relies upon exclusively licensed patent rights from third parties which are subject to termination or expiration.
- If the Company is unable to obtain and maintain sufficient patent protection for its products, the Company's ability to commercialize such products successfully may be adversely affected.
- The Company 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 its products
- The Company could become involved in intellectual property litigation that could be costly, result in the diversion of management's time and efforts.
- Issued patents covering one or more of the Company's products could be found invalid or unenforceable if challenged in patent office proceedings, or in court.
- If the Company is unable to protect the confidentiality of its trade secrets, the value of its technology could be adversely and materially affected, and its business could be harmed.
- Competitors may develop superior products based on new technologies.
- Changes to the patent law in the United States and other jurisdictions could diminish the value of the Company's patents in general, thereby impairing the Company's ability to protect its products.
- Intellectual property rights do not necessarily address all potential threats to the Company's competitive advantage.
- The Company may obtain only limited geographical protection with respect to certain patent rights,
- The Company does not have long-term experience operating as a United States public company.
- The Company's 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 the Company.
- The Company identified a material weakness in its internal control over financial reporting, which may result in restatements of financial statements.
- The Company 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

#### **Risks Relating to the Company's Financial Condition**

***The Company has incurred significant losses since its inception and anticipates that it will continue to incur significant losses for the foreseeable future.***

The Company is a medical technology company focused primarily on developing and commercializing its lead product candidate, the SCD, for pediatric and adult AKI indications. The Company applied for a HDE for SCD in June 2022 for the treatment of pediatric patients with AKI on CRRT. On September 29, 2023, the Company received

a correspondence from the FDA indicating that this HDE is approvable for use in children weighing 10 kilograms or more with AKI and sepsis or a septic condition requiring CRRT in the hospital ICU. On October 30, 2023, the Company announced that it received the approvable letter from the FDA, which outlined remaining administrative steps that must be finalized before the HDE can be approved and active for commercialization. On February 22, 2024, the Company announced the receipt of the approval order from the FDA. The Company believes the approval of its HDE will confirm SCD and its technology as an effective tool to treat hyperinflammation related diseases, which will enable us to successfully execute our business and growth strategies.

In addition, on February 9, 2023, the Company received approval from the FDA of its IDE application to conduct a pivotal study evaluating the effectiveness of its SCD in reducing hyperinflammation in adults with AKI requiring CRRT. The Company began enrollment in June 2023 and expects to generate interim study results by mid-2024 and topline study results and submission of a PMA application by the end of 2024, and the Company is targeting FDA approval by the end of 2025. However, there is no guarantee that the Company will complete any planned clinical trial in a timely manner, or at all, nor will there be any assurance that positive data will be generated from such a trial. Even if the Company is able to generate positive results from this trial, the FDA and other regulatory agencies may require the Company to conduct additional trials to support the study or disagree with the design of the trial and request changes or improvements to such design.

To date, the Company has not obtained regulatory approval to commercialize or sell any of its SCD product candidates, and it does not expect to generate any significant revenue for the foreseeable future. The Company has incurred significant net losses since its inception and had an accumulated deficit of \$106.1 million and \$69. million as of December 31, 2023 and 2022, respectively.

The Company has devoted most of its financial resources to research and development, including clinical trials and non-clinical development activities, and to obtain regulatory approval of its SCD product candidates. Since the completion of the Business Combination, the Company relied primarily on the sales of securities to fund its operations and are limited as the Company needs to meet certain conditions before such funding becomes available. The size of its future net losses will depend, in part, on the rate of future expenditures and its ability to generate revenues. To date, none of its product candidates have generated revenue, and if its product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, it will not achieve profitability and its business may fail. Even if the Company successfully obtains regulatory approval to market its product candidates in the United States, its revenues are also dependent upon the size of the markets outside of the United States, regulatory approval outside of the United States, and its ability to obtain market approval and achieve commercial success.

The Company expects to continue to incur substantial and increased expenses as it expands research and development activities and advances clinical programs through the regulatory approval process. The Company also expects an increase in its expenses associated with preparing for the potential commercialization of its products and creating additional infrastructure to support operations as a public company. As a result of the foregoing, it expects to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

***The Company has not generated any significant revenue and may never be profitable.***

The Company's ability to generate revenue and achieve profitability depends on its ability, alone or with collaborators, to successfully complete the development, obtain the necessary regulatory approvals of and commercialize its lead product candidate, the SCD. It does not anticipate generating revenues from its product candidates' sales for the foreseeable future. Its ability to generate future revenues from product sales depends heavily on its success with the following items:

- completing the clinical development of its SCD, initially for the treatment of adult AKI in the hospital setting;
- obtaining regulatory approval for its SCD for the designated indication, including the HDE in pediatrics and PMA for adults;
- launching and commercializing its SCD, including building a hospital-directed sales force and collaborating with third parties;

- obtaining third party reimbursement status from government agencies and insurance carriers; and
- entering into collaboration agreement and partnerships to commercialize its products.

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

Even if its product candidates are approved for commercial sale, the Company anticipates incurring significant costs associated with commercializing any approved product candidate. In the case of its SCD product candidate for the treatment of pediatric AKI, even if the Company receives approval from the FDA for its HDE application, the Company will be limited in its ability to sell and distribute its SCD units 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 the Company. Even if it is able to generate revenues from the sale of its products, the Company may not become profitable and may need to obtain additional funding to continue operations.

***The Company has a limited operating history, which makes it difficult to forecast its future results of operations.***

The Company has not received approval from the FDA and other regulatory authorities to sell its SCD product candidates and therefore it has a limited commercial operating history. According, the Company's ability to accurately forecast future results of its operations is limited and subject to a number of uncertainties and risks, including its ability to plan for and model future growth. If the Company receives regulatory approval to market and sell its SCD product candidates, its revenue growth could slow in the future, or its revenue could decline or fluctuate for a number of reasons, including slowing demand for its products, increasing competition, changing demand in the markets, new scientific or technological developments, a decrease in the growth of its overall market, its failure to attract more customers, the inability to obtain reimbursement for its products by government agencies and insurers, or its failure, for any reason, to continue to take advantage of growth opportunities. If its assumptions regarding these risks and uncertainties and its future revenue growth are incorrect or change, or if it does not address these risks successfully or forecast its results accurately, the Company's operating and financial results could differ materially from its expectations, and its business could suffer.

***If the Company fails to obtain additional financing, it would be forced to delay, reduce or eliminate its product development program, which may result in the cessation of its operations.***

Developing medical device products, including conducting preclinical studies and clinical trials, is expensive. The Company expects its research and development expenses to substantially increase in connection with its ongoing activities, particularly as it advances its clinical programs. As of December 31, 2023 and 2022, SeaStar Medical had negative working capital of \$4.2 million and \$3.8 million, respectively. The Company currently does not have sufficient capital to support its operations and complete its planned regulatory approval process. The Company will need to secure additional capital to continue its operation, and such funding may not be available on acceptable terms, or at all. In addition, the Company incurred a significant amount of debt in connection with the Closing, including the issuance of unsecured and secured promissory notes to LM Funding America, Inc. ("LMFA"), LMFAO Sponsor (the "Sponsor") and Maxim ("Maxim"), and convertible notes to 3i LP ("3i"), an affiliate of Tumim Stone Capital ("Tumim"), and the Company may not have sufficient funds to repay these loans. Even if the Company obtains additional funding, the Company will be required to make certain mandatory payments under such promissory notes, which will reduce the amount of proceeds available for the Company to operate its business.

On August 23, 2022, LMF and the Predecessor entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with Tumim for the purchase of up to \$100.0 million in shares of the common stock ("Common Stock") after the consummation of the Business Combination. There were certain conditions and limitations on the Company's ability to utilize the \$100.0 million equity line with Tumim. The Company was required to satisfy various conditions, which include, among others: (1) delivery of a compliance certificate; (2) filing of an initial registration statement; and (3) customary bring-down opinions and negative assurances, in order to commence the selling of Common Stock to Tumim under the Purchase Agreement. Once such conditions were satisfied, Tumim's purchases were subject to various restrictions and other limitations, including a cap on the number of shares of

Common Stock that we could sell based on the trading volume of our Common Stock, as well as certain beneficial ownership restrictions of Tumim. The Company has received a total of \$1.9 million from the Purchase Agreement through February 15, 2024, when the Purchase Agreement was terminated by mutual consent of the parties thereto pursuant to its terms.

In March 2023, the Company entered into a securities purchase agreement with an 3i (as amended from time to time, the "March 2023 SPA") for the purchase and sale of convertible notes and warrants (together with the March 2023 SPA, the "Note Documents"). The Note Documents include various restrictions and covenants, including an optional redemption provision that provides such investor the right to require the Company to use up to 20% of the proceeds of any subsequent financing, including this offering, to repay outstanding balance of the notes (the "Optional Redemption Rights"). In connection with this offering, the institutional investor agreed to waive its Optional Redemption Rights and any event of default that may arise thereunder with respect to this offering and suspend the Optional Redemption Rights for a period of sixty (60) days following the closing of this offering (the "Suspension Period"), and the Company granted the institutional investor a right to redeem all or a portion of the then outstanding Conversion Amount (as defined in the Note Documents) within three (3) trading days after the Suspension Period at an amount equal to 200% of the Conversion Amount. As of the date of this Form 10-K, the aggregate Conversion Amount under the Note Documents is approximately \$1.0 million. Failure to meet the restrictions, obligations, and limitations under the Notes Documents or the securities issued thereunder may result in an event of default in accordance with the terms of the convertible notes issued thereunder. An event of default would, among other things, provide the noteholder with the right to increase the outstanding balance by 15%. Additionally, upon an event of default, the noteholder may consider the convertible note immediately due and payable. Furthermore, upon an event of default, the interest rate may also be increased to 12% per annum

Even if the Company receives sufficient capital in the future, the Company will be required to raise additional funds to support its own operations and complete its planned regulatory approval process, and such funding may not be available in sufficient amounts or on acceptable terms to the Company, or at all. If it is unable to raise additional capital when required or on acceptable terms, the Company may be required to:

- significantly delay, scale back or discontinue the development or commercialization of its product candidates;
- seek corporate partners on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, its rights to technologies or product candidates that it otherwise would seek to develop or commercialize itself;

If it is unable to raise additional capital in sufficient amounts or on acceptable terms, the Company will be prevented from pursuing development and commercialization efforts, including completing the clinical trials and regulatory approval process for its SCD product candidates, which would have a material adverse impact on its business, results of operations and financial condition.

***The Company's ability to use its net operating losses to offset future taxable income may be subject to certain limitations.***

As of December 31, 2023, the Company had net operating loss ("NOL") carryforwards for federal and state (Colorado, California, and Florida) income tax purposes of \$106.2 million and \$2.0 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. The Company's federal NOLs include \$53.4 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. A lack of future taxable income would adversely affect the Company's ability to utilize these NOLs before they expire.

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. The Company may experience a future ownership change under Section 382 of the Code that could affect its ability to utilize the NOLs to offset its income. 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. Furthermore, the Company's ability to utilize NOLs of companies that it 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, the Company's existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, the Company may not be able to utilize a material portion of the NOLs reflected on its balance sheet, even if it attains profitability, which could potentially result in increased future tax liability to the Company and could adversely affect its business, results of operations and financial condition.

***We may suffer from lack of availability of additional funds.***

We expect to have ongoing needs for working capital in order to fund operations, continue to expand our operations and recruit experienced personnel. To that end, we will be required to raise additional funds through equity or debt financing. 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 severe liability for us. If we are unsuccessful, we may need to (a) initiate cost reductions; (b) forego business development opportunities; (c) seek extensions of time to fund liabilities, or (d) seek protection from creditors. In addition, any future sale of our equity securities would dilute the ownership and control of your shares and could be at prices substantially below prices at which our shares currently trade. Our inability to raise capital could require us to significantly curtail or terminate our operations altogether. We may seek to increase our cash reserves through the sale of additional equity or debt securities. 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 increased debt service obligations and could result in operating and financing covenants that would restrict our operations and liquidity. In addition, our ability to obtain additional capital on acceptable terms is subject to a variety of uncertainties.

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 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 our Company.

***The Company has a limited operating history, which makes it difficult to forecast its future results of operations.***

The Company has not received approval from the FDA and other regulatory authorities to sell its SCD product candidates and therefore it has a limited commercial operating history. According, the Company's ability to accurately forecast future results of its operations is limited and subject to a number of uncertainties and risks, including its ability to plan for and model future growth. If the Company receives regulatory approval to market and sell its SCD product candidates, its revenue growth could slow in the future, or its revenue could decline or fluctuate for a number of reasons, including slowing demand for its products, increasing competition, changing demand in the markets, new scientific or technological developments, a decrease in the growth of its overall market, its failure to attract more customers, the inability to obtain reimbursement for its products by government agencies and insurers, or its failure, for any reason, to continue to take advantage of growth opportunities. If its assumptions regarding these risks and uncertainties and its future revenue growth are incorrect or change, or if it does not address these risks successfully or forecast its results accurately, the Company's operating and financial results could differ materially from its expectations, and its business could suffer.

## **Risks Related to the Company's Business Operations**

***The Company has not received, and may never receive, approval from the FDA to market its product in the United States or abroad.***

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

The Company is required to submit a substantial amount of supporting documentation for its HDE application to demonstrate the eligibility of the SCD to treat pediatric patients. The Company submitted an application for a HDE for SCD in June 2022 for the treatment of pediatric patients with AKI on CRRT. On September 29, 2023, the Company received correspondence from the FDA indicating that this HDE is approvable for use in children weighing 10 kilograms or more with AKI and sepsis or a septic condition requiring CRRT in the hospital ICU. On October 30, 2023, the Company announced that it received the approvable letter from the FDA. On February 22, 2024, the Company announced the receipt of the approval order from the FDA. The Company believes the approval of its HDE will confirm SCD and its technology as an effective tool to treat hyperinflammation related diseases, which will enable us to successfully execute our business and growth strategies.

The Company believes that its novel therapeutic device is readily applicable for use in other indications, which will require additional clinical studies and FDA approval. For example, on September 28, 2023, the Company received Breakthrough Device Designation for our patented and cell-directed SCD 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, and on October 18, 2023, the Company received Breakthrough Device Designation for our patented and cell-directed SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure. While the Company expects the Breakthrough Device Designation to expedite the clinical development and regulatory review of the SCD program for use in this patient population, there is no guarantee that the Company will be able to expedite the clinical development or obtain regulatory approval.

While the Company recently obtained approval from the FDA to conduct the AKI adult pivotal trial for SCE, there is no guarantee that the Company will be able to complete such trial in a timely manner, or at all, nor will there be any assurance that positive data will be generated from such trials. Even if the Company is able to generate positive results from this trial, the FDA and other regulatory agencies may require the Company to conduct additional trials to support the study or disagree with the design of the trial and request changes or improvements to such design. The Company is 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 SeaStar Medical to conduct additional testing or increase the size and complexity of its pivotal study;
- a failure to obtain a sufficient supply of filters to conduct its trial;
- an inability to enroll a sufficient number of subjects;
- a shortage of necessary raw materials, such as calcium; and
- delays and failures to train qualified personnel to operate the SCD therapy.

Even if the Company obtains approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Any delay in, or failure to receive or maintain, clearance or approval for its future products could prevent the Company from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on the Company, could dissuade some physicians from using its products and adversely affect its reputation and the perceived safety and efficacy of its 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:

- the Company's inability to demonstrate the safety or effectiveness of the SCD or any other product it develops to the FDA's satisfaction;
- insufficient data from its preclinical studies and clinical trials, including for its SCD, to support approval;
- failure of the facilities of its third-party manufacturers or suppliers to meet applicable requirements;
- inadequate compliance with preclinical, clinical or other regulations;
- its 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 the Company is not able to obtain regulatory approval of its SCD in a timely manner or at all, it may not be able to continue to operate its business and may be forced to shut down its operations.

***The Company is subject to certain risks relating to pursuing an FDA approval via the HDE pathway, including limitations on the ability to profit from sales of the product.***

Except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of the research and development, fabrication, and distribution of the device (i.e., for profit). Currently, under section 520(m)(6)(A)(i) of the Food, Drug, and Cosmetic Act, as amended (the "FD&C Act") by the Food and Drug Administration Safety and Innovation Act, a Humanitarian Use Device ("HUD") is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that 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 (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet this eligibility criteria, the device cannot be sold for profit. With enactment of the FDA Reauthorization Act of 2017, Congress provided that the exemption for the HUD/HDE profitability is available as long as the request for an exemption is submitted on or before October 1, 2022. Not receiving an exemption for the HUD/HDE profitability would have a material adverse effect on the Company's business, results of operations and financial condition.

In addition, if the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA approval or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the FD&C Act.

***The Company plans to expand its operations and it may not be able to manage its growth effectively, which could strain its resources and delay or derail implementation of its business objectives.***

The Company will need to significantly expand its operations to implement its longer-term business plan and growth strategies, including building and expanding its internal organizational infrastructure to complete the regulatory approval process with the FDA. The Company 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 the Company to significantly improve or replace its existing managerial, operational and financial systems, and procedures and controls; to improve the coordination between its various corporate functions; and to manage, train, motivate and maintain a growing employee base. The time and costs to effectuate these steps may place a significant strain on its management personnel, systems and resources, particularly if there are limited financial resources and skilled employees available at the time. The Company cannot assure that it will institute, in a timely manner or at all, the improvements to its managerial, operational and financial systems, procedures and controls necessary to support its anticipated increased levels of



operations and to coordinate its various corporate functions, or that it will be able to properly manage, train, motivate and retain its anticipated increased employee base. If it cannot manage its growth initiatives, the Company will be unable to commercialize its products on a large-scale in a timely manner, if at all, and its business could fail.

***The Company will initially depend on revenue generated from a single product and in the foreseeable future will be significantly dependent on a limited number of products.***

If the Company receives approval from the FDA and other regulatory authorities, the Company will initially depend on revenue generated from its SCD product candidate for pediatric and adult patients with AKI and in the foreseeable future will be significantly dependent on a single or limited number of products. Given that, for the foreseeable future, the Company's business will depend on a single or limited number of products, to the extent a particular product is not well-received by the market, the Company's sales volume, prospects, business, results of operations and financial condition could be materially and adversely affected.

***If the Company fails to comply with extensive regulations of United States and foreign regulatory agencies, the commercialization of its products could be delayed or prevented entirely.***

The Company's 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. The determination of when and whether a product is ready for large-scale purchase and potential use in the United States will be made by the United States government through consultation with a number of governmental agencies, including the FDA, the National Institutes of Health and the Centers for Disease Control and Prevention. The Company's SCD has not received regulatory approval from the FDA, or any foreign regulatory agencies, to be commercially marketed and sold. 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. The Company is 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 the Company interprets 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 the Company to administrative or judicially imposed sanctions, including:

- warning letters, untitled letters or other written notice of violations;
- civil penalties;
- criminal penalties;
- injunctions;
- product seizure or detention;
- product recalls; and
- total or partial suspension of productions.

***Delays in successfully completing the Company's planned clinical trials could jeopardize its ability to obtain regulatory approval.***

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

- slow patient enrollment;
- serious adverse events related to its medical device candidates;
- insufficient funding to engage or continue to engage 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 the Company's anticipated schedules; and
- different interpretations of the Company's pre-clinical and clinical data, which could initially lead to inconclusive results.

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

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

The Company currently relies on a single supplier for the filters used in the SCD device for the pediatric AKI indications pursuant to a supply agreement. In the event the current supplier is unable to provide filters for the SCD device or otherwise fails to meet its obligations under the agreement, the Company may not be able to obtain a sufficient number of filters to conduct its trials and commercialize its products. In addition, the supplier may decide to discontinue or terminate the specific type of filters that are required for its SCD for reasons beyond the Company's control, in which case the Company will be forced to identify and secure an alternative source that may not be available immediately or at all. FDA review and approval of a new supplier may be required if these materials become unavailable from the Company's current suppliers. Although there may be other suppliers that have equivalent materials that would be available to the Company, FDA review of any alternate suppliers, if required, could take several months or more to obtain, if it is able to be obtained at all. Any delay, interruption, or cessation of production by the Company's third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay the Company's ability to manufacture its SCD.

The Company believes that it has sufficient access to the SCD inventory to conduct its current and near future clinical trials, but it is possible that the need for its SCD could increase that may require the Company to acquire more filters than it is currently able to purchase under its agreement with its supplier, and the Company may not be able to negotiate a new supply agreement successfully. If the Company is unable to find alternative sources of supply in a timely manner, any such delay could limit the Company's ability to meet demand for the SCD and delay its ongoing clinical trials, which would have a material adverse impact on its business, results of operations and financial condition.

***The Company has limited experience in identifying and working with large-scale contracts with medical device manufacturers.***

To achieve the levels of production necessary to commercialize its SCD and any other future products, the Company will need to secure large-scale manufacturing agreements with contract manufacturers that comply with the manufacturing standards prescribed by various federal, state, and local regulatory agencies in the United States and

any other country of use. The Company has limited experience coordinating and overseeing the manufacturing of medical device products on a large-scale. Manufacturing and control problems could arise as the Company attempts to commercialize its products and manufacturing may not be completed in a timely manner or at a commercially reasonable cost. In addition, the Company may not be able to adequately finance the manufacturing and distribution of its products on terms acceptable to the Company, if at all. If the Company cannot successfully oversee and finance the manufacturing of its products after receiving regulatory approval, it may not generate sufficient revenue to become profitable.

***Difficulties in manufacturing the Company's SCD could have an adverse effect upon its revenue and expenses.***

The Company currently outsources all of the manufacturing of its SCD. The manufacturing of its SCD is difficult and complex. To support its current clinical trial needs, the Company complies with and intends to continue to comply with current Good Manufacturing Practice ("cGMP") in the manufacturing of its products. The Company's ability to adequately manufacture and supply its SCD in a timely matter is dependent on the uninterrupted and efficient operation of its third-party manufacturers, and those of the third parties producing raw materials and supplies upon which it relies on for the manufacturing of its products. The manufacturing of the Company's products may be impacted by:

- the availability or contamination of raw materials and components used in the manufacturing process, particularly those for which it has no other supplier;
- its ability to comply with new regulatory requirements and cGMP;
- potential facility contamination by microorganisms or viruses;
- updating of its manufacturing specifications;
- product quality success rates and yields; and
- global viruses and pandemics, including the current COVID-19 pandemic.

If efficient manufacture and supply of its SCD is interrupted, the Company may experience delayed shipments or supply constraints. If it is at any time unable to provide an uninterrupted supply of its products, the Company's ongoing clinical trials may be delayed, which could materially and adversely affect its business, results of operations and financial condition.

***The Company's SCD technology may become obsolete.***

The Company's 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 the Company's products. Any one of the Company's competitors could develop a more effective product which would render the Company's technology obsolete. In addition, it is possible that competitors may use similar technologies, equipment or devices, including using certain "off-the-shelf" filters unauthorized by the FDA, to attempt to create a similar treatment mechanism as the SCD. Further, new technological and scientific developments within the hospital setting could cause the Company's 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 regional citrate as an anticoagulant. Further developments in these areas could require the Company to reconfigure its SCD product candidates, which may not be commercially feasible, or cause them to become obsolete. Lastly, the Company's ability to achieve significant and sustained growth in its key target markets will depend upon its success in hospital penetration, utilization, publication, its SCD's reimbursement status and medical education. The Company's products may not remain competitive with products based on new technologies. If it fails to sell products that satisfy its customers' demands or respond effectively to new product announcements by its competitors, then market acceptance of the Company's products could be reduced and its business, results of operations and financial condition could be adversely affected.

***The Company faces intense competition in the medical device industry.***

The Company competes with numerous United States and foreign companies in the medical device industry, and many of its competitors have greater financial, personnel, operational and research and development resources than the Company. The Company believes that multiple competitors are or will be developing competing technologies to address cytokine storms. Progress is constant in the treatment of the immune system, which may reduce opportunities for the SCD. The Company's commercial opportunities will be reduced or eliminated if its competitors develop and market products for any of the diseases it targets that:

- are more effective;
- have fewer or less severe adverse side effects;
- are better tolerated;
- are easier to administer; or
- are less expensive than SeaStar Medical's products or its product candidates.

Even if the Company is successful in developing the SCD and any other future products and obtains FDA and other regulatory approvals necessary for commercializing them, its products may not compete effectively with other products. Researchers are continually learning more about diseases, which may lead to new technologies for treatment. The Company's competitors may succeed in developing and marketing products that are either more effective than those that it may develop or that are marketed before any SeaStar Medical products. The Company's competitors include fully integrated pharmaceutical & medical device companies and biotechnology companies, universities, and public and private research institutions. Many of the organizations competing with the Company have substantially greater capital resources, larger research and development staffs and facilities, greater experience in product development and in obtaining regulatory approvals, and greater marketing capabilities. If the Company's competitors develop more effective treatments for infectious disease or hyperinflammation or bring those treatments to market before the Company can commercialize the SCD for such uses, it may be unable to obtain any market traction for its products, or the diseases it seeks to treat may be substantially addressed by competing treatments. If the Company is unable to successfully compete against larger companies in the pharmaceutical industry, it may never generate significant revenue or be profitable.

***If the Company's products, or the malfunction of its products, cause or contribute to a death or a serious injury, the Company 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 the Company fails to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against the Company. Any such adverse event involving the Company's 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 the Company's time and capital, distract management from operating its business, and may harm the Company's reputation and financial results.

***The Company outsources many of its operational and development activities for which it may not have full control.***

The Company relies on third-party consultants or other vendors to manage and implement much of the day-to-day responsibilities of conducting clinical trials and manufacturing its current product candidates. Accordingly, the Company is and will continue to be dependent on the timeliness and effectiveness of the efforts of these third parties. The Company's dependence on third parties includes key suppliers and third-party service providers supporting the development, manufacturing, and regulatory approval of its SCD, as well as support for its information technology systems and other infrastructure. While its 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 the Company's business, results of

operations and financial condition. It is possible that the current COVID-19 pandemic might constrain the ability of third-party vendors to provide services that the Company requires.

If a clinical research organization that the Company utilizes is unable to allocate sufficient qualified personnel to its studies in a timely manner or if the work performed by it does not fully satisfy the requirements of the FDA or other regulatory agencies, the Company may encounter substantial delays and increased costs in completing its development efforts. Any manufacturer of the Company's products may encounter difficulties in the manufacturing of enough new product to meet demand, including problems with product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for FDA approval of new manufacturing processes and facilities. If any of these occur, the development and commercialization of the Company's product candidates could be delayed, curtailed, or terminated because the Company may not have sufficient financial resources or capabilities to continue such development and commercialization on its own.

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

If the Company or its manufacturers or other third-party contractors fail to comply with applicable federal, state or foreign laws or regulations, the Company could be subject to regulatory actions, which could affect its ability to successfully develop, market and sell its SCD product candidate or any future product candidates under development and could harm its reputation and lead to reduced or non-acceptance of its 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. For example, the Institutional Review Board for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing. This would have a material adverse effect on the value of the product candidate and the Company's business, results of operations and financial condition.

***If the Company obtains approval for its products, SeaStar Medical may still be subject to enforcement action if it engages in improper marketing or promotion of its products.***

The Company is not permitted to promote or market its product candidates until FDA approval is obtained. After approval, its 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 the Company's 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 the Company's promotional materials or training constitutes promotion of an off-label use, it could request that the Company modify its training or promotional materials or subject the Company 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 the Company's 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, the Company's reputation could be damaged, which may lead to reduced or non-acceptance of its proposed product candidates by the market. In addition, the off-label use of the Company's products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert the attention of the Company's management, result in substantial damage awards against the Company, and harm its reputation.

***The Company intends to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of its SCD or any future product candidates that it may develop, and its future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.***

The Company does not have the required financial and human resources to carry out on its own all the pre-clinical and clinical development for its SCD product candidate or any other or future product candidates that it may

develop, and do not have the capability and resources to manufacture, market or sell its SCD product candidate or any future product candidates that it may develop. The Company's business model calls for the partial or full outsourcing of the clinical, development, manufacturing, sales, and marketing of its product candidates in order to reduce its capital and infrastructure costs as a means of potentially improving its financial position. The Company's success will depend on the performance of these outsourced providers. If these providers fail to perform adequately, the Company's development of product candidates may be delayed and any delay in the development of the Company's product candidates may have a material and adverse effect on its business, results of operations and financial condition.

***The Company is and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon it should it be sued.***

The Company's business exposes it to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of medical devices. Claims may be asserted against it. A successful liability claim or series of claims brought against it could have a material adverse effect on the Company's business, results of operations and financial condition. The Company 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 the Company may obtain could have a material adverse effect on its business, results of operations and financial condition.

The Company's 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 the Company's products to function as designed, or its products are designed inappropriately, the Company may be subject to lawsuits seeking significant compensatory and punitive damages. The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing, and sale of medical products. The Company intends to obtain general clinical trial liability insurance coverage; however, its insurance coverage may not be adequate or available. In addition, the Company 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 the Company may obtain could have a material adverse effect on its business, results of operations and financial condition. Moreover, a product recall could generate substantial negative publicity about the Company's 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 the Company to obtain regulatory approval of its product candidates and to manufacture, market and distribute its 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 the Company's business and its 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 the Company's new product development efforts.

***The Company is subject to stringent and changing privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security.***

The Company collects, receives, stores, processes, uses, generates, transfers, discloses, makes accessible, protects, and shares personal information and other information ("Process" or "Processing"), including information it collects in connection with clinical trials, as necessary to operate its 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. The Company is subject, and may become subject in the future, to certain of these laws, regulations, and guidance, and it is also subject to the terms of its 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 the Company fails, or is perceived to have failed, to address or comply with such obligations, it could:

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

Additionally, given that these obligations impose complex and burdensome obligations and that there is substantial uncertainty over the interpretation and application of these obligations, the Company may be required to incur material costs, divert management attention, and change its business operations, including its clinical trials, in an effort to comply, which could materially adversely affect its business, results of operations and financial condition.

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 the Company's business activities depending on how they are interpreted.

***The Company's business operations will be adversely affected if its security measures, or those maintained on its behalf, are compromised, limited or fails.***

In the ordinary course of its business, the Company handles and processes 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. The Company may use and share such sensitive information with service providers and other third parties. If the Company, its 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 SeaStar Medical's business, results of operations and financial condition, including the diversion of funds to address the breach, and interruptions, delays, or outages in its 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 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). The Company 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 its business, results of operations and financial condition.

***Should the Company's products be approved for commercialization, a lack of third-party coverage and reimbursement for the Company's devices could delay or limit their adoption.***

In both the United States and international markets, the use and success 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 the Company's 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 the Company's future products, including the SCD, on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of the Company's future products by health technology assessment bodies. These assessments are outside the Company's control, and any such evaluations may not be conducted or have a favorable outcome.

If approved for use in the United States, the Company expects that any products that it develops, including the SCD, will be purchased primarily by medical institutions through their operations budget. Payors may include the Centers for Medicare & Medicaid Services ("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 the Company's ability to demonstrate that the treatment is "reasonable and necessary" for Medicare beneficiaries. Even if products utilizing the Company's 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 the Company's 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. However, no uniform policy for coverage and reimbursement of medical devices exists among third-party payors in the United States. 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 SeaStar Medical products.

***Should any of its future products, including the SCD, be approved for commercialization, adverse changes in reimbursement policies and procedures by payors may impact the Company's ability to market and sell its products.***

Healthcare costs have risen significantly over the past decade, and there have been and continue to be proposals by legislators, regulators and third-party payors to decrease costs. 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.

For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), among other things, reduced and/or limited Medicare reimbursement to certain providers. However, on December 14, 2018, a Texas United States District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017. Additionally, on June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA remains in effect without the "individual mandate."

Further, prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and litigation, and the healthcare reform measures of the Biden administration will impact the ACA and the Company's business. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by 2% through fiscal year 2031. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in



the final fiscal year of this sequester. 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. In addition, Congress is considering additional health reform measures. Legislation could be adopted in the future that limits payments for the Company's products from governmental payors. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Furthermore, commercial payors such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products. Therefore, it is possible that SeaStar Medical's products or the procedures or patient care performed using its products will not be reimbursed at a cost-effective level.

The Company faces similar risks relating to adverse changes in reimbursement procedures and policies in other countries where it may market its products. Reimbursement and healthcare payment systems vary significantly among international markets. The Company's inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect its ability to sell its products in foreign markets and have a material adverse effect on its business, results of operations and financial condition.

***The Company depends on key personnel and its inability to attract and retain qualified personnel could impede its ability to achieve its business objectives.***

The Company's success depends on the continuing service of key employees, especially its Chief Executive Officer, Eric Schlorff. The loss of any of these individuals could have a material and adverse effect on the Company's business, results of operations and financial condition. The Company will also be required to hire and recruit highly skilled managerial, scientific, and administrative personnel to fully implement its business plan and growth strategies. Due to the specialized scientific nature of its business, the Company is highly dependent upon its ability to attract and retain qualified scientific, technical and managerial personnel. Competition for these individuals is intense and the Company may not be able to attract, assimilate or retain additional highly qualified personnel in the future. The Company may not be able to engage the services of qualified personnel at competitive prices or at all, particularly given the risks of employment attributable to its limited financial resources and lack of an established track record. Also, if the Company is required to attract personnel from other parts of the United States or abroad, it may have significant difficulty doing so because of the costs associated with moving personnel to the area. If the Company cannot attract and retain qualified staff and executives, it may be unable to develop its products and achieve regulatory clearance, and its business could fail.

***The Company's 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, under their own initiative, 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 the Company's products would divert managerial and financial resources and have an adverse effect on the Company's reputation, business, results of operations and financial condition, which could impair its ability to produce its products in a cost-effective and timely manner in order to meet its customers' demands.

The Company may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on its future sales and its ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or the competent authority of another country. The Company may initiate voluntary recalls involving its products in the future that it determines do not require notification of the FDA or the competent authority of another country. If the FDA disagrees with the Company's determinations, they could require the Company to report those actions as recalls. A future recall announcement could harm the Company's reputation with customers and negatively affect its sales. Moreover, the FDA could take

enforcement action for failing to report recalls. The Company is also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals.

***The Company's business is subject to risks arising from future pandemics.***

Worldwide pandemics have presented substantial public health and economic challenges and has affected the Company's employees, patients, communities, and business operations, as well as the United States and global economy and financial markets.

A future pandemic may directly or indirectly impact the timeline for the launch of its SCD product candidate. The Company may experience disruptions that could severely impact its business, clinical trials, and manufacturing and supply chains, including:

- further delays or difficulties in enrolling patients in its clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- the diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospital staff supporting the conduct of its clinical trials;
- the interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- the interruption of, or delays in receiving, supplies of its product candidates from its contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in clinical sites receiving the supplies and materials needed to conduct its clinical trials and interruptions in global shipping may affect the transport of clinical trial materials;
- limitations on employee resources that would otherwise be focused on the conduct of its clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving feedback or approvals from the FDA or other regulatory authorities with respect to future clinical trials or regulatory submissions;
- changes in local regulations as part of a response to a future pandemic, which may require it to change the ways in which its clinical trials are conducted, resulting in unexpected costs, or discontinuing the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations on employee resources or the forced furlough of government employees;
- the refusal of the FDA to accept data from clinical trials in affected geographies; and
- difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

In addition, the spread of a future pandemic may negatively impact the Company's ability to raise additional capital on a timely basis or at all.

The extent to which a future pandemic may impact the Company's business, including its clinical trials, manufacturing and supply chains and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the continued geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, continued business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

***A small number of the Company's stockholders, including its major stockholders, the Dow Pension Funds, could significantly influence its business.***

The Company has a few significant stockholders who own a substantial percentage of its outstanding shares of Common Stock, including Dow Employees' Pension Plan Trust and Union Carbide Employees' Pension Plan Trust. These few significant shareholders, either individually or acting together, may be able to exercise significant influence over matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of the Company or its assets. This concentration of ownership may make it more difficult for other shareholders to effect substantial changes in the Company, may have the effect of delaying, preventing or expediting, as the case may be, a change in control of the Company and may adversely affect the market price of the Common Stock. Further, the possibility that one or more of these significant shareholders may sell all or a large portion of their Common Stock in a short period of time could adversely affect the trading price of our Common Stock.

***The Company's forecasted operating and financial results rely in large part upon assumptions and analyses developed by the Company. If these assumptions and analyses prove to be incorrect, the Company's actual operating and financial results may be significantly below its forecasts.***

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

- whether the Company can obtain sufficient capital to develop and commercialize its SCD product candidate and grow its business;
- whether the Company can manage relationships with key suppliers;
- the ability to obtain necessary regulatory approvals;
- demand for the Company's products;
- the timing and costs of new and existing marketing and promotional efforts;
- competition, including from established and future competitors;
- the Company's 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 it operates or intends 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 the Company's control, could materially and adversely affect its business, results of operations and financial condition.

***The Company's 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 the Company's industry and the markets in which the Company intends to operate, are obtained from publicly available information released by independent industry and research organizations and other third party sources. Although the Company is responsible for the disclosure provided in this Annual Report and believes such third-party information is reliable, the Company has not independently verified any such third-party information. In addition, projections, assumptions and estimates of the future performance of the industry in which the Company operates 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 the Company's internal business planning and in the analysis of investors.

## **Risks Relating to the Company's Intellectual Property**

***The Company relies 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, the Company's competitive position could be materially harmed.***

The Company relies in part upon exclusively licensed patent rights for the development of its SCD technology. For example, the Company co-owns with, and exclusively licenses from, the University of Michigan patents related to the SCD technology. If UOM were to terminate its license with the Company, it would no longer have exclusive rights to the co-owned patents and UOM would be free to license UOM's interest in the co-owned patents to a competitor of the Company.

The Company may become reliant in the future upon licenses to certain third-party patent rights and proprietary technologies necessary to develop and commercialize its SCD technology or other technologies. If the Company is unable to timely obtain these licenses on commercially reasonable terms, if at all, its 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 the Company chooses to develop or commercialize its technology and products, it may not be able to prevent competitors from developing and commercializing competitive products in such territories. Even if the Company is able to obtain necessary licenses, it may be required to pay significant licensing fees in order to market its products.

Should any of the Company's 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, the Company's research and commercialization efforts could be materially and adversely affected. The Company's licenses may not continue in force for as long as is required to fully develop and market its 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 the Company, if at all. There is also the related risk that the Company may not be able to make the required payments under any patent license, in which case the licensor may terminate the license.

Further, the Company's licensors may not successfully prosecute the patent applications which it has licensed and on which the Company's business depends or may prosecute them in a manner not in the best interests of the Company. 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 of the Company's best efforts, a licensor could claim that the Company has materially breached a license agreement and terminate the license, thereby removing the Company's ability to obtain regulatory approval for and to market any product covered by such license. If the Company's 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 the Company's 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 the Company might enter into in the future;
- the Company's 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 the Company and its licensors; and
- the priority of invention of patented technology.

If disputes over intellectual property that the Company has licensed prevent or impair its ability to maintain its current licensing arrangements on acceptable terms, it may be unable to successfully develop and commercialize the affected product candidates.

***If the Company is unable to obtain and maintain sufficient patent protection for its 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 it relies to protect its intellectual property are inadequate, its competitors could develop and commercialize similar or identical products, and the Company's ability to commercialize such products successfully may be adversely affected.***

The Company's success depends in large part on its ability to protect its proprietary rights to the technologies incorporated into its products, including its ability to obtain and maintain patent protection in the United States and other countries related to its SCD technology and other technologies that it deems important to its business. The Company relies on a combination of patent protection, trade secret laws and nondisclosure, confidentiality, and other contractual restrictions to protect its proprietary technology. If the Company does not adequately protect its intellectual property, competitors may be able to erode or negate any competitive advantage it may have, which could harm its business, result of operations and financial condition. To protect the Company's proprietary technologies, it has pursued patent protection in the United States and abroad related to its SCD technology and other technologies that are important to its business. The patent application and approval process are expensive and time-consuming. The Company 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 the Company's ability to develop and market its products. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

The Company cannot be certain that any patents that it has been issued or granted will not later be found to be invalid and/or unenforceable. The Company 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, the Company's 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, the Company does not know the degree of future protection that it will have for its technology. As a result, the issuance, scope, validity, enforceability, and commercial value of the Company's 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, the Company cannot be certain that it was the first to make the inventions claimed in its patents or pending patent applications, or that it was 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, the Company patents or pending patent applications may be challenged in the courts or by the USPTO or by foreign patent offices. For example, the Company 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 parties review or interference proceedings, in the United States or elsewhere, challenging its 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 the Company's ability to stop others from using or commercializing similar products, or limit the duration of the Company's patent protection. In addition, given the amount of time required for the development, testing and

regulatory review of medical devices, the Company's patents might expire before or shortly after such products receive FDA approval and are commercialized, or before it receives approval to market its products in a foreign country.

Patent applications may not result in patents being issued which protect any current and future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the Company's patents or narrow the scope of its patent protection. In addition, the laws of foreign countries may not protect the Company's 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 the Company believes that certain of its patents and applications, if they are granted, will help protect the proprietary nature of its SCD technology, this protection may not be sufficient to protect the Company during the development of that technology. Even if the Company's patent applications are issued as patents, they may not be issued in a form that will provide it with any meaningful protection, prevent competitors from competing with it or otherwise provide it with any competitive advantage. The Company's competitors may be able to circumvent its patents by developing similar or alternative technologies or products in a non-infringing manner. The Company's competitors may also seek approval to market their own products similar to or otherwise competitive with any of the Company's products. Thus, even if the Company has valid and enforceable patents, these patents still may not provide protection against competing products or technologies sufficient to achieve its business objectives.

***If the Company does not obtain protection under the Hatch-Waxman Act and similar non-United States legislation for extending the term of patents covering its products, its 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. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents related to the Company's products, or their uses are obtained, once the patent life has expired, the Company 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 the Company's products might expire before or shortly after such products receive FDA approval and are commercialized. As a result, the Company's patent portfolio may not provide the company with sufficient rights to exclude others from commercializing similar or identical products.

Depending upon the timing, duration and requirements of FDA marketing approval of the Company's product candidates, its 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, the Company's 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 the Company's product candidates are not classified as Class III devices, it 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, the Company 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 the Company is unable to obtain a patent term extension or the term of any such extension is less than requested, the period during which the Company can enforce its patent rights for that product will be shortened and competitors may obtain approval to market competing products sooner than expected. As a result, the Company's business, results of operations and financial condition could be adversely and materially affected.

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

The Company's commercial success depends, in part, on its ability to develop and market its SCD technology, as well as any future technologies that it develops, 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 the Company is unaware that its products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against the Company increases as the number of competitors increases, as it introduces new products and achieves more visibility in the marketplace.

Any infringement claim against the Company, even if without merit, may cause the Company to incur substantial costs, and would place a significant strain on its financial resources, divert the attention of management from its core business, and harm its 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 the Company's patents may provide little or no deterrence. If the Company is found to infringe any patents, the Company could be required to pay substantial damages, including triple damages if an infringement is found to be willful. The Company also could be forced, including by court order, to cease developing, manufacturing, or commercializing infringing products. The Company also could be required to pay royalties and could be prevented from selling its products unless it obtains a license or is able to redesign its products to avoid infringement. The Company may not be able to obtain a license enabling it to sell its products on reasonable terms, or at all. If the Company fails to obtain any required licenses or makes any necessary changes to its technologies or the products, the Company may be unable to commercialize one or more of its products or may have to withdraw products from the market, either of which would have a material adverse effect on its business, results of operations and financial condition.

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

***Issued patents covering one or more of the Company's products could be found invalid or unenforceable if challenged in patent office proceedings, or in court.***

Competitors may infringe the Company's patents, trademarks, or other intellectual property. To counter infringement or unauthorized use of its intellectual property, the Company may be required to initiate legal proceedings against a third party to enforce its intellectual property rights. If the Company were to file a claim against a third party to enforce a patent covering one of its products, the defendant could counterclaim that the Company's 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, including, for example, lack of novelty, obviousness, lack of written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. 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 the Company does not have the right to stop the other party from using the invention at issue on the grounds that the Company's patent claims do not cover the invention at issue.

An adverse outcome in a litigation or proceeding involving the Company's patents could limit its ability to assert its patents against those other parties and other competitors, which may curtail or preclude its ability to exclude third parties from selling similar products. Any of these occurrences could adversely and materially affect the Company's business, results of operations and financial condition.

Even if the Company establishes 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 the Company's 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.

Although the Company believes that it has conducted its patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, the Company cannot be certain that there is no invalidating prior art, of which it and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, the Company would lose some or all of the patent protection for one or more of its products. Such a loss of patent protection could have a material adverse impact on its business, results of operations and financial condition. Further, intellectual property litigation could lead to unfavorable publicity that could harm the Company's reputation.

Other parties may challenge certain of the Company's foreign patent applications. If any such parties are successful in opposing its foreign patent applications, the Company 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 the Company's 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 the Company's patents. While the Company has entered into assignment of intellectual property agreements with its employees, consultants, and collaborators and believes that it owns its patents and applications, the assignment and other ownership agreements that it relies on could be challenged. If a court or administrative body determined that the Company's does not own certain of its patents or patent applications, or that inventorship of certain of its patents is incorrect, the Company's title to its patents could be invalidated and its ability to develop and commercialize its technology could be materially harmed.

***If the Company is unable to protect the confidentiality of its trade secrets, the value of its technology could be adversely and materially affected, and its business could be harmed.***

The Company has also entered into non-disclosure and confidentiality agreements with all of its employees, advisors, consultants, contract manufacturers, clinical investigators and other third parties involved in the development and commercialization of its technology in order to protect its 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 the Company's trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. For example, trade secrets and confidential know-how can be difficult to maintain as confidential. Although the Company uses reasonable efforts to protect its trade secrets, any party with whom it has executed a confidentiality agreement could breach that agreement and disclose the Company's confidential information.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. Accordingly, the Company may not be able to obtain adequate remedies for such breaches, despite any legal action it might take against persons making such unauthorized disclosure. In addition, courts outside the United States sometimes are less willing than in the United States to protect trade secrets.

If any of the Company's trade secrets were to be lawfully obtained or independently developed by a competitor, it 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 the Company. If any of its trade secrets were to be disclosed to or independently developed by a competitor, its business, results of operations and financial condition.

Those with whom the Company collaborates on research and development related to current and future technologies and products may have rights to publish data and other information to which the Company has rights. In addition, the Company sometimes engages individuals or entities to conduct research relevant to its 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 the Company's confidential information. If the Company does not apply for patent protection prior to such publication, or if it cannot otherwise maintain the confidentiality of its proprietary technology and other confidential information, then its ability to obtain patent protection or to protect its trade secret information may be jeopardized.

***New technology may lead to the Company's competitors developing superior products which would reduce demand for its products regardless of any patent protection it may have.***

Research into technologies similar to the Company's technologies is proceeding at a rapid pace, and companies and research institutions are actively engaged in the development of products similar to the Company's products. These new technologies may, if successfully developed, offer significant performance or price advantages when compared with the Company's technologies. The Company's existing patents or its pending and proposed patent applications may not offer meaningful protection if a competitor develops a novel product based on a new technology.

***The United States government may exercise certain rights with regard to the Company's 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 the Company's exclusively owned patents and patent applications and those patents and applications that it co-owns with and exclusively licenses 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 SeaStar Medical's 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 the Company's confidential information to third parties and to exercise march-in rights to use or to allow third parties to use the Company's 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 the Company fails 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, the Company's 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 the Company fails 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, the Company may not be able to develop or commercialize its product candidates effectively or profitably, or at all, which could harm the Company's business, results of operations and financial condition. In addition, if any intellectual property owned or licensed by the Company 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 the Company's intellectual property and could adversely affect its business.

The Company also sometimes collaborates with academic institutions to accelerate its research or development. While the Company tries to avoid engaging its academic partners in projects in which there is a risk that federal funds may be co-mingled, it 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, the Company co-owns or licenses technology which is critical to its business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, its 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 the Company's ability to protect its products.***

As is the case with other medical device companies, the Company's success is heavily dependent on intellectual property, particularly patents. 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, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act included a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, such as through post grant and inter parties review proceedings at the USPTO. In addition, the Leahy-Smith Act transformed the United States patent system into a "first to file" system effective March 2013. The Leahy-Smith Act and its implementation could make it more difficult for the Company to obtain patent protection for its inventions and increases the uncertainties and costs surrounding the prosecution of the Company's patent applications and the enforcement or defense of its issued patents, all of which could harm its business, results of operations and financial condition.

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. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact the Company's ability to enforce its proprietary technology. 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 the Company's ability to obtain new patents or to enforce its existing and future patents.

***Intellectual property rights do not necessarily address all potential threats to the Company's competitive advantage.***

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

- others may be able to make products that are the same as or similar to the Company's products but that are not covered by the claims of patents that it owns or has rights to;

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

***Obtaining and maintaining the Company's patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and its 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 the Company or its licensors fail to maintain the patents and patent applications covering the Company's products, its competitive position would be adversely affected.

***The Company may obtain only limited geographical protection with respect to certain patent rights, which may diminish the value of its intellectual property rights in those jurisdictions and prevent it from enforcing its intellectual property rights throughout the world.***

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Accordingly, the Company has not and in the future may not file for patent protection in all national and regional jurisdictions where such protection may be available. In addition, it may decide to abandon national and regional patent applications before grant, or to not pay maintenance fees on granted patents in certain jurisdictions. Finally, the grant proceeding of each national/regional patent office is an independent proceeding that may lead to situations in which applications in some jurisdictions are refused by the relevant patent offices, while other applications are granted. 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 the Company's technologies to develop their own products in jurisdictions where the Company has not obtained patent protection and, further, may export otherwise infringing products to territories where the Company has patent protection, but where patent enforcement is not as strong as that in the United States. These products may also compete with the Company's products in jurisdictions where it does not have any issued or licensed

patents or where the Company's patent or other intellectual property rights are not effective or sufficient to prevent these products from competing with the Company.

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 the Company to stop the infringement of its patents or the misappropriation of its other intellectual property rights in these countries. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If the Company or any of its licensors is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired and its business, results of operations and financial condition may be adversely affected. Consequently, the Company may not be able to prevent third parties from practicing its inventions in certain countries outside the United States and Europe. Competitors may use the Company's technologies to develop their own products in jurisdictions where the Company has not obtained patent protection. Furthermore, they may export otherwise infringing products to jurisdictions where the Company has patent protection, if the Company's ability to enforce its patents to stop the infringing activities in those jurisdictions is inadequate.

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

### **Risks Related to Being a Public Company**

***The Company does 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.***

The Company is building experience operating as a United States public company, of which, the Company's 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. The Company's failure to comply with all laws, rules and regulations applicable to United States public companies could subject the Company and its management to regulatory scrutiny or sanction, which could harm its reputation and share price. Although the Company is developing and implementing governance, compliance, risk management and control framework and culture required for a public company, the Company may not be able to meet the requisite standards expected by the SEC and/or its investors. The Company may also encounter errors, mistakes, and lapses in processes and controls resulting in failures to meet the requisite standards expected of a public company.

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

If it fails to adequately implement the required governance and control framework, the Company could be at greater risk of failing to comply with the rules or requirements associated with being a public company. Such failure could result in the loss of investor confidence, could harm the Company's reputation, and cause the market price of the Company's securities to decline. Other challenges in complying with these regulatory requirements may arise because the Company may not be able to complete its 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, the Company's 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 the Company's 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 the Company.***

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.

On June 14, 2023, we received a letter from the Listing Qualifications Department of Nasdaq notifying us that the Market Value of Listed Securities ("MVLS") of our Common Stock had been below the minimum \$35,000,000 required for continued listing as set forth in Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement").

The letter also stated that we would be provided 180 calendar days, or until December 11, 2023, to regain compliance with the MVLS Requirement. On December 13, 2023, we received a notification from the Listing Qualification Department of Nasdaq that we had not regain compliance with the MVLS Requirement and that our Common Stock would be subject to delisting unless we timely request a hearing before a Nasdaq Hearing Panel (the "Panel"). On December 19, 2023, we submitted a hearing request to the Panel to appeal the delisting determination. On the same date, we received a notice from Nasdaq stating that its delisting action had been stayed pending a final written decision by the Panel and that a hearing would be held on March 12, 2024. On February 6, 2024, we received notification from Nasdaq that we had regained compliance with the MVLS Requirement.

On June 26, 2023, we received a letter from the Listing Qualifications Department of Nasdaq notifying us that the Company was not in compliance with the \$1.00 per share minimum requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 555(a)(2) (the "Bid Price Requirement").

This letter had no immediate effect on the listing of the Company's Common Stock on Nasdaq and the Company had 180 calendar days from the date of the notice, or until December 26, 2023, to regain compliance with the Bid Price Requirement. On December 27, 2023, we received notification from Nasdaq that the Company had not regained compliance with the Bid Price Requirement and that the Panel will consider this matter in rendering a determination regarding the Company's continued listing on The Nasdaq Capital Market. Pursuant to Listing Rule 5810(d), the Company should present its views with respect to this deficiency at its Panel hearing to be held on March 12, 2024. If we fail to address the aforementioned issue, the Panel will consider the record as presented at the hearing and will make its determination based upon that information.

There is no guarantee that the Panel will render a favorable decision to permit the continuing list of our Common Stock, and failure to obtain such favorable decision will result in the delisting of our Common Stock, which will have a material adverse effect on our business operations and financial conditions.

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

***The Company identified a material weakness in its internal control over financial reporting. If the Company is unable to develop and maintain an effective system of internal controls over financial reporting, the Company may***

***not be able to accurately report its financial results in a timely manner, which may materially and adversely affect the Company's business, results of operations and financial condition.***

The Company's 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. The Company's management also evaluates the effectiveness of its internal controls, and the Company discloses any changes and material weaknesses identified through such evaluation of its 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 the Company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

In the course of preparing the consolidated financial statements that are included in this Annual Report, SeaStar Medical has identified material weaknesses in its internal controls over financial reporting as of December 31, 2023 and 2022, which relates to a deficiency in the design and operation of its financial accounting and reporting controls. Specifically, the material weaknesses resulted from (i) a lack of segregation of duties within the financial accounting and reporting processes, including the absence of an independent review and approval process in recording transactions to the consolidated financial statements, disbursement and payroll systems. and (ii) a lack of resources with the knowledge and experience to identify, analyze and conclude on the accounting for complex financial instruments in accordance with US GAAP. While the Company intends to implement measures to remediate the material weakness including hiring additional accounting staff with requisite experiences and skills, there is no guarantee that it can be remediated in a timely fashion or at all. The Company's failure to correct this material weakness could result in inaccurate consolidated financial statements and could also impair its ability to comply with the applicable financial reporting requirements on a timely basis. These compliance issues could cause investors to lose confidence in the Company's reported financial information and may result in volatility in and a decline in the market price of the Company's securities.

While the Company is currently taking steps to develop and enhance its internal control process the Company's management may conclude that its internal control over financial reporting is not effective, or the level at which the Company's controls are documented, designed, or reviewed is not adequate, and may result in the Company's independent registered public accounting firm issuing a report that is qualified. In addition, the reporting obligations may place a significant strain on the Company's management, operational and financial resources and systems for the foreseeable future. The Company may be unable to complete its evaluation testing and any required remediation in a timely manner.

During the course of documenting and testing the Company's internal control procedures, in order to satisfy the requirements of Section 404, the Company may subsequently identify deficiencies in its internal control over financial reporting. Moreover, if the Company fails to maintain the adequacy of its internal control over financial reporting, as these standards are modified, supplemented, or amended from time to time, it may not be able to conclude on an ongoing basis that it has effective internal control over financial reporting in accordance with Section 404. If the Company fails to achieve and maintain an effective internal controls environment, it could result in material misstatements in its consolidated financial statements and a failure to meet its reporting obligations, which may cause investors to lose confidence in its reported financial information. This could in turn limit the Company's access to capital markets and harm its results of operations.

Irrespective of the current restatement of the fiscal years ended December 31, 2023 and 2022, the Company may also be required to restate its consolidated financial statements from prior periods if further deficiencies are identified. Additionally, ineffective internal control over financial reporting could expose it to increased risk of fraud or misuse of corporate assets and subject it to potential delisting from Nasdaq, regulatory investigations and civil or criminal sanctions. All of these consequences could adversely impact the Company's reputation, business, results of operations, financial condition and share price.

***The Company 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). The Company has 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 give proper notice of such redemption and provided certain other conditions are met. If and when the 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 warrants could force you (i) to exercise your warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your warrants at the then-current market price when you might otherwise wish to hold your warrants or (iii) to accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants. None of the private placement warrants will be redeemable by us so long as they are held by the Sponsor or its permitted transferees.

***Our management team has limited experience operating a public company.***

Most members of our management team have limited experience operating a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, results of operations, cash flows and financial condition.

#### **Risks Related to Ownership of Our Common Stock**

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

Our Common Stock could be subject to wide fluctuation in response to many risk factors listed in this section, and others beyond our control, including:

- market acceptance and commercialization of our products;
- our being able to timely demonstrate achievement of milestones, including those related to revenue generation, cost control, cost effective source supply and regulatory approvals;
- regulatory developments or enforcements in the United States and non-U.S. countries with respect to our products or our competitors' products;
- failure to achieve pricing acceptable to the market;
- actual or anticipated fluctuations in our financial condition and operating results, or our continuing to sustain operating losses;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- announcement or expectation of additional financing efforts, particularly if our cash available for operations significantly decreases;

- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- entry by us into any material litigation or other proceedings;
- sales of our Common Stock by us, our insiders, or our other stockholders;
- market conditions for stocks in general; and
- general economic and market conditions unrelated to our performance.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political, and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our Common Stock. In addition, 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. If the market price of shares of our Common Stock after this offering does not exceed the price at which you obtain shares of our Common Stock, you may not realize any return on your investment in us and may lose some or all your investment.

***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 downgraded our stock or change their opinion 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 (the “JOBS Act”), 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 of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding 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. We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us under the JOBS Act and intend to continue to do so if we qualify as an “emerging growth company.” For example, so long as we qualify as an “emerging growth company,” we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would have otherwise been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate us.

We cannot predict if investors will find our Common Stock less attractive because we will rely on these exemptions. 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.

Because of the exemptions from various reporting requirements provided to us as an “emerging growth company,” we may be less attractive to investors, and it may be difficult for us to raise additional capital as and when we need it. 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**

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 use a widely-adopted risk quantification model to identify, measure and prioritize cybersecurity and technology risks and 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 located at 3513 Brighton Boulevard, Suite #410, Denver, Colorado 80216 pursuant to a lease agreement on a month-to-month basis. We believe this property is adequate to operate our business.

**Item 3. Legal Proceedings.**

From time to time, we may become involved in various claims and legal proceedings. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**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 30, 2024, there were 76 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

##### *PIPE Financing*

On August 23, 2022, following the execution of the Merger Agreement, LMAO entered into subscription agreements with three institutional investors (the "PIPE Investors") whereby, the PIPE Investors collectively subscribed for an aggregate of 700,000 shares of Common Stock at \$10.00 per share, and 700,000 warrants for aggregate gross proceeds of \$7.0 million (the "PIPE Financing"). The PIPE Financing was consummated concurrently with the Closing of the Business Combination.

The shares of Common Stock issued to the PIPE Investors were issued in accordance with the exemption from registration under the Securities Act, under Section 4(a)(2) promulgated under the Securities Act.

The issuance of Class A Common Stock upon the automatic conversion of the Class B Common Stock and the issuance of Common Stock upon the automatic conversion of the Class A Common Stock at the Closing has not been registered under the Securities Act in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act.

##### *Convertible Note Financing*

###### *The Original and Amended Institutional Investor SPA*

On March 15, 2023, we entered into a Securities Purchase Agreement ("SPA") with an institutional investor ("Investor D") (the "Investor D SPA"), whereby we agreed to issue a series of four senior unsecured convertible notes (collectively the "Investor D Convertible Notes"), with principal proceeds totaling up to \$9.8 million, and warrants to purchase shares of our common stock.

On March 15, 2023, the Company issued the first senior unsecured convertible note (the "First Investor D Note") in the amount of approximately \$3.3 million, convertible into 1,207,729 shares of our common stock at an initial conversion price of \$2.70. The First Investor D Note was issued at an 8.0% discount, bears interest at 7.0% per annum, matured on June 15, 2024, and requires monthly installments of principal and interest. The First Investor D Note is

redeemable, in whole or part, at our discretion. In addition, we issued warrants to purchase 328,352 shares of common stock with a strike price of \$2.97 (the "First Investor D Note Warrants"). The First Investor D Warrants have an initial exercise price of \$2.97 per share of common stock, expire in five years from their issuance date, and contain a cashless exercise provision.

On May 12, 2023, we issued the second senior unsecured convertible note (the "Second Investor D Note") in the amount of approximately \$2.2 million, convertible into 805,153 shares of common stock at an initial conversion price of \$2.70. The Second Investor D Notes were issued at an 8.0% discount and bear interest at 7.0% per annum and mature on June 15, 2024, and August 12, 2024. The Second Investor D Notes are redeemable, in whole or in part, at any time at our discretion. In addition, we issued warrants to purchase 218,901 shares of common stock (the "Second Investor D Note Warrants"). The Second Investor D Warrants have an initial exercise price of \$2.97 per share of common stock, expire five years from their issuance date, and contain cashless exercise provisions.

#### *First Amendment to the Investor D SPA*

On August 7, 2023, we entered into an amendment to the Investor D SPA, whereby the provisions of the third closing are amended (the "First Amended Investor D SPA"). The institutional investor shall have the discretion to purchase additional shares of our common stock in an aggregate principal amount of \$2.0 million (the "Third Investor D Note"). The Third Investor D Note consisted of four tranches which closed on August 7, 2023, August 30, 2023, September 26, 2023, and November 27, 2023, respectively. Each tranche of the Third Investor D Note was issued at an 8.0% discount, bear interest at 7.0% per annum and require monthly installments of principal and interest. Each tranche of the Third Investor D Notes is convertible into 2,717,144 shares of common stock at an initial conversion price of \$0.20, in a principal amount of \$0.5 million, and includes a warrant to purchase up to 738,791 shares of common stock with an exercise price of \$0.20 per share of common stock. The Third Investor D Notes mature on November 6, 2024, November 29, 2024, December 25, 2024, and February 26, 2025, respectively.

Also on August 7, 2023, we entered into a side letter with Investor D (the "Letter Agreement"), pursuant to which we agreed to adjust the conversion price of the First and Second Investor D Notes to the lowest of (i) \$0.20, (ii) the closing sale price of common stock on the trading day immediately preceding the date of the conversion, and (iii) the average closing sale price of common stock for the five consecutive trading days immediately preceding the date of the conversion (the "Amended First Investor D Note" and Amended Second Investor D Note"). We also agreed to issue a warrant to purchase up to 4,765,620 shares of common stock with an exercise price of \$0.20 per share of common stock as part of Letter Agreement (the "Investor D Letter Agreement Warrants").

#### *The Second Amendment to the Investor D SPA*

On December 11, 2023, we entered into the Second Amendment to the Investor D SPA (the "Second Investor D SPA") and closed on a fourth convertible note (the "Fourth Investor D Note") in a principal amount of approximately \$1.1 million, which is convertible into shares of common stock at a conversion price of \$0.56 per share, beginning on the earlier of June 11, 2024 (or earlier upon mutual written agreement between us and the purchaser), or the date of an event of default, as defined in the Fourth Investor D Note, with a maturity date of March 11, 2025. The Company also issued two warrants, each to purchase up to 527,708 shares of our common stock with an exercise price of \$0.56 per share.

For the purposes of defining the collection of the various agreements and instruments by and between Investor D and us:

- the Investor D SPA, First Amended Investor D SPA, and Second Amended Investor D SPA are referred to as the "Original and Amended Investor D SPA".
- All Investor D convertible notes issued and/or amended under the Original and Amended Investor D SPA are collectively referred to as the "Investor D Convertible Notes".
- All warrants issued under the Original and Amended SPA or Letter Agreement are collectively referred to as the "Investor D Convertible Note Warrants"

The Notes, Warrants, and shares of Common Stock issuable upon conversion of the Notes and upon exercise of such Warrants, have not been registered under the Securities Act of 1933, as amended (the "Securities Act") and were

issued and sold to an accredited investor in reliance upon the exemption from registration contained in Regulation D promulgated under the Securities Act.

**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 the Company's 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, LMF 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, LMF was renamed SeaStar Medical Holdings Corporation (as defined above).

We are a medical technology company developing a platform therapy to reduce the consequences of hyperinflammation on vital organs. 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. If the inflammatory response becomes excessive and dysregulated, normal neutrophil die off may be delayed, altering feedback mechanisms that regulate the immune system. This results of damaging hyperinflammation spreading uncontrollably to other parts of the body, often leading to acute chronic solid organ dysfunction or failure, including heart, lung, kidney and liver diseases. 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. The cytokine storm, when left uncontrolled, can lead to organ damage and even death.

We are initially using our proprietary Selective Cytopheretic Device ("SCD") technology platform to clinically validate several acute organ injury indications, including kidneys and lungs. Our investigational SCD is an extracorporeal synthetic membrane device designed to be easily integrated into existing Continuous Renal Replacement Therapy ("CRRT") systems that are commonly installed in hospitals, including in Intensive Care Units throughout the United States. Once approved and commercialized, the SCD would initially target acute kidney injury in both the pediatric CRRT population as well as adults on CRRT. In addition, we are developing our SCD to address inflammation associated with chronic dialysis and chronic heart failure. The regulatory approval process for our SCD product candidates is costly and involves significant risks and uncertainties. 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, 2023 and 2022, we had an accumulated deficit of approximately \$114.7 million and \$88.5 million, respectively. Our net losses were \$26.2 million and \$12.2 million for the years ended December 31, 2023 and 2022, respectively. Approximately 54% of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. The remaining 36% of our 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 year ended December 31, 2023, these non-cash, non-operating losses were related to change in fair value of convertible notes, change in fair value of forward option-prepaid forward contracts and loss on extinguishment of convertible notes, which were partially offset by gains from the change in fair value of warrants liability and gain on

sale of recycled shares. For the year ended December 31, 2022, certain losses were related to the Business Combination, including costs to obtain the forward contracts and the change in fair value of the forward option derivatives.

As of December 31, 2023 and 2022, we had cash of approximately \$0.2 million and \$0.0 million, respectively.

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.

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 from the date the consolidated financial statements are made available. See Note 1 to our audited consolidated financial statements for the year-ended December 31, 2023, included elsewhere in this Annual Report for additional information on our assessment.

Our need for additional capital will depend in part on the scope and costs of our development activities. To date, we have not generated any significant revenue from the sale of commercialized products. Our ability to generate product revenue will depend on the successful development and eventual commercialization of our products. 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**

To date, we have not generated any revenue from the sale of commercialized products. Revenue has been primarily derived from government and other grants. We may generate revenue in the future based on payments from future license or collaboration agreements and government and other grants, and, if our products receive regulatory approval for commercialization, from product sales. We expect that any revenue we generate will fluctuate from quarter to quarter. If we fail to complete the development of or obtain regulatory approval for commercialization of our products in a timely manner, our ability to generate future revenue and our results of operations and financial position, would be materially adversely affected.

### **Research and Development Expenses**

Since our inception, we have focused our resources on our 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 products.

### **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. 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, a new enterprise resource planning platform, and branding.

### Origination Cost of Forward Contracts

The origination cost of forward contracts consists primarily of consideration related to the forward purchase agreements.

### Loss from Operations and Operating Margin

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

### Other Income (Expense), Net

Total other income (expense), net primarily consists of interest expense relating to interest incurred on our notes, financing fees related to our convertible notes, gain on issuance of convertible notes, change in fair value of convertible notes, change in fair value of warrants liability, change in fair value of forward-option forward contracts, and gain on sale of recycled shares, gains from early extinguishment of convertible notes, and changes in fair value of the derivative liability related to the conversion option of convertible notes.

### Net Loss

Net loss consists of our loss from operations, less other expenses, net.

### Factors Affecting the Company's 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, 2023 to Year Ended December 31, 2022

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	
	2023	2022	\$	%
Revenue	\$ —	\$ —	\$ —	—
Operating expenses				
Research and development	5,973	2,503	3,470	139 %
General and administrative	8,237	6,916	1,321	19 %
Origination cost of prepaid forward contracts	—	2,190	(2,190)	(100) %
Total operating expenses	14,210	11,609	2,601	22 %
Loss from operations	(14,210)	(11,609)	(2,601)	22 %
Total other income (expense)	(12,022)	(580)	(11,442)	1973 %
Loss before income tax provision	(26,232)	(12,189)	(14,043)	115 %
Income tax provision (benefit)	—	1	(1)	(100) %
Net loss	\$ (26,232)	\$ (12,190)	\$ (14,042)	115 %

### Research and Development Expenses



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

(\$ in thousands)	Year Ended December 31,		Change	
	2023	2022	\$	%
Clinical trials	\$ 2,546	\$ —	\$ 2,546	100 %
External services	1,111	1,681	(570)	(34) %
Payroll and personnel expenses	2,164	658	1,506	229 %
Other research and development expenses	152	164	(12)	(7) %
	<u>\$ 5,973</u>	<u>\$ 2,503</u>	<u>\$ 3,470</u>	<u>139 %</u>

Research and development expenses for the years ended December 31, 2023 and 2022 were approximately \$6.0 million and \$2.5 million, respectively. The increase in research and development expenses of \$3.5 million, or 139%, was primarily driven by increases in clinical trial expenses of \$2.5 million, an increase in payroll and personnel expenses of \$1.5 million, partially offset by a decrease of external services of \$0.6 million.

#### *General and Administrative Expenses*

General and administrative expenses for the years ended December 31, 2023 and 2022 were \$8.2 million and \$6.9 million, respectively. The increase in general and administrative expenses of \$1.3 million, or 19% is due primarily to an increase in insurance expense of \$1.4 million, increased fees related to SEC reporting of \$0.7 million, an increase in payroll related expenses of \$0.2 million, an increase in legal and professional fees of \$1.0 million, an increase in Director's compensation expense of \$0.3 million, an increase of warrant expense of \$0.2 million, and an increase in a legal settlement of \$0.2 million, partially offset by a decrease in commitment fees for the equity line of credit of \$2.5 million.

#### *Other Income (Expense)*

Other income (expense) for the years ended December 31, 2023 and 2022 was expense of \$12.0 million and \$0.6 million, respectively. The increase of \$11.4 million primarily resulted from an increase in interest expense of \$0.5 million, unrealized loss on our convertible notes of \$5.4 million, and loss on extinguishment of convertible notes of \$4.9 million, coupled with a \$10.8 million reduction in unrealized gains from declines in the fair value of our derivative warrants liability. This was offset by a decline in the loss recognized in the change in fair value of the forward purchase agreement derivative liability of \$8.9 million, other income of \$0.2 million, and finally in fiscal year-ended December 31, 2022, we incurred a \$0.6 million loss on changed in fair value of our pre-merger convertible notes payable derivative liability, for which those liabilities did not exist in the fiscal year-ended December 31, 2023.

#### *Income Tax Provision (Benefit)*

SeaStar Medical recorded a provision for income taxes of \$0.0 million for the years ended December 31, 2023 and 2022.

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. SeaStar Medical considers 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 2023 and 2022, the Company 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 \$25.6 million and \$21.2 million was recorded for the years ended December 31, 2023 and 2022, respectively.

#### *Net Loss*

During the year ended December 31, 2023, SeaStar Medical had a net loss of \$26.2 million compared to a net loss of \$12.2 million for the year ended December 31, 2022. The increased net loss of \$14.0 million primarily resulted from increases in general and administrative expenses of \$1.3 million, increases in research and development expenses of \$3.5 million, offset by a decline in origination costs on prepaid forward contracts of approximately \$2.9 million. Other expenses increased by (i) \$11.4 million, primarily resulting from an increase in interest expense of \$0.5 million, an unrealized loss on the change in fair value of convertible notes of \$5.4 million that the Company entered into in 2023, (ii) a loss on extinguishment of convertible notes of \$4.9 million, and (iii) a decline in unrealized gains from declined in derivative warrant liability of \$10.3 million. This was offset by a declines in (i) unrealized losses on the change in the fair value of forward purchase agreement derivative liabilities of \$8.5 million, (ii) unrealized losses on our notes payable derivative liability, and (iii) other income increased by \$0.2 million.

## **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, 2023 and December 31, 2022, we had an accumulated deficit of \$114.7 million and \$88.5 million, respectively.

As of December 31, 2023 and December 31, 2022, we had cash of \$0.2 million and \$0.0 million, respectively. We expect that our existing cash will be insufficient to fund our operations, including clinical trial expenses and capital expenditure requirements. We believe that this raises 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 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 period ended December 31, 2023.

## ***Fiscal Year-Ended December 31, 2023***

At the beginning of the fiscal year-ended December 31, 2023, our outstanding debt consisted of the following:

- Credit Agreement with LM Funding America, Inc. ("LMFA") with an outstanding balance of approximately \$0.7 million (the "LMFA Note"),
- Amended and restated promissory note with LMFAO Sponsor, LLC with an outstanding balance of approximately \$2.8 million the ("LMFAO Note"),
- A note payable to Maxim ("Maxim") with an outstanding balance of approximately \$4.2 million (the "Maxim Note"), and
- A financing agreement with a lender to finance a portion of the annual premium of an insurance policy with an outstanding balance of approximately \$0.9 million.

## **2023 Convertible Notes**

### ***The Original and Amended Institutional Investor SPA***

On March 15, 2023, we entered into a Securities Purchase Agreement ("SPA") with an institutional investor ("Investor D") (the "Investor D SPA"), whereby we agreed to issue a series of four senior unsecured convertible notes (collectively the "Investor D Convertible Notes"), with principal proceeds totaling up to \$9.8 million, and warrants to purchase shares of our common stock.

On March 15, 2023, the Company issued the first senior unsecured convertible note (the "First Investor D Note") in the amount of approximately \$3.3 million, convertible into 1,207,729 shares of our common stock at an initial conversion price of \$2.70. The First Investor D Note was issued at an 8.0% discount, bears interest at 7.0% per annum, matured on June 15, 2024, and requires monthly installments of principal and interest. The First Investor D Note is redeemable, in whole or part, at our discretion. In addition, we issued warrants to purchase 328,352 shares of common stock with a strike price of \$2.97 (the "First Investor D Note Warrants"). The First Investor D Warrants have an initial

exercise price of \$2.97 per share of common stock, expire in five years from their issuance date, and contain a cashless exercise provision.

On May 12, 2023, we issued the second senior unsecured convertible note (the "Second Investor D Note") in the amount of approximately \$2.2 million, convertible into 805,153 shares of common stock at an initial conversion price of \$2.70. The Second Investor D Notes were issued at an 8.0% discount and bear interest at 7.0% per annum and mature on June 15, 2024, and August 12, 2024. The Second Investor D Notes are redeemable, in whole or in part, at any time at our discretion. In addition, we issued warrants to purchase 218,901 shares of common stock (the "Second Investor D Note Warrants"). The Second Investor D Warrants have an initial exercise price of \$2.97 per share of common stock, expire five years from their issuance date, and contain cashless exercise provisions.

#### *First Amendment to the Investor D SPA*

On August 7, 2023, we entered into an amendment to the Investor D SPA, whereby the provisions of the third closing are amended (the "First Amended Investor D SPA"). The institutional investor shall have the discretion to purchase additional shares of our common stock in an aggregate principal amount of \$2.0 million (the "Third Investor D Note"). The Third Investor D Note consisted of four tranches which closed on August 7, 2023, August 30, 2023, September 26, 2023, and November 27, 2023, respectively. Each tranche of the Third Investor D Note was issued at an 8.0% discount, bear interest at 7.0% per annum and require monthly installments of principal and interest. Each tranche of the Third Investor D Notes is convertible into 2,717,144 shares of common stock at an initial conversion price of \$0.20, in a principal amount of \$0.5 million, and includes a warrant to purchase up to 738,791 shares of common stock with an exercise price of \$0.20 per share of common stock.. The Third Investor D Notes mature on November 6, 2024, November 29, 2024, December 25, 2024, and February 26, 2025, respectively.

Also on August 7, 2023, we entered into a side letter with Investor D (the "Letter Agreement"), pursuant to which we agreed to adjust the conversion price of the First and Second Investor D Notes to the lowest of (i) \$0.20, (ii) the closing sale price of common stock on the trading day immediately preceding the date of the conversion, and (iii) the average closing sale price of common stock for the five consecutive trading days immediately preceding the date of the conversion (the "Amended First Investor D Note" and Amended Second Investor D Note") . We also agreed to issue a warrant to purchase up to 4,765,620 shares of common stock with an exercise price Of \$0.20 per share of common stock as part of Letter Agreement (the "Investor D Letter Agreement Warrants").

#### *The Second Amendment to the Investor D SPA*

On December 11, 2023, we entered into the Second Amendment to the Investor D SPA (the "Second Investor D SPA") and closed on a fourth convertible note (the "Fourth Investor D Note") in a principal amount of approximately \$1.1 million, which is convertible into shares of common stock at a conversion price of \$0.56 per share, beginning on the earlier of June 11, 2024 (or earlier upon mutual written agreement between us and the purchaser), or the date of an event of default, as defined in the Fourth Investor D Note, with a maturity date of March 11, 2025. The Company also issued two warrants, each to purchase up to 527,708 shares of our common stock with an exercise price of \$0.56 per share.

For the purposes of defining the collection of the various agreements and instruments by and between Investor D and us:

- the Investor D SPA, First Amended Investor D SPA, and Second Amended Investor D SPA are referred to as the "Original and Amended Investor D SPA".
- All Investor D convertible notes issued and/or amended under the Original and Amended Investor D SPA are collectively referred to as the "Investor D Convertible Notes".
- All warrants issued under the Original and Amended SPA or Letter Agreement are collectively referred to as the "Investor D Convertible Note Warrants"

#### Notes Payable and Other Financings

On March 15, 2023, we amended our LMFA notes, LMFAO note and Maxim note, extending their maturity dates to June 15, 2024. In consideration for such extension, we agreed to pay the noteholders an aggregate amount of

\$0.1 million in cash upon receipt of proceeds from the issuance of the Second Investor D Notes. The mandatory repayment provisions of the notes were waived for the First Investor D Note drawn on March 15, 2023.

On May 12, 2023, we amended its LMFA notes, LMFAO note and Maxim note. The mandatory repayment provisions of the notes were waived for the LMFA notes, and LMFAO note for the Second Investor D Note drawn on May 12, 2023. The mandatory repayment for the Maxim note was reduced to \$0.1 in full satisfaction of the obligation under the promissory note with respect to the closing of the Second Investor D Note.

On August 7, 2023, we entered into certain amendments and waivers for the Maxim Note, LMFA Note, and LMFAO Note. The lenders waved their rights to receive any mandatory prepayments for proceeds received us from the convertible note financings and agreed to extend the maturity dates to 91 days after the last maturity date applicable to any of the notes issued pursuant to the Original and Amended Investor D SPA.

In April 2021 we received loan proceeds in the amount of \$0.1 million, under the PPP as established under the CARES Act. The loan and accrued interest were forgivable as long as we used the loan proceeds for eligible purposes, including payroll, employee benefits, rent and utilities, and maintained its payroll levels. During the year ended December 31, 2021, \$0.1 million of our PPP loan was forgiven.

## ***Fiscal Year Ended December 31, 2022***

### ***Business Combination***

Upon consummation of the Business Combination, we received \$17.0 million in cash, primarily due to \$7.0 million in gross proceeds from the PIPE Investment and \$10.0 million in proceeds from the trust account, partially offset by cash payments that were disbursed at the closing of the Business Combination which included Maxim's deferred fee, professional service fees for the legal counsels, transfer agent, consultants, and auditors, a commitment fee, director and officer insurances, and prepayments to the forward purchase agreement sellers totaling approximately \$16.6 million.

In connection with the Business Combination, over 8 million shares were submitted for redemption for an aggregate redemption amount of approximately \$92.0 million. The proceeds we received in connection with the Business Combination were significantly less than the total potential proceeds of \$103.5 million (assuming no redemptions). The reduction in available cash upon the Closing due to share redemptions has negatively impacted our growth initiatives, our revenue and net loss projections prepared in connection with LMAO's evaluation of the Business Combination, and our liquidity, including the likelihood that holders of warrants will exercise their warrants and we will receive cash proceeds from the warrants.

### ***Convertible Notes***

During the year ended December 31, 2022, we issued convertible notes totaling \$1.7 million to certain existing holders of our issued and outstanding preferred stock, including six convertible notes in the aggregate principal amount of \$1.2 million to an employee pension fund ("Investors A"). The maturity dates for the convertible notes range from one to three years from their respective issuance dates. These notes were unsecured obligations of SeaStar Medical and borrowings on the convertible notes bore interest at 8.0 %. Immediately prior to the Closing, all principal amounts and accrued interest under the convertible notes were converted into shares of our Common Stock at a conversion price of \$10.00 per share.

In addition, two other convertible notes that were issued prior to the 2022 fiscal year, (i) investors involved in commercialization efforts arising from academic research initiatives ("Investors C") and, (ii) an employee pension plan ("Investor B") had all principal and accrued interest converted into shares of our common stock as a result of the Closing.

### ***Proceeds from Warrants***

To the extent any warrants are issued on a "cashless basis," the amount of cash we would receive from the exercise of the warrants will decrease. We would expect to use any such proceeds received from warrants that are

exercised for cash in the future for general corporate and working capital purposes, which would increase our liquidity. However, we will only receive such proceeds if and when the warrant holders exercise the warrants. The exercise of the warrants, and any proceeds we may receive from their exercise, are highly dependent on the price of our Common Stock and the spread between the exercise price of the warrant and the price of our common stock at the time of exercise. There is no assurance that the warrant holders will elect to exercise for cash any or all of such warrants, and we believe that any such exercise currently is unlikely to occur as described below. As of the date of this Annual Report, we have neither included nor intend to include any potential cash proceeds from the exercise of our warrants in our short-term or long-term liquidity projections. We will continue to evaluate the probability of warrant exercise over the life of our warrants and the merits of including potential cash proceeds from the exercise in our liquidity projections.

We do not expect to rely on the cash exercise of warrants to fund our operations. Instead, we intend to rely on our primary sources of cash discussed elsewhere in this Annual Report to continue to support our operations.

#### *2023 Private Warrants*

As noted above, the following summarizes Investor D Convertible Note Warrants issued in connection with the Original and Amended Investor D SP during the fiscal-year ended December 31, 2023::

- On March 15, 2023, as part of the issuance of the First Investor D Note, 328,352 convertible note warrants were issued with an exercise price of \$2.97 per share.
- On May 12, 2023, as part of the issuance of the Second Investor D Note, 218,901 convertible note warrants were issued with an exercise price of \$2.97 per share.
- On August 7, 2023, as part of the Letter Agreement, 4,765,620 convertible note warrants were issued with an exercise price of \$0.20 per share. Also on August 7, 2023, as part of the issuance of the first tranche of the Third Investor D Note, 738,791 Convertible Note Warrants were issued with an exercise price of \$0.20 per share.
- On August 30, 2023, as part of the issuance of the second tranche of the Third Investor D Note, 738,791 convertible note warrants were issued with an exercise price of \$0.20 per share.
- On September 26, 2023, as part of the issuance of the third tranche of the Third Investor D Note, 738,791 convertible note warrants were issued with an exercise price of \$0.20 per share.
- On November 27, 2023, as part of the issuance of the fourth tranche of the Third Investor D Note, 738,791 convertible note warrants were issued with an exercise price of \$0.20 per share.
- On December 11, 2023, in connection with the Second Amended Investor D SPA, and as a result the Fourth Investor D Note, the Company issued two warrants, each to purchase up to 527,708 shares of common stock with an exercise price of \$0.56 per share.
- In December 2023, 2,955,164 warrants from the Third Convertible Notes were converted into shares at an exercise price of \$0.20.

The convertible note warrants expire five years from their issuance date and contain cashless exercise provisions. The Company does not have the ability to redeem the convertible note warrants.

#### *2022 Public Warrants*

As part of the Closing, the Company issued 10,350,000 registered warrants (Ticker: ICUWW) with an exercise price of \$11.50 per share. If exercised in full, we would receive the proceeds from any exercise of any warrants that are exercised for cash pursuant to their terms. Assuming the exercise in full of all of the warrants for cash, we would receive an aggregate of approximately \$185.0 million, but would not receive any proceeds from the sale of the shares of common stock issuable upon such exercise.

However, as of December 31, 2023, our common stock was trading at approximately \$0.44 per share. Accordingly, we believe that it is currently unlikely that warrant holders will exercise their warrants. The likelihood

that warrant holders will exercise the warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our common stock. If the trading price for our common stock remains less than \$11.50 per share, we believe our warrant holders will be unlikely to exercise their warrants. There is no guarantee that the warrants will be in the money following the time they become exercisable and prior to their expiration, and as such, the warrants may expire worthless, and we may not receive any proceeds from the exercise of the warrants. To the extent that any of the warrants are exercised on a "cashless basis," the amount of cash we would receive from the exercise of the warrants will decrease.

#### **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 Food and Drug Administration ("FDA"), and (ii) if regulatory approval is obtained, to launch and commercialize our product in the U.S. market, including subsequent launches in key international 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:

- our ability to receive cash proceeds from our existing funding sources, including 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 commercialize our products, we expect to continue financing our operations through the sale of equity, 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 to us when needed or on acceptable terms.

Based on our results of operations and liquidity as of December 31, 2023, we believe our cash and cash equivalents, including the cash we obtained from the Business Combination and the PIPE Investment, as well as potential proceeds available under the Purchase Agreement with Tumim Stone Capital ("Tumim") and from the Forward Purchase Agreements ("FPA"), are 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 year ended December 31, 2023. 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 are seeking 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 and cash equivalents 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.

## 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,	
	2023	2022
<b>Statement of cash flow data:</b>		
Total cash (used in)/provided by:		
Operating activities	\$ (10,285)	\$ (7,794)
Investing activities	—	—
Financing activities	10,414	7,331
	\$ 129	\$ (463)

### Cash Flow from Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was \$10.3 million compared to \$7.8 million for the year ended December 31, 2022. The increase in cash used for operating activities of \$2.5 million is primarily due to the increased activity related to the clinical trial, and increase in expenses related to SEC reporting, and an increase in insurance expense.

### Cash Flow from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was \$10.4 million, primarily related to the issuance of new shares of common stock, proceeds from convertible notes, and the sale of recycled shares, partially offset by payments of notes payable, and payment of convertible notes. Cash provided by financing activity for the year ended December 31, 2022, was \$7.3 million, primarily related to the Business Combination in the fourth quarter of 2022.

## 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 forward option on forward purchase agreement, derivative liability, convertible note warrants, convertible notes at fair value, and the amount of share-based compensation expense.

While our significant accounting policies are described in Note 2 - Summary of Significant Accounting Policies to the notes to our audited 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 financial statements.

**Prepaid Forward Purchase Agreement Derivative Liability.** The prepaid forward purchase agreement derivative liability (the "FPA Derivative Liability") is required to be recognized as a liability as the financial instrument fails the "Indexation Guidance" of ASC 815-10 in addition having certain settlement features that could or will require settlement in cash or shares, depending on the feature. The FPA Derivative Liability was initially recorded at \$5.2 million on October 28, 2022 (see Note 5). The FPA Derivative Liability was remeasured each reporting period using a Monte-Carlo Simulation in a risk-neutral framework (a special case of the Income Approach). Specifically, the future

stock price is simulated assuming a Geometric Brownian Motion ("GBM"). For each simulated path, the forward purchase value was calculated based on the contractual terms and then discounted at the term-matched risk-free rate. Finally, the value of the forward was calculated as the average present value over all simulated paths. Changes in the fair value of the FPA Derivative Liability are recorded each reporting period to the change in the fair value of the forward purchase agreement derivative liability in the consolidated statement of operations.

**Investor D Convertible Notes.** The convertible notes are recorded as liabilities and are recorded at fair value based on Level 3 measurements. The estimated fair values of the convertible notes are each determined based on the aggregated, probability-weighted average of the outcomes of certain possible scenarios. The combined value of the probability-weighted average of those outcomes is then discounted back to each reporting period in which the convertible notes are outstanding, in each case, based on a risk-adjusted discount rate estimated based on the implied interest rate using the changes in observed interest rates of corporate rate debt that we believe is appropriate for those probability-adjusted cash flows. The change in fair value of the Investor D Convertible Notes each reporting period is recorded to the Change in fair value of convertible notes in the consolidated statement of operations.

**Pre-Merger Notes Derivative Liability.** Pre-Merger Notes derivative liabilities in the amounts of approximately \$0.1 million were recorded during the first quarter of 2022 for the issuance of notes along with a corresponding debt discount (see Note 8). The notes liabilities are remeasured each reporting period using a probability-weighted model and assumption related to the conversion price and timing of conversion. The put option liability was valued based on the calculated returns as a result of the various discounts included in our notes and the related probability assessments of the various settlement scenarios. The notes derivative liability was extinguished as of the closing of the Business Combination (the "Closing"), as a result of the conversion of the notes. On October 28, 2022, the put option liability was settled upon the Closing and reclassified to additional paid-in capital. Changes in fair value of the Pre-Merger Notes Derivative Liability each reporting period is recorded to the Change in fair value of notes payable derivative liability in the consolidated statement of operations.

**Liability Classified Warrants.** We have entered into or assumed as part of the Business Combination 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 the remeasure the warrants. The liability classified warrants consist of the following: (see Note 11 for more information):

**Private Placement Warrants.** We assumed 5,738,000 Private Placement warrants as part of the Business Combination.

**PIPE Warrants.** The PIPE Warrants were entered into in congruence with the Business Combination, and include features similar to the Private Placement Warrants which require liability classification.

**Investor D Warrants.** During the fiscal year ended December 31, 2023, we entered into various convertible credit agreements with an institutional investor ("Investor D") which included detachable and separately exercisable warrants to purchase shares of our common stock (the "Investor D Convertible Note Warrants").

We use a Black-Scholes option pricing model to fair value the Investor D Convertible Note 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 Investor D Convertible Note Warrants each reporting period is recorded to the change in fair value of warrants liability in the consolidated statement of operations.

## Emerging Growth Company Status

We are an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups ("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 emerging growth company 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 \$1.07 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.

## **Business Combination**

On October 28, 2022, LMAO consummated a series of transactions that resulted in the combination of LMF Merger Sub, Inc. and the Predecessor (the "Business Combination"), pursuant to an Agreement and Plan of Merger as described further in this Annual Report. LMAO was renamed to "SeaStar Medical Holding Corporation." The Business Combination was treated as the equivalent of the Predecessor issuing shares for the net assets of LMAO, accompanied by a recapitalization. The net assets of LMAO were stated at historical cost. Operations prior to the Business Combination are those of the Predecessor.

The aggregate consideration payable to the stockholders of the Predecessor at October 28, 2022 (the "Closing"), was \$85.4 million. The consideration consisted of \$85.0 million; minus any the Predecessor indebtedness; minus the Predecessor transaction expenses in excess of a cap of \$0.8 million; plus the aggregate exercise price of unexercised the Predecessor warrants and options issued and outstanding immediately prior to the Closing; less the value of the shares of common stock underlying the assumed equity (the "Closing Consideration"). The Closing Consideration was payable solely in shares of LMAO common stock, par value \$0.0001 per share, valued at \$10.00 per share, resulting in the issuance of 8,540,552 shares of common stock to holders of stock of the Predecessor, immediately prior to the Closing. At the Closing, shares of class B common stock, par value \$0.001 per share, of LMAO ("Class B Common Stock") automatically converted into shares of class A common stock, par value \$0.001 per share, of LMAO ("Class A Common Stock") on a one-to-one basis, and pursuant to the charter of LMAO after the Business Combination, Class A and Class B common stock was reclassified as common stock.

At the Closing, each of the Predecessor's issued and outstanding convertible notes automatically converted into shares of SeaStar Medical Holding Corporation common stock. Immediately prior to the effectiveness of the Business Combination, each share of the Predecessor's issued and outstanding preferred stock automatically converted into shares of SeaStar Medical Holding Corporation common stock and those the Predecessor warrants that would be exercised or exchanged in connection with the Business Combination were exercised for shares of the Predecessor common stock. At Closing, the (i) the Predecessor warrants that would not be exercised or exchanged in connection with the Business Combination were assumed by LMAO and converted into warrants to purchase common stock, (ii) outstanding options for shares of the Predecessor common stock under the Predecessor's equity plan were assumed by LMAO and converted into options to purchase common stock, and (iii) issued and outstanding restricted stock unit awards under the Predecessor's current equity plan were assumed by LMAO and converted into LMAO restricted stock units.

## Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2023:

(\$ in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual Obligations:					
LMFA note payable	296	—	296	—	—
LMFAO note payable	1,128	—	1,128	—	—
Maxim note payable	2,771	—	2,771	—	—
Convertible Notes	3,154	2,719	435	—	—
Insurance Financing	565	565	—	—	—
Total contractual obligations	\$ 7,914	\$ 3,284	\$ 4,630	\$ —	\$ —

### Director Nomination Agreement

On October 28, 2022, the Sponsor and LMAO entered into the Director Nomination Agreement, providing the Sponsor certain director nomination rights, including the right to appoint or nominate for election to the Board, as applicable, two individuals, to serve as Class II directors of the Company, for a certain period following the Closing (the "Director Nomination Agreement").

### Equity Line of Credit

On August 23, 2022, the Predecessor, LMAO, and Tumim entered into an equity line financing arrangement through a Common Stock Purchase Agreement ("Purchase Agreement") providing the right to sell Tumim up to \$100 million worth of shares of common stock. The Purchase Agreement is subject to certain limitations and conditions and provided for a \$2.5 million commitment fee payable to Tumim. The Company paid \$1.0 million of the commitment fee in cash at Closing. The Company recorded an accrued expense for the remaining \$1.5 million of the commitment fee as of December 31, 2022. The \$2.5 million commitment fee was recorded in general and administrative expenses in the consolidated statements of operations for the year ended December 31, 2022. The Company paid previously accrued commitment fees of \$1.5 million during the year ended December 31, 2023, of which \$1.0 million was paid in 218,842 shares of common stock and \$0.5 million was paid in cash. During the year ended December 31, 2023, the Company sold 6,500,000 shares of common stock to Tumim for \$4.7 million as part of the equity line financing arrangement.

### Convertible Notes

As noted in the above Liquidity and Capital Resources Section, during the 2023 fiscal year-ended December 31, 2023, the Company entered into the Original and Amended Investor D SPA for up to \$9.8 million dollars in proceeds from four tranches of convertible debt, and associated warrants which are liability classified. Of the four Investor D Convertible Notes, the Amended First Investor D Note and Second Investor D Note were fully converted into shares of our common stock as of December 31, 2023. The remaining Investor D Convertible Notes are remeasured at each reporting period date.

Convertible notes that existed prior to the Business Combination had all principal and accrued interest fully converted into shares of our common stock upon the closing of the Business Combination in October 2022.

### LMFA Notes Payable

On September 9, 2022, the Predecessor entered into a Credit Agreement ("LMFA Note") with LM Funding America, Inc. ("LMFA") whereby LMFA agreed to make advances to the Predecessor of up to \$0.7 million for general corporate purposes at an interest rate of 15% per annum. All advances made to the Predecessor under the LMFA Note and accrued interest were due and payable to LMFA on the maturity date, which is the earlier of (a) October 25, 2022, (b) the consummation of the Business Combination, and (c) the termination of the Merger agreement. As of December 31, 2022, the Company has borrowed \$0.7 million under the LMFA Note.

On October 28, 2022, SeaStar Medical Holding Corporation and LMFA entered into the First Amendment to Credit Agreement, dated September 9, 2022 between LMFA and SeaStar Medical Holding Corporation whereby (i) the maturity date of the loan under the LMFA Note was extended to October 30, 2023; (ii) the Company is required to use 5.0% of the gross cash proceeds received from any future debt and equity financing to pay the outstanding balance of LMFA Note, provided that such repayment is not required for the first \$0.5 million of cash proceeds; (iii) the interest rate of the LMFA Note is reduced from 15% to 7% per annum; and (iv) the default interest rate is reduced from 18% to 15%. The LMFA Note contains customary representations and warranties, affirmative and negative covenants and events of default.

In addition, on October 28, 2022, the parties entered into a security agreement, pursuant to which SeaStar Medical Holding Corporation granted LMFA a security interest in substantially all of the assets and property of the Company, subject to certain exceptions, as collateral under the amended LMFA Note. In addition, the Company entered into a guaranty, dated October 28, 2022, whereby SeaStar Medical Holding Corporation unconditionally guarantees and promises to pay to LMFA the outstanding principal amount under the LMFA Note.

On March 15, 2023, the Company amended its LMFA note payable, extending the maturity date to June 15, 2024. On August 7, 2023, the Company entered into certain amendments and waivers for the LMFA note payable. The lender waived their rights to receive any mandatory prepayments for proceeds received by the Company from the convertible note financings and agreed to extend the maturity date to June 10, 2025.

#### *LMFAO Note Payable*

On October 28, 2022, the Company entered into a consolidated amended and restated promissory note with LMFAO Sponsor, LLC, LMAO's sponsor and the sole holder of founding shares as the lender, for an aggregate principal amount of \$2,785 (the "LMFAO Note") to amend and restate in its entirety (i) the promissory note, dated July 29, 2022, for \$1,035 in aggregate principal amount issued by LMAO to the Sponsor and (ii) the Amended and Restated Promissory Note, dated July 28, 2022, for \$1,750 in aggregate principal amount, issued by LMAO to the Sponsor (collectively, the "Original Notes"). The LMFAO Note amended the Original Notes to: (i) extend maturity dates of the Original Notes to October 30, 2023; (ii) permit outstanding amount due under the LMFAO Note to be prepaid without premium or penalty; and (iii) require the Company to use 20.0% of the gross cash proceeds received from any future debt and equity financing to pay the outstanding balance of LMFAO Note, provided that such repayment is not required for the first \$500 of cash proceeds. The LMFAO Note carries an interest rate of 7% per annum and contains customary representations and warranties and affirmative and negative covenants.

The LMFAO Note is subject to events of default, which may result in the LMFAO Note becoming immediately due and payable, with interest of 15.0% per annum. In addition, on October 28, 2022, the parties entered into a security agreement whereby the Company granted the Sponsor a security interest in substantially all of the assets and property of the Company, subject to certain exceptions, as collateral to secure the Company's obligations under the LMFAO Note.

On March 15, 2023, the Company amended its LMFAO note payable, extending the maturity date to June 15, 2024. On August 7, 2023, the Company entered into certain amendments and waivers for the LMFAO note payable. The lender waived their rights to receive any mandatory prepayments for proceeds received by the Company from the convertible note financings and agreed to extend the maturity date to June 10, 2025.

#### *Maxim Note Payable*

On October 28, 2022, we entered into a promissory note with Maxim as the lender, for an aggregate principal amount of \$4.2 million (the "Maxim Note"). The Maxim Note had a maturity date of October 30, 2023 and any outstanding amount may be prepaid without premium or penalty. If the Company receives any cash proceeds from a debt or equity financing transaction prior to the maturity date, then we are required to prepay the indebtedness equal to 25.0% of the gross amount of the cash proceeds, provided that such repayment obligation does not apply to the first \$0.5 million of the cash proceeds received by the Company. Interest on the Maxim Note is due at 7.0% per annum.

The Maxim Note contains customary representations and warranties, and affirmative and negative covenants. The Maxim Note is subject to events of default, which may result in the Maxim Note becoming immediately due and payable, with interest of 15.0% per annum.

On March 15, 2023, the Company amended its Maxim note payable, extending the maturity date to June 15, 2024. On August 7, 2023, the Company entered into certain amendments and waivers for the Maxim note payable. The lender waived their rights to receive any mandatory prepayments for proceeds received by the Company from the convertible note financings and agreed to extend the maturity date to June 10, 2025.

#### *Insurance Financing*

In October 2023, 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 is due at 9.55% per annum. Eight monthly installments of principal and interest will be made during the year ended December 31, 2024.

#### *Intercreditor Agreement*

On October 28, 2022, Maxim, LMFA, the Sponsor (collectively, the "Creditors"), the Predecessor and the Company entered into the Intercreditor Agreement in order to set their relative rights under the LMFA Note, LMFAO Note and Maxim Note, including the payments of amounts by the Company upon an event of default under such notes. Each Creditor agrees and acknowledges that LMFA and the Sponsor have been granted liens on the collateral as set forth in the applicable LMFA security agreement and the sponsor security agreement. Each creditor also agrees and acknowledges that Maxim's indebtedness under the Maxim Note is unsecured.

#### **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.

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<a href="#"><u>Report of Independent Registered Public Accounting Firm (PCAOB ID: 32)</u></a>	82
<a href="#"><u>100</u></a>	
<a href="#"><u>Report of Independent Registered Public Accounting Firm (PCAOB ID: 32)</u></a>	83
<a href="#"><u>Consolidated Balance Sheets as of December 31, 2023 and 2022</u></a>	86
<a href="#"><u>Consolidated Statements of Operations for the Years Ended December 31, 2023 and 2022</u></a>	87
<a href="#"><u>Consolidated Statements of Changes in Stockholders' Deficit for the Years Ended December 31, 2023 and 2022</u></a>	88
<a href="#"><u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2023 and 2022</u></a>	89
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	91

## **Report of Independent Registered Public Accounting Firm**

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

### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of SeaStar Medical Holding Corporation and its subsidiary (the "Company") as of December 31, 2023, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year then ended, 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, 2023, and the results of its operations and its cash flows for the year then ended 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 its 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.

### **Emphasis of the Matter – Restatement of Unaudited Condensed Consolidated Interim Financial Statements**

As discussed in Note 19 to the consolidated financial statements, the unaudited condensed consolidated interim financial statements as of and for the three months ended March 31, 2023, as of and for the three and six months ended June 30, 2023, and as of and for the three and nine months ended September 30, 2023 have been restated to correct certain misstatements.

### **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 audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

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

East Brunswick, New Jersey  
April 16, 2024

PCAOB ID No. 100

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of SeaStar Medical Holding Corporation  
Denver, Colorado

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of SeaStar Medical Holding Corporation ("the Company") as of December 31, 2022, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year ended December 31, 2022, 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, 2022, and the results of their operations and their cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

### **Going Concern**

The 2022 consolidated financial statements were prepared assuming that the Company would continue as a going concern. As of December 31, 2022, the Company had suffered recurring losses from operations, incurred negative cash flows from operating activities, and had stated that substantial doubt exists about the Company's ability to continue as a going concern. The 2022 consolidated financial statements did not include any adjustments that might result from the outcome of this uncertainty.

### **Restatement of the 2022 Financial Statements**

As discussed in Note 3 to the consolidated financial statements, the Company has restated its consolidated financial statements as of and for the year ended December 31, 2022 to correct certain misstatements.

### **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 audit. 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 audit 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.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Armanino LLP  
Bellevue, Washington

March 30, 2023, except for the effects of the restatement discussed in Note 3 to the consolidated financial statements, as to which the date is April 16, 2024.

We began serving as the Company's auditors in 2021. In 2023, we became the predecessor auditor.



**SeaStar Medical Holding Corporation**  
**Consolidated Balance Sheets**  
**As of December 31, 2023 and 2022**  
(in thousands, except for share and per-share amounts)

	<u>2023</u>	<u>2022</u> (As Restated)
<b>ASSETS</b>		
Current assets		
Cash	\$ 176	\$ 47
Other receivables	—	12
Prepaid expenses	2,132	1,460
Total current assets	2,308	1,519
Other assets	1,205	1,519
Total assets	\$ <u>3,513</u>	\$ <u>3,038</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities		
Accounts payable	\$ 4,372	\$ 1,927
Accrued expenses	1,523	2,245
Contingent upfront payment for license agreement	100	—
Notes payable, net of deferred financing costs	565	1,178
Convertible notes, current portion	4,179	—
Forward purchase agreement derivative liability	—	10,211
Liability classified warrants	2,307	587
Total current liabilities	13,046	16,148
Notes payable, net of deferred financing costs	4,143	7,652

Convertible notes, net of current portion	194	—
Total liabilities	17,383	23,800
Commitments and contingencies (Note 14)		
Stockholders' deficit		
Preferred stock - \$		
0.0001		
par value,		
10,000,000		
and		
10,000,000		
shares authorized at December 31, 2023 and 2022, respectively;		
no		
shares issued and outstanding at December 31, 2023 and 2022, respectively.	—	—
Common stock - \$		
0.0001		
par value per share;		
500,000,000		
and		
100,000,000		
shares authorized		
at December 31, 2023 and 2022, respectively;		
47,615,285		
and		
12,699,668		
shares issued and		
outstanding at December 31, 2023 and 2022, respectively	5	1
Additional paid-in capital	100,859	67,739
	(	(
	114,734	88,502
Accumulated deficit	)	)
	(	(
	13,870	20,762
Total stockholders' deficit	)	)
Total liabilities and stockholders' deficit	3,513	3,038
	\$ <u>                    </u>	\$ <u>                    </u>

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



**SeaStar Medical Holding Corporation**  
**Consolidated Statements of Operations**  
**For the Years Ended December 31, 2023 and 2022**  
(in thousands, except for share and per-share amounts)

	<u>2023</u>	<u>2022</u> (As Restated)
Operating expenses		
Research and development	\$ 5,973	\$ 2,503
General and administrative	8,237	6,916
Origination cost of prepaid forward contracts	—	2,190
Total operating expenses	14,210	11,609
	(	(
Loss from operations	14,210 )	11,609 )
Other income (expense)		
	(	(
Interest expense	1,081 )	630 )
	(	
Change in fair value of convertible notes	5,380 )	—
	545	10,863
Change in fair value of warrants liability		(
	—	602 )
Change in fair value of notes payable derivative liability		(
	1,308 )	10,211 )
	(	
Loss on extinguishment of convertible notes	4,949 )	—
	151	—
Other income	(	(
Total other income (expense), net	12,022 )	580 )
	(	(
Loss before provision for income taxes	26,232 )	12,189 )
	—	1
Provision for income taxes		

	(	(
	26,232	12,190
Net loss	<u>)</u>	<u>)</u>
	(	(
	1.21	1.48
Net loss per share of common stock, basic and diluted	<u>\$ )</u>	<u>\$ )</u>
	21,670,330	8,211,256
Weighted-average shares outstanding, basic and diluted	<u></u>	<u></u>

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

**SeaStar Medical Holding Corporation**  
**Consolidated Statements of Changes in Stockholders' Deficit**  
**For the Years Ended December 31, 2023 and 2022**  
(in thousands, except for share and per-share amounts)

	Stockholders' Deficit				
	Common Shares		Additional Paid-In Capital	Accumulated	Total Stockholders'
	Shares	Amount		Deficit	Deficit
				(	(
Balance, December 31, 2021	7,238,767	\$ 1	\$ 73,495	\$ 76,312	\$ 2,816
				)	)
Reverse recapitalization on October 28, 2022	4,162,040	—	3,294	—	3,294
Conversion of notes payable to common shares	598,861	—	5,989	—	5,989
PIPE financing, net of liability classified PIPE warrants	700,000	—	5,744	—	5,744
			(		(
Issuance of liability classified warrants	—	—	10,194	—	10,194
Forward purchase agreement prepayment			(		(
	—	—	11,900	—	11,900
			)		)
Stock-based compensation	—	—	1,311	—	1,311
				(	(
Net loss	—	—	—	12,190	12,190
				)	)
				(	(
Balance, December 31, 2022 (Restated)	12,699,668	1	67,739	88,502	20,762
				)	)
Issuance of shares - equity line of credit	6,500,000	1	4,741	—	4,742
Issuance of shares - commitment fee for equity line of credit	218,842	—	1,000	—	1,000
Issuance of shares - conversion of convertible notes	22,847,745	2	10,409	—	10,411
Issuance of shares - exercise of warrants	2,955,164	1	1,651	—	1,652

Issuance of shares - vesting of RSUs	205,947	—	—	—	—
Issuance of shares - prepaid forward contracts	1,096,972	—	1,870	—	1,870
Forward purchase agreement derivative liability	—	—	11,519	—	11,519
Stock-based compensation	1,090,947	—	1,930	—	1,930
Net loss	—	—	—	26,232	26,232
				(	(
<b>Balance, December 31, 2023</b>	<b>47,615,285</b>	<b>5</b>	<b>100,859</b>	<b>114,734</b>	<b>13,870</b>
	<u>          </u>	<u>\$          </u>	<u>\$          </u>	<u>\$          </u> )	<u>\$          </u> )

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

**SeaStar Medical Holding Corporation**  
**Consolidated Statements of Cash Flows**  
**For the Years Ended December 31, 2023 and 2022**  
(in thousands, except for shares and per-share amounts)

	<u>2023</u>	<u>2022</u>
		(As Restated)
Cash flows from operating activities		
Net loss	( 26,232 )	( 12,190 )
	\$	\$
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of discount on notes payable	—	242
Amortization of deferred financing costs	48	—
Non-cash accrued interest related to convertible notes	—	341
Change in fair value of notes payable derivative liability	—	602
Change in fair value of convertible notes	5,380	—
Change in fair value of forward purchase agreement derivative liability	1,308	10,211
Change in fair value of liability classified warrants	( 545 )	( 10,863 )
Loss on extinguishment of convertible notes	4,949	—
Stock-based compensation	1,930	1,311
Changes in operating assets and liabilities		
Other receivables	12	4
Prepaid expenses	( 97 )	( 1,073 )
Accounts payable	2,445	1,548
Accrued expenses	517	2,073
Net cash used in operating activities	( 10,285 )	( 7,794 )
Cash flows from financing activities		
Proceeds from issuance of convertible notes	8,000	1,681



Proceeds from recapitalization	—	9,961
Payment of recapitalization transaction costs	—	(1,211)
Proceeds from PIPE Investors	—	7,000
Payment for forward contracts	—	(11,940)
Payment of convertible notes	(400)	—
Proceeds from issuance of shares	4,742	—
Proceeds from exercise of convertible note warrants	592	—
Additional warrants	180	—
Payment of commitment fee - equity line of credit	(500)	—
Proceeds from sale of recycled shares	1,870	40
Proceeds from notes payable	800	1,878
Payment of notes payable	(4,870)	(15)
Payment of Government loans	—	(63)
Net cash provided by financing activities	10,414	7,331
Net increase (decrease) in cash	129	(463)
Cash, beginning of period	47	510
Cash, end of period	176	47
	\$ <u>176</u>	\$ <u>47</u>

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



**SeaStar Medical Holding Corporation**  
**Consolidated Statements of Cash Flows, cont'd**  
**For the Years Ended December 31, 2023 and 2022**  
(in thousands, except for shares and per-share amounts)

Supplemental disclosure of cash flow information	2023	2022
		(As Restated)
Cash paid for income taxes	\$ —	\$ 1
Cash paid for interest	\$ 1,126	\$ 6
Supplemental disclosure of noncash financing activities		
Value of derivative liability on issuance of convertible notes	\$ —	\$ 52
Noncash conversion of accrued expenses into convertible notes	\$ —	\$ 96
Conversion of notes payable to common stock	\$ —	\$ 5,989
Recapitalization transaction costs in accounts payable	\$ —	\$ 294
Recapitalization transaction costs in notes payable	\$ —	\$ 2,209
Shares issued as payment of convertible notes	\$ 10,411	\$ —
Shares issued to settle forward option-prepaid forward contracts	\$ 1,870	\$ —
Issuance of convertible note warrants	\$ 2,705	\$ —

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

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**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 in the pre-revenue stage 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.

On October 28, 2022, LMF Merger Sub, Inc., a wholly owned subsidiary of LMF Acquisition Opportunities, Inc., ("LMF" or the "Sponsor"), 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."

**Liquidity and going concern**

As of December 31, 2023, the Company has an accumulated deficit of approximately \$

114.7

million and cash of approximately \$

0.2

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, it has not generated any revenue from the sales of commercialized products. Its ability to generate product revenue will depend on the successful development and eventual commercialization of its product. Until such time, if ever, it expects to finance its operations through the sale of equity or debt, 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.

**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**

**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").

In connection with the preparation of the 2023 annual consolidated financial statements, the Company identified errors in its previously issued financial statements.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

In accordance with SEC Staff Accounting Bulletin ("SAB") No. 99, *Materiality*, and SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, the Company assessed the materiality of these errors to its previously issued consolidated financial statements. Based upon the Company's evaluation of both quantitative and qualitative factors, the Company concluded the errors were material to the Company's previously issued consolidated financial statements. Accordingly, the Company has restated its previously issued consolidated financial statements as shown in Note 3, Restatement of Previously Issued Consolidated Financial Statements and Note 19, Restatement of Quarterly Unaudited Results. All relevant footnotes have also been adjusted to reflect the impact of the restatements.

**Principles of consolidation.** The Company's consolidated financial statements include the accounts of SeaStar Medical Holding Corporation, and its wholly owned subsidiary, the Predecessor. All significant intercompany balances and transactions have been eliminated in consolidation.

**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 include the valuation of the liability classified warrants, prepaid forward purchase agreement derivative liability, provision for income taxes, convertible debt measured at fair value, and the amount of 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 has periodically maintained balances in excess of federally insured limits. The company did not have any cash equivalents for fiscal year 2023 or 2022.

**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.

**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.

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.

**Fair value option of accounting**

Generally, when financial instruments are first acquired and are not required to be recorded at fair value in accordance with ASC 825, *Financial Instruments*, which 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

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

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 concluded that its convertible notes (see Note 9) 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 contain 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. 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.

***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 statement 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.

***Forward Purchase Agreement Derivative Liability.*** The prepaid forward purchase agreement derivative liability (the "FPA Derivative Liability") is required to be recognized as a liability as the financial instrument fails the "*Indexation Guidance*" of ASC 815-10 in addition to having certain settlement features that could or will require settlement in cash or shares, depending on the feature. The FPA Derivative Liability was initially recorded at \$

5.2

million on October 28, 2022 (see Note 5). The FPA Derivative Liability was remeasured each reporting period using a Monte-Carlo Simulation in a risk-neutral framework (a special case of the Income Approach). Specifically, the future stock price is simulated assuming a Geometric Brownian Motion ("GBM"). For each simulated path, the forward purchase value was calculated based on the contractual terms and then discounted at the term-matched risk-free rate. Finally, the value of the forward was calculated as the average present value over all simulated paths. Changes in the fair value of the FPA Derivative Liability are recorded each reporting period to the change in the fair value of the forward purchase agreement derivative liability in the consolidated statement of operations.

***Investor D Convertible Notes.*** The convertible notes are recorded as liabilities and are recorded at fair value based on Level 3 measurements. The estimated fair values of the convertible notes are each determined based on the aggregated, probability-weighted average of the outcomes of certain possible scenarios. The combined value of the probability-weighted average of those outcomes is then discounted back to each reporting period in which the convertible notes are outstanding, in each case, based on a risk-adjusted discount rate estimated based on the implied interest rate using the changes in observed interest rates of corporate rate debt that the Company believes is appropriate for those probability-adjusted cash flows. The change in fair value of the Investor D Convertible Notes each reporting period is recorded to the change in fair value of convertible notes in the consolidated statement of operations.

***Pre-Merger Notes Derivative Liability.*** Pre-merger notes derivative liabilities in the amounts of approximately \$

0.1

million were recorded during the first quarter of 2022 for the issuance of notes along with a corresponding debt discount (see Note 8). The notes liabilities are remeasured each reporting period using a probability-weighted model and assumption related to the conversion price and timing of conversion. The put option liability was valued based on the calculated returns as a result of the various discounts included in the Company's notes and the related probability assessments of the various settlement scenarios. The notes derivative liability was extinguished as of the closing of the Business Combination (the "Closing"), as a result of the conversion of the notes. On October 28, 2022, the put option liability was settled upon the Closing and reclassified to additional paid-in capital. Changes in fair value of the Pre-Merger Notes Derivative Liability each reporting period is recorded to the change in fair value of notes payable derivative liability in the consolidated statement of operations.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**Liability Classified Warrants.** During the fiscal year ended December 31, 2023 and 2022, the Company has entered into or assumed as part of the Business Combination various financial instruments, in the form of warrant agreements, that require classification as liabilities. This classification requires that the Company measure the warrants at fair value at inception, and the remeasure the warrants. The liability classified warrants consist of the following (see Note 11 for more information):

**Private Placement Warrants.** The Company assumed

5,738,000

Private Placement warrants as part of the Business Combination.

**PIPE Warrants.** The PIPE Warrants were entered into in congruence with the Business Combination, and include features similar to the Private Placement Warrants which require liability classification.

**Investor D Warrants.** During the fiscal year ended December 31, 2023, the Company entered into various convertible credit agreements with an institutional investor ("Investor D") which included detachable and separately exercisable warrants to purchase shares of the Company's common stock (the "Investor D Convertible Note Warrants").

The Company uses a Black-Scholes option pricing model to fair value 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 statement of operations.

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

**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 expected volatility, expected term, risk-free interest rate and expected dividends 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 (see Note 12).

Prior to the Business Combination, due to the absence of an active market for the Company's common stock, the Company utilized methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company considered the fair value of the Company as of the grant date. The fair value of the Company was determined based upon a variety of factors, including the Company's financial position, historical performance and operating results, the Company's stage of development, the progress of the Company's research and development programs, the prices at which the Company sold its convertible preferred stock, the superior rights, preferences and privileges of the Company's convertible preferred stock relative to its common stock, external market conditions affecting the biotechnology industry, the lack of marketability of the Company's common stock and the prospects of a liquidity event and the analysis of initial public offering and market performance of similar companies as well as recently completed mergers and acquisition of peer companies. Significant changes to the key assumptions underlying the factors used could result in different fair values of the Company at each valuation 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.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

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.

***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.

***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 17 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 period presented, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for this period.

***Recently issued accounting standards not yet adopted***

In December 2023, the Financial Accounting Standards Board (“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 is permitted.

***Recently adopted accounting standards***

In March 2022, the FASB issued ASU 2022-02, *Financial Instruments—Credit Losses (Topic 326) Troubled Debt Restructurings and Vintage Disclosures*. ASU 2022-02 provides resources to monitor and assist stakeholders with the implementation of ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments*. The amendments in this update were adopted by the Company on January 1, 2023. There was no impact on the consolidated financial statements as a result of the adoption of ASU 2022-02.

**Note 3. Restatement of Previously Issued Consolidated Financial Statements**

As previously disclosed in the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on March 27, 2024, certain of the Company's previously filed interim unaudited and annual audited consolidated financial statements should no longer be relied upon and a restatement is required for these previously issued consolidated financial statements. The Company has restated herein its consolidated financial statements as of and for the year ended December 31, 2022. In addition, the Company has restated its unaudited quarterly financial statements for the first three quarters of the year ended December 31, 2023 as presented in Note 19, Restatement of Unaudited Quarterly Results. We have also restated related amounts within the accompanying footnotes to the consolidated financial statements



**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

to conform to the corrected amounts in the consolidated financial statements. In addition to those items previously disclosed as requiring the Company to restate certain previously filed financial statements, the Company also made certain immaterial reclassifications for presentation purposes related to legal fees previously classified in research and development on the Company's statement of operations.

The following financial statements provide a reconciliation from the originally "as reported" financial information to the now "as restated" financial information included in Note 3 as of and for the year ended December 31, 2022.

***Reconciliation of the Original and Restated Balance Sheet as of December 31, 2022***

(in thousands)	Year-ended December 31, 2022			
	As Previously Reported	Restatement Impacts	As Restated	Ref.
<b>ASSETS</b>				
Current assets				
Cash	\$ 47	\$ —	\$ 47	
Other receivables	12	—	12	
Prepaid expenses	2,977	(1,517)	1,460	5
Total current assets	3,036	(1,517)	1,519	
Forward option-prepaid forward contracts, net	1,729	(1,729)	-	1
Other assets	2	1,517	1,519	5
Total assets	<u>\$ 4,767</u>	<u>\$ 1,729</u>	<u>\$ 3,038</u>	
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>				
Current liabilities				
Accounts payable	\$ 1,927	\$ —	\$ 1,927	
Accrued expenses	2,245	—	2,245	
Notes payable, net of deferred financing costs	1,178	—	1,178	
Forward purchase agreement derivative liability	—	10,211	10,211	2

	—	587	587	3
Liability classified warrants				
	5,350	10,798	16,148	
Total current liabilities				
	7,652	—	7,652	
Notes payable, net of deferred financing costs				
	13,002	10,798	23,800	
Total liabilities				
Commitments and contingencies (see Note 14)				
Stockholders' deficit				
Common stock - \$				
0.0001	1	—	1	
par value per share				
		(		
	91,089	23,350	67,739	1,3
Additional paid-in capital		)		
	(		(	
	99,325	10,823	88,502	4
Accumulated deficit	)		)	
	(	(		
	8,235	12,527	20,762	
Total stockholders' deficit	)	)	)	
		(		
	4,767	1,729	3,038	
Total liabilities and stockholders' deficit	\$	\$	\$	

1. Impact from the derecognition of the asset portions of the previously recognized prepaid forward purchase agreements which, after further analysis, were determined by the Company to be an equity-type subscription receivable.

2. The the impact from the recognition of certain embedded features related to the prepaid forward purchase agreement. The embedded features are comprised of (i) a forward purchase agreement to purchase remaining unsold shares of the Company's stock for \$

10.37  
per share, and (ii) certain additional settlement features that require the Company to pay an addition \$

2.50  
per remaining unsold shares or additional cash consideration in the event the Company's common stock is delisted.

3. Recognition of liability classified warrants that were previously classified as components of equity.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

4. Cumulative and current year impacts of corrections of errors to the consolidated statement of operations.

5. Reclassification of certain prepaid insurance contracts with terms in excess of one year from the balance sheet date, that were previously classified as current.

**Reconciliation of the Original and Restated Statement of Operations for the Year Ended December 31, 2022**

(in thousands)	Year-ended December 31, 2022			
	As Previously Reported	Restatement Adjustments	As Restated	Ref.
Operating expenses				
	\$	\$(	\$	
Research and development	2,819	316	2,503	1
		)		
General and administrative	6,600	316	6,916	1
Origination cost of prepaid forward contracts	2,190	—	2,190	
Total operating expenses	11,609	—	11,609	
	(		(	
Loss from operations	11,609	—	11,609	
	)		)	
Other income (expense)				
	(		(	
Interest expense	630	—	630	
	)		)	
Change in fair value of liability classified warrants	—	10,863	10,863	3
	(		(	
Change in fair value of notes payable derivative liability	602	—	602	
	)		)	
	(	(	(	
Change in fair value of forward purchase agreement derivative liability	10,170	41	10,211	2
	)	)	)	
	(			
Gain (loss) on sale of recycled shares	1	1	—	4
	)			
	(		(	
Total other income (expense), net	11,403	10,823	580	
	)		)	
	(		(	
Loss before provision for income taxes	23,012	10,823	12,189	
	)		)	
Provision for income taxes	1	—	1	
	\$(	\$	\$(	
Net loss	23,013	10,823	12,190	
	)		)	

	\$ (	\$	\$ (
	2.80	1.32	1.48
Net loss per share of common stock, basic and diluted	)	)	)

	8,211,256	8,211,256	8,211,256
Weighted-average shares outstanding, basic and diluted (1)			

(1) Retroactively restated to give effect to the reverse recapitalization

1. Presentation reclassification of legal expenses previously classified as research and development expense, reclassified to general and administrative expense.

2. Recognition of certain embedded features related to the prepaid forward purchase agreement, including (i) a forward purchase agreement to purchase remaining unsold shares of the Company's stock for \$

10.37

per share, and (ii) certain additional settlement features that require the Company to pay an addition \$

2.50

per remaining unsold shares or additional cash consideration in the event the Company's common stock is delisted.

3. Unrealized gain for the decline in fair value of liability classified warrants for the immediate post-Merger period to December 31, 2022, which were previously classified as a component of equity.

4. Elimination of gains or losses on sales of Recycled shares that were originally connected to the asset component of the prepaid forward purchase agreements that were determined to be more akin to an equity classified "subscription receivable."

#### ***Reconciliation of the Original and Restated Statement of Cash Flows for the Year Ended December 31, 2022***

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

(in thousands)	Year-Ended December 31, 2022			
	As Previously Reported	Restatement adjustments	As Restated	Ref.
Cash flows from operating activities				
Net loss	(	(	(	
	23,013	10,823	12,190	
	\$ )	\$ )	\$ )	1
Adjustments to reconcile net loss to net cash used in operating activities				
Amortization of discount on notes payable	242	—	242	
Non-cash accrued interest related to convertible notes	341	—	341	
Change in fair value of notes payable derivative liability	602	—	602	
Change in fair value of forward purchase agreement settlement derivative liability	10,170	41	10,211	3
Change in fair value of warrants liability	—	(	(	
		10,863	10,863	
		)	)	2
(Gain) loss on sale of recycled shares		(		
	1	1	—	4
		)		
Stock-based compensation	1,311	—	1,311	
Changes in operating assets and liabilities				
Other receivables	4	—	4	
Prepaid expenses	(		(	
	1,073	—	1,073	
	)		)	
Accounts payable	1,548	—	1,548	
Accrued expenses	2,073	—	2,073	
Net cash used in operating activities	(		(	
	7,794		7,794	
	)	—	)	
Cash flows from financing activities				
Proceeds from issuance of convertible notes	1,681	—	1,681	
Proceeds from recapitalization	9,961	—	9,961	
Payment of recapitalization transaction costs	(		(	
	1,211	—	1,211	
	)		)	
Proceeds from PIPE Investors	7,000	—	7,000	

Payment for forward contracts	(		(
	11,940	—	11,940
	)		)
Proceeds from sale of recycled shares			
	40	—	40
Proceeds from notes payable			
	1,878	—	1,878
Payment of notes payable	(		(
	15	—	15
	)		)
Payment of Government loans	(		(
	63	—	63
	)		)
Net cash provided by financing activities			
	7,331	—	7,331
Net decrease in cash	(		(
	463	—	463
	)		)
Cash, beginning of 2023			
	510	—	510
Cash, end of 2023			
	47	—	47
	<u>\$</u>	<u>\$</u>	<u>\$</u>

	As Previously Reported	Restatement adjustments	As Restated	Ref.
Supplemental disclosure of cash flow information				
Cash paid for income taxes				
	1	-	1	
Cash paid for interest				
	6	-	6	
Supplemental disclosure of noncash financing activities				
Value of derivative liability on issuance of convertible notes				
	52	-	52	
Non-cash conversion of accrued expenses into convertible notes				
	96	-	96	
Conversion of notes payable to common stock				
	5,989	-	5,989	
Recapitalization transaction costs in accounts payable				
	294	-	294	
Recapitalization transaction costs in notes payable		-		
	2,209		2,209	

Shares issued as payment of convertible notes	-	-	-
Shares issued to settle forward option-prepaid forward contracts	-	-	-
Issuance of convertible note warrants	-	-	-

1. Accumulated effects of adjustments due to the restatement to the consolidated statement of operations for the year ended December 31, 2022.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

2. As a result of the recognition of formerly equity classified warrants as liabilities at the October 28, 2022, merger date, the decline in fair value of those warrants to December 31, 2022, was not previously recognized in earnings.
3. Result of the derecognition of the asset components to the prepaid forward purchase agreement, which, upon reassessment, determined to be a subscription receivable, and therefore, classified as a component of equity. However, certain embedded features related to the prepaid forward purchase agreement, including (i) a forward purchase agreement to purchase remaining unsold shares of the Company's stock for \$
- 10.37  
per share, and (ii) certain additional settlement features that require the Company to pay an addition \$
- 2.50  
per remaining unsold shares or additional cash consideration in the event the Company's common stock is delisted.
4. Elimination of gains or losses on sales of recycled shares that were originally connected to the asset component of the prepaid forward purchase agreements.



***Reconciliation of the changes in Original and Restated Statement of Stockholders' Deficit for the Year Ended December 31, 2022***

**As Restated**

		\$	(	(	
	7,238,767	1	73,495	76,312	2,816
Balance - January 1, 2022				)	)
	4,162,040	—	3,294	—	3,294
Reverse recapitalization on October 28, 2022					
	598,861	—	5,989	—	5,989
Conversion of notes payable to common shares					
	700,000	—	5,744	—	5,744
PIPE financing, net of liability classified PIPE warrants					
Issuance of liability classified warrants	—	—	(	—	(
			10,194		10,194
			)		)
Prepaid forward purchase agreement			(		(
			11,900		11,900
			)		)
Stock-based compensation					
			1,311		1,311
	—	—			
Net loss				(	(
				12,190	12,190
				)	)
	\$		\$		\$
		\$		\$(	
	12,699,668	1	67,739	88,502	20,762
Balance - December 31, 2022 (as restated)				)	)

1. Impact from the recognition of previously equity classified warrants as liability classified, requiring the issuance date fair value to be reclassified from equity to a liability.
2. Derecognition of the asset related forward purchase agreement, which, after further consideration should have been accounted for as a subscription receivable.
3. Accumulated impact of the above adjustment to the consolidated statement of operations.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**Note 4. Business Combination and Recapitalization**

On October 28, 2022, LMF, the Sponsor, 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, as described in Note 1.

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, LMF was treated as the acquired company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Business Combination, the Predecessor's stockholders have the majority of the voting power of the combined entity, the Predecessor comprised all of the ongoing operations of the combined entity, the Predecessor comprised a majority of the governing body of the combined entity, and the Predecessor's senior management comprised all of the senior management of the combined entity. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of the Predecessor issuing shares for the net assets of LMF, accompanied by a recapitalization.

Since this is considered a recapitalization for accounting purposes, the net assets of LMF were not remeasured at fair value but were stated at historical cost and there was no goodwill or intangibles recognized. Operations prior to the Business Combination are those of the Predecessor.

The aggregate consideration to the stockholders of the Predecessor at the closing of the Business Combination was approximately \$

85.4  
million, which consisted of shares of the Company's Class A common stock, par value \$

0.0001  
per share, valued at \$

10.00  
per share, resulting in the issuance of

8,540,552  
shares.

Upon the Closing, each of the Predecessor's outstanding convertible notes, in the amount of approximately \$

4.6  
million and related accrued interest totaling approximately \$

0.3  
million, less approximately \$

0.2  
million in unamortized discounts converted into

598,861  
shares of the Company's Class A common stock valued at \$

10.00  
per share. The excess fair value of shares transferred for convertible note conversion of approximately \$

1.2  
million is recorded in the consolidated statement of operations for the year ended December 31, 2022.

Also, upon the Closing,

633,697  
shares of Series B Preferred stock,

1,576,154  
shares of Series A-1 Preferred stock, and

577,791  
shares of Series A-2 Preferred stock of the Predecessor converted into

7,238,767  
shares of SeaStar Medical Holding Corporation Class A common stock. The Predecessor's

57,942  
outstanding warrants were assumed by LMF and converted into

69,714  
warrants to purchase SeaStar Medical Holding Corporation Class A common stock. The Predecessor's

271,280  
outstanding options were assumed by LMF and converted into

326,399  
options to purchase SeaStar Medical Holding Corporation Class A common stock. The Predecessor's

255,000  
outstanding restricted stock unit awards were assumed by LMF and converted into

306,811

SeaStar Medical Holding Corporation restricted stock units. The increase in the number of stock-based awards was accounted for as a modification (see Note 13).

As part of the Business Combination, approximately \$

92.1

million was paid to redeem Class A shares from LMF existing shareholders.

4,162,040

Class A shares remained unredeemed at the time of the Business Combination. LMF had

10,350,000

public warrants and

5,738,000

private placement warrants at the time of the Business Combination. The public warrants and the private placement warrants are classified as equity. The Company received net cash consideration of approximately \$

10.0

million and net liabilities of LMF of approximately \$

14.4

million. The net liabilities of LMF were as follows (in thousands):

Other receivables	\$	16
Prepaid expenses		1,871
		(
Accrued expenses		82
		)
		(
Public warrants liability		1,241
		)
Private placement warrants liability		10,194
		)
		(
LMFAO note payable		2,785
		)
		(
Maxim note payable		1,973
		)
		(
	\$	14,388

The table below summarizes the shares of Class A common stock issued immediately after the Closing as well as the

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

impact of the transaction on the consolidated statement of changes in stockholders' deficit as of October 28, 2022.

(\$ in thousands)	Common Shares Shares	Amount	Additional Paid-In Capital
			(
SPAC financing	4,162,040	—	921
		\$	\$ )
Public warrants liability reclassified to equity	—	—	1,241
			(
Transaction costs	—	—	3,714
			)
			(
Reverse recapitalization on October 28, 2022	4,162,040	—	3,394
	<u>                    </u>	<u>\$</u>	<u>\$</u> )

**Note 5. Forward Purchase Agreements**

In October 2022, LMF, the Sponsor entered into a Forward Purchase Agreements ("FPAs") with Vellar Opportunity Fund SPV LLC – Series 4 and HB Strategies LLC ("FPA Sellers"), whereby, prior to the Business Combination, the FPA Sellers purchased

1,151,400  
LMF Class A Shares from redeeming holders (the "Recycled Shares"), and an additional

200,000  
LMF Class A Shares constituting share consideration, each at an average price per share of \$

10.37  
. Pursuant to the FPA, the FPA Sellers waived their redemption rights under the governing documents of LMF Merger Sub, Inc. in connection with the Business Combination.

At the Closing, LMF paid to Vellar, out of funds held in the LMF trust account, aggregate amounts of approximately \$

14.4  
million, an amount equal to

1,173,400  
LMF Class A Shares ("Recycled Shares"), multiplied by \$

10.37  
, the redemption price, approximately \$

2.1  
million for the purpose of repayment of the FPA Sellers having purchased

200,000  
shares from third parties in the open market, and reimbursement of legal expenses and a commission fee in the amount of approximately \$

0.2  
million.

The FPA Sellers could, at their discretion, sell Recycled Shares ("Terminated Shares"). The Company was entitled to proceeds from such sales of Terminated Shares equal to the number of Terminated Shares multiplied by the reset price (the "Reset Price"). The Reset Price was initially the per-share redemption price, but was adjusted on a monthly basis to the lower of (a) the then-current Reset Price, (b) \$

10.00  
and (c) the volume weighted-average price ("VWAP") price of the last ten trading days of the prior calendar month, but not lower than \$

5.00  
; provided, however, that if the Company offered and sold Class A common stock, or then outstanding or future issued securities were exercised or converted, at a price lower than then then-current Reset Price, then the Reset Price would be modified to equal such reduced price.

In the event that the VWAP Price was less than \$

3.00  
per share for 20 trading days during any 30 trading-day-period, then the FPA Sellers could accelerate the maturity date ("Maturity Date"), which otherwise would have been the third anniversary of the Closing. Upon the occurrence of the Maturity Date, the Company was obligated to pay to the

FPA Sellers an amount equal to the number of unsold Recycled Shares, multiplied by \$

2.50  
(the "Maturity Consideration").

The Maturity Consideration was payable by the Company in cash, or at the Company's option, as equity, issued in Class A common stock, with a per share issue price based on the average daily VWAP Price over 30 scheduled trading days. FPA Sellers would then deliver to the Company the number of unsold Recycled Shares.

During the year ended December 31, 2022,

3,995  
recycled shares were sold by FPA Sellers. There were

1,147,405  
recycled shares remaining at December 31, 2022.

During the year ended December 31, 2023,

374,005  
recycled shares were sold by FPA Sellers. The Company received approximately \$

1.9  
million for the shares sold and recognized a gain of approximately \$

1.3  
million on the sale. Losses on remeasurement of approximately \$

1.7  
million were recorded in change in fair value of forward option-prepaid forward contracts on the consolidated statement of operations for the year ended December 31, 2023.

The FPAs were determined to have the following features:

- A host loan to two shareholders consisting of a subscription receivable on the Company's own common stock.
- Forward purchase agreement to purchase any unsold shares of the Company's stock at the maturity date for \$

10.37  
per share. Some of all of the subscription receivable could be applied to settle this obligation.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

- Embedded settlement features to be settled in cash or the Company's common stock depending on the cause and timing of the settlement (the "Settlement Features").

In accordance with ASC 815, *Derivatives and Hedging*, the Company had determined that the forward option within the Forward Purchase Agreement, coupled with certain settlement features were embedded features that required bifurcation and recognition as a liability.

The Company performed fair value measurements for the FPA Derivative Liabilities as of the Merger date, recognizing a liability of approximately \$

5.2 million. The derivative liability is being remeasured at each reporting date, with an additional \$

5.0 million recognized at December 31, 2022, as a result of the decline in the Company's stock price. During the twelve-months ended December 31, 2023, the Company recognized an additional \$

2.3 million of losses related to the further decline in the Company's stock price.

In March 2023, the price of the Company stock was below \$

3.00 for more than 20 trading days and the FPA Sellers at their discretion had the ability to specify the maturity dates for the FPAs. During the year ended December 31, 2023, the FPA Sellers specified the maturity dates and the FPAs matured and were settled by transferring (i)

1,096,972 shares to the FPA Sellers and (ii) all remaining

773,400 unsold Recycled Shares. Upon the final settlement of the forward purchase agreement, the Company recognized an approximately \$

1.0 million gain as the ultimate amount to settle the repurchase of the Company's shares of common stock underlying this purchase agreement was reduced by the counterparties to the agreements. Approximately \$

11.5 million was reclassified to equity as a result of the settlement of the forward purchase agreements.

**Note 6. Accrued Expenses**

Accrued expenses consisted of the following amounts as of December 31, 2023 and 2022:

(\$ in thousands)	December 31, 2023	December 31, 2022
Accrued bonus	501	450
	\$	\$
Accrued director compensation	427	61
Accrued research and development	507	—
Accrued legal	43	—
Accrued interest	19	112
Accrued commitment fee, equity line of credit	-	1,500
Other	26	122

Total accrued expenses		
	1,523	2,245
	\$ _____	\$ _____

**Note 7. Equity Line of Credit**

In August 2022, the Predecessor, LMAO, and Tumim Stone Capital LLC ("Tumim") entered into an equity line financing arrangement through a Common Stock Purchase Agreement ("Purchase Agreement") providing the right to sell Tumim up to \$

100 million worth of shares of common stock. The Purchase Agreement is subject to certain limitations and conditions and provided for a \$

2.5 million commitment fee payable to Tumim. The Company paid \$

1.0 million of the commitment fee in cash on the closing date of the Business Combination. The Company has recorded an accrued expense for the remaining \$

1.5 million of the commitment fee as of December 31, 2022, of which \$

1.0 million was paid in

218,842 shares of common stock and \$

0.5 million was paid in cash during the year ended December 31, 2023. The \$

2.5 million commitment fee was recorded in general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2022.

During the year ended December 31, 2023, the Company sold

6,500,000 shares of common stock to Tumim for proceeds of approximately \$

4.7 million as part of the Purchase Agreement. As of December 31, 2023, approximately \$

95.3



**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

million was available to draw. However, in February 2024, the Company and Tumim agreed to terminate the Purchase Agreement (see Note 15).

**Note 8. Notes Payable**

Notes payable consisted of the following as of December 31:

(\$ in thousands)	December 31, 2023	December 31, 2022
LMFA notes payable	296	968
	\$	\$
LMFAO note payable	1,128	2,785
Maxim note payable	2,771	4,167
Insurance financing	565	910
Unamortized deferred financing costs	( 52 )	—
	4,708	8,830
Less current portion	( 565 )	( 1,178 )
	4,143	7,652
	\$ <u>4,143</u>	\$ <u>7,652</u>

Future maturities of principal repayment of the notes payable as of December 31, 2023 are as follows:

(\$ in thousands)	
2024	565
	\$
2025	4,143
	4,708
	\$ <u>4,708</u>

On March 15, 2023, the Company amended its LMFA notes payable, LMFAO note payable, and Maxim note payable, extending their maturity dates to June 15, 2024. Additionally, the noteholders agreed to waive their right to receive mandatory prepayments for proceeds received from the first closing of the convertible note financings discussed in Note 9, but designated a mandatory prepayment amount to be paid upon the second closing of the convertible note financings. On May 12, 2023, another amendment was executed whereby the mandatory prepayment amount related to the second closing of the convertible note financings was waived. In consideration for such extensions, the Company agreed to pay the noteholders an aggregate amount of \$

0.1 million in cash upon receipt of proceeds from the issuance of the note at the second closing under the Securities Purchase Agreement ("SPA") (see Note 9). The \$

0.1 million consideration for the modification was capitalized as a deferred financing cost. The Company amortized \$

48 of the deferred financing cost during the year ended December 31, 2023.

On August 7 and December 11, 2023, the Company entered into certain amendments and waivers for the LMFA notes payable, LMFAO note payable, and Maxim note payable. The lenders waved their rights to receive any mandatory prepayments for proceeds received by the Company from the convertible note financings and agreed to extend the maturity dates to 91 days after the last maturity date applicable to any of the notes issued

pursuant to the amended SPA (see Note 9). In relation to the amendment to the Maxim note payable on December 11, 2023, the Company agreed to make a loan payment of \$

0.1  
million and \$

0.1  
million for placement and other past due fees.

**Senior Secured LMFA Notes Payable**

On September 9, 2022, the Predecessor entered into a Credit Agreement ("LMFA Note") with LM Funding America, Inc. ("LMFA") whereby LMFA agreed to make advances to the Predecessor of up to \$

0.7  
million for general corporate purposes at an interest rate of

15  
% per annum. All advances made to the Predecessor under the LMFA Note and accrued interest were due and payable to LMFA on the maturity date. The maturity date of the loan was the earlier of (a) October 25, 2022, (b) the consummation of the Business Combination, and (c) the termination of the Merger agreement.

On October 28, 2022, SeaStar Medical Holding Corporation and LMFA entered into the First Amendment to Credit Agreement, dated September 9, 2022, between LMFA and the Predecessor whereby (i) the maturity date of the loan under the LMFA Note was extended to October 30, 2023 ; (ii) the Company is required to use

5.0  
% of the gross cash proceeds received from any future debt and equity financing to pay outstanding balance of LMFA Note, provided that such repayment

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

is not required for the first \$

0.5  
million of cash proceeds; (iii) the interest rate of the LMFA Note is reduced from

15  
% to

7  
% per annum; and (iv) the default interest rate is reduced from

18  
% to

15  
%. The LMFA Note contains customary representations and warranties, affirmative and negative covenants, and events of default. The balance due was approximately \$

0.3  
million and \$

0.7  
million as of December 31, 2023 and 2022, respectively. The Company recorded interest expense of \$

33  
thousand and \$

19  
thousand for the years ended December 31, 2023 and 2022, respectively.

In addition, on October 28, 2022, the parties entered into a security agreement, pursuant to which SeaStar Medical Holding Corporation granted LMFA a security interest in substantially all of the assets and property of the Company, subject to certain exceptions, as collateral under the amended LMFA Note. In addition, the Company entered into a guaranty, dated October 28, 2022, whereby SeaStar Medical Holding Corporation unconditionally guarantees and promises to pay to LMFA the outstanding principal amount under the LMFA Note.

On November 2, 2022, the Company entered into an additional promissory note in the amount of approximately \$

0.3  
million with LMFA. The promissory note was noninterest bearing and was due on demand at any time on or after March 31, 2023. The note was paid in full in January 2023.

**Senior Secured LMFAO Note Payable**

On October 28, 2022, the Company entered into a consolidated amended and restated promissory note with LMFAO Sponsor, LLC, LMAO's sponsor and the sole holder of founding shares (the "Sponsor") as the lender, for an aggregate principal amount of \$

2.8  
million (the "LMFAO Note") to amend and restate in its entirety (i) the promissory note, dated July 29, 2022, for \$

1.0  
million in aggregate principal amount issued by LMAO to the Sponsor and (ii) the Amended and Restated Promissory Note, dated July 28, 2022, for \$

1.8  
million in aggregate principal amount, issued by LMAO to the Sponsor (collectively, the "Original Notes"). The LMFAO Note amended the Original Notes to (i) extend maturity dates of the Original Notes to October 30, 2023 ; (ii) permit outstanding amount due under the LMFAO Note to be prepaid without premium or penalty; and (iii) require the Company to use

20.0  
% of the gross cash proceeds received from any future debt and equity financing to pay outstanding balance of LMFAO Note, provided that such repayment is not required for the first \$

500  
of cash proceeds. The LMFAO Note carries an interest rate of

7  
% per annum and contains customary representations and warranties and affirmative and negative covenants.

The LMFAO Note is subject to events of default, which may result in the LMFAO Note becoming immediately due and payable, with interest of

15.0  
% per annum. In addition, on October 28, 2022, the parties entered into a security agreement whereby the Company granted the Sponsor a security interest in substantially all of the assets and property of the Company, subject to certain exceptions, as collateral to secure the Company's obligations under the LMFAO Note. The balance due was \$

1.1  
million and \$

2.8

million as of December 31, 2023 and 2022, respectively. The Company recorded interest expense of \$

127  
thousand and \$

35  
thousand for the years ended December 31, 2023 and 2022, respectively.

#### **Unsecured Maxim Note Payable**

Pursuant to an engagement letter between the Company and Maxim dated October 28, 2022, the Company was required to pay Maxim, as its financial advisor, an amount equal to \$

4.2  
million in cash as professional fees (\$

2.0  
million assumed from LMAO and \$

2.2  
million related to professional fees of the Company). Upon the Closing, the parties agreed that such amount would be paid in the form of a promissory note. Accordingly, on October 28, 2022, the Company entered into a promissory note with Maxim as the lender, for an aggregate principal amount of \$

4.2  
million (the "Maxim Note"). The Maxim Note had a maturity date of October 30, 2023 and outstanding amounts may be prepaid without premium or penalty. If the Company receives any cash proceeds from a debt or equity financing transaction prior to the maturity date, then the Company is required to prepay the indebtedness equal to

25.0  
% of the gross amount of the cash proceeds, provided that such repayment obligation shall not apply to the first \$

0.5  
million of the cash proceeds received by the Company. Interest on the Maxim Note is due at

7.0  
% per annum.

The Maxim Note contains customary representations and warranties, and affirmative and negative covenants. The Maxim Note is subject to events of default, which may result in the Maxim Note becoming immediately due and payable, with interest of

15.0  
% per annum. The balance of the Maxim Note was \$

2.8  
million and \$

4.2  
million as of December 31, 2023 and 2022, respectively. The Company recorded interest expense of \$

12  
thousand and \$

249  
thousand for the years ended December 31, 2023 and 2022, respectively.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**Insurance Financing**

In October 2022, the Company entered into a financing agreement with a lender to finance a portion of the annual premium of an insurance policy in the amount of \$

0.9  
million. Interest on the financing agreement is due at

7.35  
% per annum. The balance due was \$

0.9  
million as of December 31, 2022. The October 2022 financing agreement was paid in full during the year ended December 31, 2023.

In October 2023, 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 is due at

9.55  
% per annum. The balance due was \$

0.6  
million as of December 31, 2023. Eight monthly installments of principal and interest will be made during the year ended December 31, 2024.

The Company recorded interest expense of \$

30  
thousand and \$

7  
thousand for the years ended December 31, 2023 and 2022, respectively, for insurance financing.

**Related Party Notes**

The Company from time to time has entered into short-term financings LMFA to provide short-term liquidity needs. A total of three notes were entered into during the fiscal year ended December 31, 2023, ranging from \$

25  
thousand to \$

0.1  
million, with a total borrowing of \$

225  
thousand during the fiscal year. All notes had annualized interest of

7.00  
% and were paid off within 30 days of each borrowing. There were

no  
related party notes outstanding at December 31, 2023.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**Note 9. Convertible Notes**

**Senior Unsecured Convertible Notes Issued In 2023**

*Investor D Unsecured Convertible Notes*

On March 15, 2023, the Company entered into a Securities Purchase Agreement ("SPA") with an institutional investor ("Investor D") (the "Investor D SPA"), whereby the Company agreed to issue a series of four senior unsecured convertible notes (collectively, the "Investor D Convertible Notes") with principal proceeds totaling up to \$

9.8  
million and warrants to purchase shares of the Company's common stock.

On March 15, 2023, the Company issued the first senior unsecured convertible note (the "First Investor D Note") in the amount of approximately \$

3.3  
million, convertible into

1,207,729  
shares of common stock at an initial conversion price of \$

2.70  
. The First Investor D Note was issued at an

8.0  
% discount, bears interest at

7.0  
% per annum, matures on June 15, 2024, and requires monthly installments of principal and interest. In addition, the Company issued warrants to purchase

328,352  
shares of common stock (the "First Investor D Warrants"). The First Investor D Warrants have an initial exercise price of \$

2.97  
per share of common stock, expire in five years from their issuance date, and contain a cashless exercise provision.

On May 12, 2023, the Company issued a second senior unsecured convertible note (the "Second Investor D Note") in the amount of approximately \$

2.2  
million, convertible into

805,153  
shares of common stock at an initial conversion price of \$

2.70  
. The Second Investor D Note was issued at an

8.0  
% discount, bears interest at

7.0  
% per annum, matures on August 12, 2024, and requires monthly installments of principal and interest. In addition, the Company issued warrants to purchase

218,901  
shares of common stock (the "Second Investor D Warrants"). The Second Investor D Warrants have an initial exercise price of \$

2.97  
per share of common stock, expire five years from their issuance date, and contain a cashless exercise provision.

*First Amendment to the Investor D SPA*

On August 7, 2023, the Company entered into an amendment to the Investor D SPA, whereby the provisions of the third closing are amended (the "First Amended Investor D SPA"). Investor D shall have the discretion to purchase additional shares of the Company's stock in an aggregate principal amount of \$

2.0  
million (the "Third Investor D Note"). The Third Investor D Note consisted of four tranches which closed on August 7, 2023, August 30, 2023, September 26, 2023, and November 27, 2023. Each tranche of the Third Investor D Note was issued at an

8.0  
% discount, bear interest at

7.0

% per annum and require monthly installments of principal and interest. Each tranche of the Third Investor D Note is convertible into

2,717,144

shares of common stock at an initial conversion price of \$

0.20

, in a principal amount of \$

0.5

million, and includes a warrant to purchase up to

738,791

shares of common stock with an exercise price of \$

0.20

per share (the "Third Investor D Warrants"). The Third Investor D Notes mature on November 6, 2024 , November 29, 2024 , December 25, 2024 , and February 26, 2025 , respectively.

Also on August 7, 2023, the Company entered into a side letter with Investor D (the "Letter Agreement"), pursuant to which the Company agreed to adjust the conversion price of the First and Second Investor D Notes to the lowest of (i) \$

0.20

, (ii) the closing sale price of common stock on the trading day immediately preceding the date of the conversion, and (iii) the average closing sale price of common stock for the five consecutive trading days immediately preceding the date of the conversion (the "Amended First Investor D Note" and the "Amended Second Investor D Note"). The Company also agreed to issue a convertible note warrant to purchase up to

4,765,620

shares of common stock with an exercise price of \$

0.20

per share of common stock (the "Investor D Letter Agreement Warrants").

The Company concluded that the August 7, 2023, amendment should be accounted for as an extinguishment of the First and Second Investor D Notes. The Company derecognized the First and Second Investor D Notes with principal amounts of approximately \$

1.9

million and \$

0.6

million, respectively, and recorded fair value amounts of approximately \$

1.6

million and \$

1.3

million, respectively. The Company then recognized the Amended First and Second Investor D Notes at fair value based on the amended terms at approximately \$

3.5

million and \$

2.7

million, respectively, and recorded a loss on extinguishment for the difference between the fair value with the amended terms and the fair value of the original terms on August 7, 2023, of approximately \$

3.3

million. The Company recorded the convertible note warrants issued with the Letter

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

Agreement as a liability measured at fair value at inception with subsequent changes in fair value recorded in earnings. The initial fair value of the convertible note warrants issued with the Letter Agreement of approximately \$

1.6  
million was also recorded as loss on extinguishment.

*The Second Amendment to the Investor D SPA*

On December 11, 2023, the Company entered into the Second Amendment to the Investor D SPA (the "Second Investor D SPA") which increased the maximum amount of additional funding from approximately \$

2.0  
million to approximately \$

4.0  
million. In addition, the Company closed on a fourth convertible note (the "Fourth Investor D Note") in a principal amount of approximately \$

1.1  
million, which is convertible into shares of common stock at a conversion price of \$

0.56  
per share, beginning on the earlier of June 11, 2024 (or earlier upon mutual written agreement of the Company and the purchaser), or the date of an event of default, as defined in the Fourth Investor D Note, with a maturity date of March 11, 2025. The Company also issued two warrants each to purchase up to

527,708  
shares of common stock with an exercise price of \$

0.56  
per share.

*Payments for Principal and Interest and Conversions of Investor D Notes During FY 2023*

During the year ended December 31, 2023, the Company made cash payments of principal and interest of approximately \$

0.2  
million and \$

21  
thousand, respectively, on the combination of the First Investor D and Amended First Investor D Notes. The Company also made additional principal and interest payments, which included accelerated payments through equity conversions. Investor D elected to convert the conversion amount (as defined in the Amended First Investor D Note into shares of common stock of the Company. The Company converted principal and interest into

12,420,783  
shares of common stock with a fair value of approximately \$

7.0  
million. The Amended First Investor D Note was fully satisfied as of December 31, 2023.

During the year ended December 31, 2023, the Company made cash payments of principal and interest of \$

21  
thousand and \$

3  
thousand, respectively, on the Second Investor D Note. The Company also made additional principal and interest payments, which included accelerated payments through equity conversions. Investor D elected to convert the conversion amount as defined in the Amended Second Investor D Note into shares of common stock of the Company. The Company converted principal and interest into

10,426,962  
shares of common stock with a fair value of approximately \$

3.4  
million. The note was fully satisfied as of December 31, 2023.

The Company did

no  
t make any payments on the first, second, third, or fourth tranches of the Third Investor D Note or Fourth Investor D Note during the year ended December 31, 2023.

For the purposes of defining the collection of the various agreements and instruments by and between Investor D and the Company:

- The Investor D SPA, First Amended Investor D SPA, and Second Amended Investor D SPA are referred to as the "Original and Amended Investor D SPA".
- All Investor D Notes issued and/or amended under the Original and Amended Investor D SPA are collectively referred to as the "Investor D Convertible Notes".
- All warrants issued under the Original and Amended SPA or Letter Agreement are collectively referred to as the "Investor D Convertible Note



Warrants".

*Accounting for the Investor D Convertible Notes and Investor D Convertible Note Warrants*

The Company concluded that for each Investor D Convertible Note issuance, which included two legally detachable and separately exercisable freestanding financial instruments, (i) the Investor D Convertible Notes and(ii) the Investor D Convertible Note Warrants. The Company concluded that the Investor D Convertible Note Warrants should be recorded as a liability (see Note 9). The Company determined the Investor D Convertible Notes are liability instruments under ASC 480, *Distinguishing Liabilities from Equity*. The Investor D Convertible Notes were then evaluated in accordance with the requirements of ASC 825, and it was concluded that the Company was not precluded from electing the FVO for the Investor D Convertible Notes. As such, the Investor D Convertible Notes are carried at fair value in the consolidated balance sheets.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

The Investor D Convertible Notes are measured at fair value each reporting date with changes in fair value recognized in the consolidated statements of operations, unless the change is concluded to be related to the changes in the Company's credit rating, in which case the change will be recognized as a component of accumulated other comprehensive income in the consolidated balance sheets.

Future maturities of principal repayment of the Investor D Convertible Notes as of December 31, 2023 are as follows:

(\$ in thousands)	
2024	
	2,719
	\$
2025	
	435
	3,154
	\$

**Pre-Merger Convertible Notes**

The following provides disclosure on certain convertible notes that existed prior to the Business Combination (the "Pre-Merger Convertible Notes"). As a result of the Business Combination, all outstanding principal and accrued interest was converted into shares of the Company's common stock, and no obligations related to the Pre-Merger Notes remained immediately after the Business Combination. Accordingly, there were no notes outstanding at December 31, 2023 and 2022.

*Accounting for the Pre-Merger Notes*

All Pre-Merger Convertible Notes had conversion features which required separate recognition and measurement. At each issuance, the fair value of the conversion features was separated from the convertible notes and reported as a derivative liability as discussed in Note 2. The convertible debt was recorded at amortized cost, net of the discount due to the fair value of the conversion feature that was bifurcated and recognized separately. The related discount was amortized over the term of each individual issuance. Amortization of the debt discounts related to the Pre-Merger Convertible Notes were amortized to interest expense over the life of the convertible notes using the effective interest method. Amortization of the debt discounts for the year ended December 31, 2022 was approximately \$

0.2 million. There was

no interest amortization during the fiscal year ended December 31, 2023, as the Pre-Merger Convertible Notes no longer existed after the Business Combination.

*Investor A Convertible Notes*

The Company had issued convertible note agreements to a large employee pension plan (the "Investor A Notes") in the following amounts (in thousands) over a period from June 2021 to April 2022:

	Issue Date	Amount	Maturity Date
June 2021			
		300	December 2022
		\$	
September 2021			
		840	December 2024
October 2021			
		240	December 2024
November 2021			
		240	December 2024
March 2022			
		120	March 2024

April 2022

480

April 2025

April 2022

120

April 2025

2,340

\$           

Interest on the unpaid balances accrued at the rate of

8  
% per year.

*Investor B Convertible Notes*

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

The Company had issued convertible note agreements to a large employee pension plan (the "Investor B Notes") in the following amounts (in thousands) over a period from June 2021 to April 2022:

	Issue Date	Amount	Maturity Date
June 2021		\$ 200	December 2022
September 2021		560	December 2024
October 2021		160	December 2024
November 2021		160	December 2024
March 2022		80	March 2024
April 2022		320	April 2025
April 2022		80	April 2025
		\$ 1,560	

Interest on the unpaid balances accrued at the rate of 8 % per year.

**Investor C Convertible Notes**

During the years ended December 31, 2023 and 2022, the Company converted unpaid invoices in the amounts of approximately \$ 0.1 million and \$ 0.1 million, respectively, into convertible note agreements with a vendor. Interest on the unpaid balances accrued at the rate of 8 % per year.

**Group Investor Convertible Notes**

During the years ended December 31, 2023 and 2022, the Company issued convertible notes to investors for approximately \$ 0.4 million and \$ 0.1 million, respectively (collectively, the "Group Investor Notes"). Interest on the unpaid balances accrued at the rate of 8 % per year.

**Note 10. Government Loans**

**Pre-Merger Government Loans**

In June 2020, the Predecessor received a loan in the amount of approximately \$

0.1 million from the U.S. Small Business Administration ("SBA") under the Economic Injury Disaster Loan assistance program established as part of the Coronavirus Aid, Relief, and Economic Security Act. The loan called for monthly payments in the amount of approximately \$

3 thousand until maturity in May 2050 . The loan accrued interest at

3.75 %.

On October 17, 2022, the Company prepaid the full balance to the SBA in the amount of approximately \$

0.1 million principal and \$

6 thousand accrued interest. Interest expense was \$

2 thousand for the year ended December 31, 2022.

**Note 11. Warrants**

The Company has the following warrants outstanding at December 31, 2023 and 2022:

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

	2023	2022
<b>Liability Classified Warrants</b>		
Investor D Warrants	6,368,289	—
Private Placement Warrants	5,738,000	5,738,000
PIPE Investor Warrants	500,000	700,000
<b>Subtotal</b>	12,606,289	6,438,000
<b>Equity Classified Warrants</b>		
Public Stockholders' Warrants	10,550,000	10,350,000
Legacy Warrants	48,914	69,714
<b>Subtotal</b>	10,598,914	10,419,714
<b>Grand Total</b>	<u>23,205,203</u>	<u>16,857,714</u>

The following tables provides the weighted-average strike price and time to maturity for each warrant tranche as of December 31, 2023 and 2022:

December 31, 2023	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Maturity
<b>Liability Classified Warrants</b>			
Investor D Warrants	6,368,289	0.50	4.65
Private Placement Warrants	5,738,000	11.50	3.82
PIPE Investor Warrants	500,000	11.50	3.82
<b>Equity Classified Warrants</b>			
Public Stockholders' Warrants	10,550,000	\$ 11.50	3.82
Legacy SeaStar Inc. Warrants	48,914	\$ 10.00	2.38

December 31, 2022	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Maturity
<b>Liability Classified Warrants</b>			

Private Placement Warrants	5,738,000	11.50	4.82
PIPE Investor Warrants	700,000	11.50	4.82
<b>Equity Classified Warrants</b>			
Public Stockholders' Warrants	10,350,000 \$	11.50	4.82
Legacy SeaStar Inc. Warrants	69,714 \$	10.00	3.38

### **Warrants Issued in FY 2023**

#### *Investor D Warrants*

As disclosed in Note 9, the following summarizes warrants issued in connection with the Original and Amended Investor D SPA during the fiscal year ended December 31, 2023:

- On March 15, 2023, as part of the issuance of the First Investor D Note,

328,352  
convertible note warrants were issued with an exercise price of \$

2.97  
per share.

- On May 12, 2023, as part of the issuance of the Second Investor D Note,

218,901  
convertible note warrants were issued with an exercise price of \$

2.97  
per share.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

- On August 7, 2023, as part of the Letter Agreement,

4,765,620  
convertible note warrants were issued with an exercise price of \$

0.20  
per share (the "Letter Agreement Warrants"). Also on August 7, 2023, as part of the issuance of the first tranche of the Third Investor D Note,

738,791  
Convertible Note Warrants were issued with an exercise price of \$

0.20  
per share.

- On August 30, 2023, as part of the issuance of the second tranche of the Third Investor D Note,

738,791  
convertible note warrants were issued with an exercise price of \$

0.20  
per share.

- On September 26, 2023, as part of the issuance of the third tranche of the Third Investor D Note,

738,791  
convertible note warrants were issued with an exercise price of \$

0.20  
per share.

- On November 27, 2023, as part of the issuance of the fourth tranche of the Third Investor D Note,

738,791  
convertible note warrants were issued with an exercise price of \$

0.20  
per share.

- On December 11, 2023, in connection with the Second Amended Investor D SPA, and as a result the Fourth Investor D Note, the Company issued

two  
warrants, each to purchase up to

527,708  
shares of common stock with an exercise price of \$

0.56  
per share.

- The convertible note warrants expire five years from their issuance date and contain cashless exercise provisions. The Company does not have the ability to redeem the convertible note warrants.

The convertible note warrants expire five years from their issuance date and contain cashless exercise provisions. The Company does not have the ability to redeem the convertible note warrants. The convertible note warrants were collectively valued at approximately \$

2.9  
million at issuance.

Since January 2024,

4,265,620  
warrants from the Letter Agreement Warrants were converted into shares at an exercise price of \$

0.20

. See Note 18 for disclosure on certain Investor D Warrant transactions after the year ended December 31, 2023.

In accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity's own Equity*, the Company determined the convertible note warrants do not meet the conditions for equity classification, due to potential cash settlement under the exchange cap provision of the Original and Amended Investor D SPA, and should be carried on the consolidated balance sheets as a liability measured at fair value, with subsequent changes in fair value recorded in the consolidated statements of operations as change in fair value of warrants liability. The fair value of the convertible note warrants was determined using a Black-Scholes option pricing model, which considers variables such as 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 .

#### **Warrants Issued Prior to FY 2023**

##### **Legacy SeaStar Inc. Warrants**

Prior to the Business Combination, the Predecessor had outstanding warrants to purchase shares of the Predecessor's preferred stock which had been issued in conjunction with various debt financings. Upon effectiveness of the Business Combination,



57,942

outstanding warrants were converted into 69,714 warrants to purchase common stock of SeaStar Medical Holding Corporation ("Legacy SeaStar Inc. Warrants") at their previous exercise prices. As of December 31, 2023 and 2022, there were

69,714

Legacy SeaStar Inc. Warrants outstanding, which are classified as a equity within stockholders' deficit.

*Public Stockholders' Warrants*

As part of LMAO's initial public offering, under the Warrant Agreement dated as of January 25, 2021 and, prior to the effectiveness of the Business Combination, LMAO issued

10,350,000

warrants each of which entitled the holder to purchase one share of common stock at an exercise price of \$

11.50

per share ("Public Stockholders' Warrants"). Upon the effectiveness of the Business Combination, the outstanding Public Stockholders' Warrants automatically converted into warrants to purchase common stock of the Company. The Company has reviewed the terms of the warrants and determined that the Public Stockholders' Warrants are required to be classified as equity within stockholders' deficit.

The Company has the ability to redeem outstanding Public Shareholders' Warrants at any time after they become

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

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, and the like) for any 20 trading days within a 30 day trading-day period.

*Private Placement Warrants*

Simultaneously with the closing of the Initial Public Offering, LMAO completed the private sale of

5,738,000

million warrants each of which entitled the holder to purchase one share of common stock at an exercise price of \$

11.50

per share, to LMF's sponsor ("Private Placement Warrants").

Upon the effectiveness of the Business Combination, the outstanding Private Placement Warrants automatically converted into warrants of SeaStar Medical Holding Corporation (see Notes 1, 3 and 19). The fair value of the private placement warrants on October 28, 2022, in the amount of approximately \$

8.0

million was recorded as a "liability classified warrant" and a reduction to "Additional paid-in capital" on the consolidated balance sheets.

The Company does not have the ability to redeem the Private Placement Warrants. The Private Placement Warrants were valued at approximately \$

8.0

million at the date of the Business Combination date. As of December 31, 2023 and 2022, there were

10,350,000

Public Shareholders' Warrants outstanding and

5,738,000

Private placement Warrants outstanding.

*2022 PIPE Investor Warrants*

On October 28, 2022, the Company entered into a Private Investment in Public Equity ("PIPE") Agreement, pursuant to which the PIPE investors purchased an aggregate of

700,000

shares of common stock at \$

10.00

per share and received

700,000

PIPE Investor Warrants ("PIPE Investor Warrants"), which entitled the holder to purchase one share of common stock of SeaStar Medical Holding Corporation for \$

11.50

per share, for an aggregate purchase price of approximately \$

7.0

million. The PIPE Warrants were initially valued at approximately \$

1.0

million at the Merger date. As of both December 31, 2023 and 2022, there were

700,000

PIPE Investor Warrants outstanding.

Originally, the Company reviewed the terms of the PIPE Warrants and concluded that they should be classified as a component of the Company's stockholders' deficit at December 31, 2022. However, through additional analysis during the 2023 fiscal year, the Company reviewed the terms of the PIPE Warrants and determined that the PIPE Warrants require liability classification due to certain features that preclude equity classification pursuant to ASC 815, *Derivatives* (see Notes 1, 3 and 19).

**Note 12. Convertible Preferred Stock, Common Stock and Preferred Stock**

During the year ended December 31, 2022, the Predecessor converted

194,494

shares of Series A-2 Preferred stock to Series B Preferred stock. Immediately prior to the Business Combination, the Predecessor converted

633,697  
shares of Series B Preferred stock,

1,576,154  
shares of Series A-1 Preferred stock and

577,791  
shares of Series A-2 Preferred stock to

7,238,767  
shares of common stock. Also, during the year ended December 31, 2022, the Predecessor converted Convertible Notes with a principal amount of \$

4,636  
, a discount amount of \$

168  
and accrued interest of \$

341  
to

598,861  
shares of common stock.

Subsequent to the Business Combination, the Company is authorized to issue

110,000,000  
shares, consisting of (a)

100,000,000  
shares of common stock and (b)

10,000,000  
shares of preferred stock (the "Preferred Stock").

#### ***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.

#### ***Voting power***

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

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, 2023 or 2022.

**Note 13. Stock-Based Compensation Awards**

***Equity incentive plan - summary***

***2020 Omnibus Incentive Plan***

The Company's Board of Directors adopted, and the shareholders approved the Predecessor's 2022 Omnibus Incentive Plan (the "Equity Incentive Plan") to provide long-term incentive for its employees and non-employee service providers. As of December 31, 2023 and 2022,

1,850,000  
and

1,270,000  
shares, respectively, were reserved for the issuance of stock options, RSUs, and stock awards to employees and non-employee service providers for the purchase of the Company's common stock. 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. There were

no  
shares available for future grant as of December 31, 2023.

***2019 Stock Incentive Plan***

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

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

However, the outstanding awards under the Stock Incentive Plan were assumed and continued in connection with the Business Combination under the provisions of the 2019 Stock Incentive Plan.

Each Predecessor Option to purchase shares of the Predecessor common stock or the Predecessor Preferred Stock ("Predecessor Option") that was outstanding and unexercised immediately prior to the Business Combination converted into an option to purchase common stock, par value \$

0.0001 per share, of SeaStar Medical Holding Corporation in accordance with its terms. The increase in the number of stock options was accounted for as a modification. The incremental fair value from the stock option modification increased stock-based compensation expense by approximately \$

0.1 million for the year ended December 31, 2022, and increased unrecognized stock-based compensation cost by approximately \$

0.2 million as of December 31, 2022.

**Equity incentive plan - stock options**

The vesting of stock options is stated in each individual grant agreement, which is generally four years. Options granted expire 10 years after the date of grant. Option activity for the years ended December 31, 2023 and 2022, is as follows:

**2022 Omnibus Incentive Plan - Options**

(\$ in thousands)	Options	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
			\$	
Outstanding as of December 31, 2021	—	—	—	
			\$	\$
Outstanding as of December 31, 2022	—	—	—	—
			\$	
Granted	351,029	1.84		
			\$	\$
Outstanding as of December 31, 2023	351,029	1.84	—	9.26
			\$	\$
Options exercisable as of December 31, 2023	351,029	1.84	—	9.26

**2019 Stock Incentive Plan**

(\$ in thousands)	Options	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
			\$	
Outstanding as of December 31, 2021	287,382	2.65		

	(	\$		
	83,928	4.63		
Forfeited prior to merger conversion	)			
		\$		
	41,338	1.84		
Additional options issued in merger conversion				
		\$	\$	
	244,792	1.84	751,851	7.65
Outstanding as of December 31, 2022				
		\$	\$	
	244,792	—	—	6.65
Outstanding as of December 31, 2023				
		\$	\$	
	201,317	—	—	6.64
Options exercisable as of December 31, 2023				

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

The Company recognized approximately \$

0.5  
million and approximately \$

0.1  
million in stock-based compensation expense in connection with options granted under the Equity Incentive Plan for the years ended December 31, 2023 and 2022. As of December 31, 2023, there was unrecognized stock-based compensation cost of approximately \$

0.2  
million, which is expected to be recognized over a term of two years. The Company granted

351,029  
options during the year ended December 31, 2023. For options granted during the year ended December 31, 2023, the weighted-average grant date fair value was \$

1.20  
per share.

No  
options were granted during the year ended December 31, 2022, other than the additional options issued in the Business Combination.

Stock-based compensation expense for options included in the consolidated statements of operations is as follows:

(\$ in thousands)

	2023	2022
Research and development	\$ 160	\$ 7
General and administrative	292	141
Total	\$ <u>452</u>	\$ <u>148</u>

**Equity incentive plan - restricted stock units**

In April 2022, the Board of Directors granted employees and members of the board restricted stock units ("RSUs"), under which the holders have the right to receive an aggregate of

255,000  
shares of common stock. The majority of the RSUs granted vest

50  
% on the first anniversary of the grant date, with the remaining

50  
% of the awards vesting monthly over a 12 -to- 24 month period following the first anniversary of the grant date. At grant date, the fair market value of an RSU was \$

8.00  
per share.

Each of the Predecessor RSU that was outstanding immediately prior to the Business Combination converted into an RSU to receive common stock, par value \$

0.0001  
per share, of SeaStar Medical Holding Corporation in accordance with its terms. The increase in the number of RSUs was accounted for as a modification. The incremental fair value from the modification increased stock-based compensation expense increased by approximately \$

0.1  
million for the year ended December 31, 2022, and increased unrecognized stock-based compensation cost by approximately \$

0.4  
million as of December 31, 2022.

During the year ended December 31, 2023, the Company granted

234,019  
RSUs that vest one year from the grant date. At grant date, the weighted-average grant date fair value was \$

1.47  
per share.

RSU activity for the years ended December 31, 2023 and 2022, was as follows:

2022 Omnibus Incentive Plan - RSUs

	Restricted Stock Units	Intrinsic Value
Outstanding as of December 31, 2021	—	
Outstanding as of December 31, 2022	—	—
Granted	234,019	
Outstanding as of December 31, 2023	234,019	\$ 103,600



**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**2019 Stock Incentive Plan - RSUs**

	Restricted Stock Units	Intrinsic Value
Outstanding as of December 31, 2021	—	
Granted	255,000	
	(	
Forfeited prior to merger conversion	7,000	
	)	
Additional RSUs issued in merger conversion	50,389	
Outstanding as of December 31, 2022	298,389	1,223,395
	(	
Vested	205,947	
	)	
Outstanding as of December 31, 2023	92,442	40,924

The Company recognized approximately \$

1.1  
million and \$

1.2  
million in stock-based compensation expense in connection with the RSUs for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, there was unrecognized stock-based compensation cost of approximately \$

0.6  
million, which is expected to be recognized over a term of 1.2 years. For RSUs granted during the years ended December 31, 2023 and 2022, the weighted-average grant date fair value was \$

1.47  
and \$

8.00  
per share, respectively. The weighted-average fair value of the additional RSUs issued in the Business Combination conversion was \$

10.00  
per share. During the year ended December 31, 2023, the Company issued

205,947  
shares of common stock for vested RSUs.

No  
RSUs vested during the year ended December 31, 2022.

Stock-based compensation expense for RSUs included in the consolidated statements of operations is as follows:

(\$ in thousands)

2023

2022

Research and development

	199	89
	\$	\$
General and administrative	868	1,074
Total	1,067	1,163
	\$	\$

**Equity incentive plan - stock awards**

During the year ended December 31, 2023, as part of the Company's efforts to conserve cash, the Company issued

1,090,947

fully vested stock awards in lieu of cash to cover a portion of certain employees' regular compensation due to them. The fair value was based on the price of the Company's stock at the date of grant of approximately \$

0.4

million.

Stock-based compensation expense for the stock awards included in the consolidated statements of operations is as follows:

(\$ in thousands)

	2023	2022
Research and development	124	—
	\$	\$
General and administrative	287	—
Total	411	—
	\$	\$

**Note 14. Commitments and Contingencies**

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

***License and distribution agreement***

On December 27, 2022, the Company entered into a license and distribution agreement ("License Agreement") with a distributor, appointing the distributor as the exclusive distributor to promote, advertise, market, distribute and sell the Selective Cytopheretic Device ("SCD") in the United States. The Company received an upfront payment of \$

0.1 million on January 3, 2023. If the Company does not receive written authorization to market the SCD, prior to the first anniversary of the effective date, the Company will repay the \$

0.1 million. The Company shall also receive milestone payments in the amounts of approximately \$

0.5 million and \$

0.4 million for obtaining FDA approval and for selling the first sixty units to any third parties. The term of the agreement is three years. The license agreement was amended in December 2023, removing the potential to require refund of the \$

0.1 million up-front payment by licensee to the Company, while extending certain milestone payment owed to the Company upon certain regulatory achievements.

***Lease agreements***

The Company is part of a membership agreement for shared office space and can cancel at any time. Rent expense was approximately \$

32

thousand for the years ended December 31, 2023 and 2022.

***Litigation***

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business.

In connection with the Business Combination, LMAO proposed, for stockholder approval, various amendments to its Amended and Restated Certificate of Incorporation, which included among other things a proposal to increase the authorized shares of common stock. A purported stockholder sent a Stockholder Litigation Demand letter (the "Demand") to the Board of Directors of LMAO alleging that the Delaware General Corporation Law required a separate class vote of the Class A common stockholders to increase the authorized shares of common stock. Following receipt of the Demand, the Company canceled and withdrew the proposal to increase the authorized shares of common stock.

The stockholder's counsel thereafter demanded that the Company pay counsel fees for the purported benefit conferred upon the Company's shareholders by causing the Company to withdraw the allegedly invalid proposal to increase the authorized shares of common stock. The Company paid approximately \$

0.2 million for a legal settlement during the year ended December 31, 2023.

**Note 15. 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, 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***

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

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, 2023 and 2022, by level within 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 at December 31, 2023	Fair Value Measurements at December 31, 2023		
		(Level 1)	(Level 2)	(Level 3)
<b>Liabilities:</b>				
Convertible notes	4,179	—	—	4,179
Liability classified warrants	2,307	—	—	2,307
	\$			\$
	6,486	—	—	6,486

	Fair Value at December 31, 2022	Fair Value Measurements at December 31, 2022		
		(Level 1)	(Level 2)	(Level 3)
<b>Liabilities:</b>				
Forward purchase agreement derivative liability	10,211	—	—	10,211
Liability classified warrants	587	—	—	587
	\$			\$
	10,798	—	—	10,798
<b>Total</b>				

**Summary of Level 3 Input Changes**

The following table presents the changes in the forward option-prepaid forward contracts, convertible notes measured at fair value, warrants liability, and the notes derivative liability for the years ended December 31, 2023 and 2022 (in thousands):

Level 3 Rollforward	Forward Purchase Agreement Derivative	Convertible Notes	Liability Classified	Notes Payable
	Liability		Warrants	Derivative Liability
Balance January 1, 2022	\$ —	\$ —	\$ —	\$ 526
Additions	—	—	11,450	52
Changes in fair value	10,211	—	10,863	602
Reclassified to additional paid-in capital	—	—	—	1,180
Balance December 31, 2022	10,211	—	587	—
Additions	—	4,855	3,325	—

		(		
Payments	—	400	—	—
	(	)		
	(	(		
Shares issued as payments	11,519	10,411	—	—
	)	)		
			(	
Changes in fair value	1,308	5,380	545	—
			)	
Warrant expense	—	4,949	—	—
			(	
Warrants exercised	—	—	1,060	—
			)	
Shares issued as maturity consideration	—	—	—	—
Balance December 31, 2023	\$ —	\$ 4,373	\$ 2,307	\$ —
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </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

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

recent reporting period date. However, for those assets or liabilities for which the Company has elected to take the FVO in accordance with ASC 825, *Financial Instruments*, then such quantitative disclosures are not required.

Liability Classified Warrants

Significant assumptions used in valuing warrants which require liability classification were as follows as of December 31, 2023, December 31, 2022, and October 28, 2022 (the Merger date).

The liability classified warrants as of December 31, 2023, include three classes of warrants, and therefore, the range of assumptions used has been provided. Prior to the 2023 fiscal years, only the Private Placement and PIPE warrants were outstanding, with each having terms such that the valuation assumptions identical.

	December 31, 2023	
	Minimum	Maximum
Expected volatility	85.00 %	90.00 %
Equivalent term	4.04	4.65
Risk-free rate	3.84 %	3.90 %
Dividend yield	0.00 %	0.00 %
Stock price	\$ 0.44	\$ 0.44
Strike price	\$ 0.50	\$ 11.50
	December 31, 2022	
Expected volatility		25.00 %
Equivalent term		4.86
Risk-free rate		4.00 %
Dividend yield		0.00 %
Stock price	\$	4.37
Strike price	\$	11.50

Due to the impact of the Company's decision that certain of its warrants should be liability classified, and the impact that such a change in conclusion has on the Company's financial statements, the Company has provided the valuation assumptions as of the Merger date when the liability classified warrants were originally measured and recognized.

October 28,  
2022

Expected volatility	25.00 %
Equivalent term	4.94
Risk-free rate	4.20 %
Liquidity discount (*)	1.00 %
Dividend yield	0.00 %
Stock price	\$ 8.90
Strike price	\$ 11.50

(\*) - The liquidity discount was necessary for the initial valuation of the Private and Pipe warrants due to a 30 day trading restriction immediately post-Merger.

Forward Purchase Agreement

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

Significant assumptions used in valuing the Forward Purchase Agreement were as follows for the year ended December 31, 2022. The Forward Purchase Agreement was terminated during the fiscal year ended December 31, 2023, and no longer existed as of December 31, 2023.

	December 31, 2022
Expected volatility	80.00 %
Equivalent term	2.83
Risk-free rate	4.25 %

**Note 16. Income Taxes**

The Company recorded approximately \$

4  
thousand and \$

1  
thousand of current income tax expense for the years ended December 31, 2023 and 2022, respectively.

The effective income tax rate of the Company's provision for income taxes differed from the federal statutory rate as follows:

(\$ in thousands)	Year Ended December 31, 2023	2022
Federal tax at statutory rate	21.00 %	21.00 %
State income tax	3.26 %	4.41 %
R&D tax credit	0.65 %	0.00 %
Meals and entertainment	0.00 %	0.02 %
Stock compensation expense	0.26 %	0.20 %
Interest on convertible notes	0.87 %	1.07 %
Unrealized gains and losses, net, for liability classified derivatives	6.11 %	0.10 %
Change in fair value of convertible notes and related warrants	3.93 %	0.00 %



Adjustment to prior period federal deferred tax assets	4.55 %	0.00 %
	-	
Non-deductible expenses	0.02 %	0.00 %
Other	0.00 %	0.56 %
	-	-
Change in valuation allowance	18.27 %	24.78 %
Total effective income tax rate	<u>0.00 %</u>	<u>0.00 %</u>

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

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

(\$ in thousands)	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating losses	21,911	18,627
	\$	\$
Finance charges and origination fees	602	1,028
Accrued compensation	232	130
Stock-based compensation	83	311
Section 174 research and development capitalization	1,642	434
Capitalized start-up fees	231	—
Tax credits	903	715
Total deferred tax assets	25,604	21,245
Valuation allowance	( 25,604 )	( 21,245 )
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, 2023 and 2022, the net increase in the valuation allowance was approximately \$

4.8  
million and \$

5.6  
million, respectively.

As of December 31, 2023 and 2022, the Company had federal net operating loss carryforwards of approximately \$

106.5  
million and \$

82.3  
million, respectively, of which approximately \$

53.7  
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 also had approximately \$

47.7  
million of state (Colorado, California, and Florida) net operating loss carryforwards, which will begin expiring in 2039. The Company has not used any net operating loss carryforwards to date.

The Company had federal energy credit carryforwards of approximately \$

0.6

million as of December 31, 2023 and 2022, which will expire starting in 2027 if not utilized. The Company has federal research and development credit carryforwards of approximately \$

0.3  
million and \$

0.1  
million as of December 31, 2023 and 2022, 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 loss ("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.

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 2023 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. The Company had

no

uncertain tax benefits as of December 31, 2023 and 2022. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months as of December 31, 2023.

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

**Note 17. 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 weighted-average 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:

	2023	2022
Public Stockholders' warrants	10,350,000	10,350,000
Private Placement warrants	5,738,000	5,738,000
PIPE Investor warrants	700,000	700,000
Convertible Note warrants	2,662,334	—
Predecessor Warrants	69,714	69,714
Options to purchase common stock	504,457	244,792
Unvested restricted stock units	256,525	298,389
<b>Total</b>	<b>20,281,030</b>	<b>17,400,895</b>

Net loss per share is calculated using the shares in connection with the Business Combination and related transactions, assuming the shares were outstanding since January 1, 2022. As the Business Combination and related transactions are being reflected as if they had occurred at the beginning of the period presented, the calculation of weighted-average shares outstanding for basic and diluted net loss per share assumes that the shares issued in connection with the Business Combination have been outstanding for the entire period presented. The calculation of weighted-average shares outstanding for basic and diluted net loss per share for the year ended December 31, 2022 has been retroactively restated to give effect to the Business Combination.

	2023	2022
Net loss	( 26,232 )	( 12,190 )
	\$ )	\$ )
Weighted-average shares outstanding - basic and diluted	21,670,330	8,211,256
Basic and diluted net loss per share	( 1.21 )	( 1.48 )
	\$ )	\$ )

## **Note 18. Subsequent Events**

### *Investor D Convertible Notes and Warrant Activity*

During the subsequent months after December 31, 2023 and up to the date of the filing of this Form 10-K, the following transactions occurred between the Company and Investor D:

- In January 2024, the Company made principal and interest payments on a portion of the Third Investor D Note, which included accelerated payments, through equity conversions. Investor D elected to convert the conversion amount (as defined by the Investor D Convertible Notes) into shares of common stock of the Company. The

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

Company converted approximately \$

0.9  
million principal and accrued interest into approximately

2.4  
million shares of common stock.

- On January 24, 2024, Investor D exercised

765,620  
warrants from the Investor D Letter Agreement Warrants at an exercise price of \$

0.20  
per warrant, for proceeds of approximately \$

0.2  
million.

- In February 2024, Investor D exercised

2,500,000  
warrants from the Letter Agreement Warrants at an exercise price of \$

0.20  
per warrant for proceeds of approximately \$

0.7  
million.

- The Company completed Additional Closings related to the Second Amendment to the Investor D SPA on January 12, 2024 and January 24, 2024, issuing notes in principal amounts of \$

0.3  
million and \$

0.8  
million, respectively (the "Fifth Investor D Note" and "Sixth Investor D Note", collectively called the "2024 Investor D Notes"). The 2024 Investor D Notes mature on April 12, 2025 and April 24, 2025, respectively. The 2024 Investor D Notes have an initial conversion price of \$

0.56

per share and are convertible into shares of common stock beginning on the earlier of June 11, 2024 (or earlier upon mutual written agreement of the Company and the purchaser), or the date of an event of default, as defined in the note. The Company also issued warrants to purchase up to

131,927  
and

395,781  
shares of common stock, respectively, with an exercise price of \$

0.56  
per share, and an additional warrants to purchase up to

131,927  
and

395,781  
shares of common stock, respectively, with an exercise price of \$

0.56  
per share.

- In February 2024, the Company made principal and interest payments on the entire unpaid principal and accrued interest to both the 2024 Investor D Notes, which included accelerated payments, through equity conversions. Investor D elected to convert the conversion amount (as defined by the Investor D Convertible Notes) into shares of common stock of the Company. The Company converted approximately \$

1.5  
million in principal and accrued interest into approximately

3.6  
million shares of common stock.

- As a result of the Investor E 2024 Offering in January 30, 2024 (see below), certain of the Investor D Warrants with strike prices above \$

0.8302  
, which was the offering price for the January 30, 2024 Investor E Offering, were lowered to \$

0.8302

due to certain down-round terms included in the Investor D Warrants.

#### *Investor E 2024 Offering*

On January 30, 2024, the Company offered

6,304,545  
shares of common stock and pre-funded warrants to purchase

4,536,216  
shares of common stock directly to a single institutional investor through a prospectus supplement. The per share offering price of the shares is \$

0.8302  
and the offering price per pre-funded warrant is \$

0.8301  
. In a concurrent private placement, the Company also offered the institutional investor series A common warrants to purchase an aggregate of up to

10,840,761  
shares of common stock and series B common warrants to purchase an aggregate of up to

5,420,381  
shares of common stock, each at an exercise price of \$

0.8302  
per share. The warrants will be immediately exercisable. The series A common warrants expire after 5 years and the series B common warrants expire after 1 year. Both series A and B warrants require shareholder approval to issue.

#### *Termination of the Equity Line of Credit Purchase Agreement*

On February 15, 2024, the Company and Tumim agreed by mutual consent and pursuant to its terms to terminate the Purchase Agreement, whereby Tumim had committed to purchasing up to \$

100  
million of the Company's common stock, effective immediately.

#### *FDA Approval for Humanitarian Device Exemption*

On February 22, 2024, the Company issued a press release announcing that the U.S. Food and Drug Administration granted to the Company a Humanitarian Device Exemption Approval Order to the Selective Cytopheretic Device Pediatric for use in children weighing 10 kilograms or more with acute kidney injury and sepsis or with a septic condition on continuous kidney replacement therapy in the hospital intensive care unit.

#### *Appointment of Chief Financial Officer*

**SeaStar Medical Holding Corporation**  
**Notes to the Consolidated Financial Statements**  
**December 31, 2023 and 2022**

As previously disclosed on a Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on January 10, 2024, the Company announced that, the Board of Directors (the "Board") of the Company appointed David Green, age 61, as the Company's Chief Financial Officer, effective as of January 10, 2024.

*Nasdaq Notice of Compliance - Market Value Rule*

On February 26, 2024, the Company received notification from the Nasdaq Listing Qualifications staff that the Company had regained compliance with the market value of listed securities requirement in Nasdaq Listing Rule 5550(b)(2) (the "Market Value Rule").

*Nasdaq Notice of Temporary Exception - Minimum Bid Price Rule*

As previously disclosed on a Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission on March 6, 2024, that the Company received a letter from the Nasdaq Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market, LLC ("Nasdaq") granting the Company a temporary exception until June 24, 2024, subject to certain milestones, to regain compliance with the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule") by evidencing a closing bid price of \$

1.00

or more per share for a minimum of ten consecutive trading sessions.

In response to such deficiency letters, the Company timely submitted a hearing request before the Nasdaq Hearings Panel, and also provided the Nasdaq Hearings Panel with a plan to regain compliance, which plan included conducting a reverse stock split of the Company's Common Stock if necessary, no later than June 7, 2024, to regain compliance with the Minimum Bid Price Rule.

The Company intends to monitor the closing bid price of its Common Stock and consider available options if its Common Stock does not trade at a level likely to result in the Company's regaining compliance with the Minimum Bid Price Rule by June 24, 2024. There can be no assurance that the Company will be able to regain compliance with the Minimum Bid Price Rule or that the Company will otherwise be or remain in compliance with the other applicable Nasdaq listing standards.

*Paydown of the Senior Secured LMFAO Note Payable*

In January 2024, the Company paid down, in full, the entire approximately \$

1.1

million of principal and accrued and unpaid interest owed on the senior secured LMFAO note payable. No further obligations, terms or features otherwise remain outstanding and this note payable no longer exists.



## 19. Restatement of Quarterly Unaudited Results

The financial results data, presented on a quarterly basis for the following interim periods: (i) three months ending March 31, 2023, (ii) three- and six-months ended June 30, 2023, and (iii) three- and nine-months ended September 30, 2023, are unaudited. This data has been prepared in accordance with US GAAP for interim financial information and, in the opinion of the Company, reflect all adjustments necessary for a fair statement of the results of operations for the periods presented.

See Note 3, *Restatement of Previously Issued Consolidated Financial Statements*, for further information. The year-ended December 31, 2023, was not subject to restatement, and is presented in Part 1 of Item 8. Financial Statements.

### Consolidated Statements of Operations by Quarter

The following represents the Company's consolidated statements of operations by quarter for the interim periods of fiscal year 2023 (in thousands):

	2023		
	Three Months Ended		
	September 30, 2023	June 30, 2023	March 31, 2023
Operating expenses			
Research and development	\$ 1,087	\$ 1,981	\$ 1,730
General and administrative	1,855	1,769	2,851
Total operating expenses	2,942	3,750	4,581
Loss from operations	( 2,942 )	( 3,750 )	( 4,581 )
Other income (expense), net			
Interest expense	( 224 )	( 225 )	( 433 )
Change in fair value of convertible notes	( 291 )	( 100 )	100
Change in fair value of forward purchase agreement derivative liability	—	910	2,218
Change in fair value of liability classified warrants	1,025	723	36
Loss on extinguishment of convertible notes	( 4,949 )	—	—
Other income	149	—	—
Total other income (expense), net	( 4,290 )	1,308	2,515
Loss before provision for income taxes	( 7,232 )	( 2,442 )	( 7,096 )
Provision for income taxes	—	5	—

Net loss	\$	(	\$	(	\$	(
		7,232		2,447		7,096
		)		)		)
Net loss per share of common stock, basic and diluted	\$	(	\$	(	\$	(
		0.36		0.16		0.54
		)		)		)
Weighted-average shares outstanding, basic and diluted (1)						
		20,048,473		14,932,866		13,025,852

(1) Retrospectively restated to give effect to the reverse recapitalization

**Consolidated Balance Sheets for Quarters Ended March 31, 2023, June 30, 2023, and September 30, 2023**

The following tables present a reconciliation of the Company's consolidated balance sheets as previously reported to the restated amounts as of March 31, 2023, June 30, 2023, and September 30, 2023.

	March, 31 2023			
	As Previously Reported	Restatement Impacts	As Restated	Ref.
<b>ASSETS</b>				
Current assets				
Cash	\$ 725	\$ —	\$ 725	
Other receivables	—	—	—	
Prepaid expenses	2,659	(1,178)	1,481	1,6
Total current assets	3,384	1,178	2,206	
Other assets	2	1,439	1,441	6
Total assets	\$ 3,386	\$ 261	\$ 3,647	
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>				
Current liabilities				
Accounts payable	\$ 3,022	\$ —	\$ 3,022	
Accrued expenses	1,531	261	1,792	1
Contingent upfront payment for license agreement	100	—	100	
Notes payable, net of deferred financing costs	493	—	493	
Convertible notes, current portion	2,390	—	2,390	
Forward purchase agreement derivative liability	—	12,429	12,429	3
Liability classified warrants	500	551	1,051	2
Total current liabilities	8,036	13,241	21,277	
Notes payable, net of deferred financing costs	5,745	-	5,745	
Forward option-prepaid forward contracts, net	489	489	-	3
Total liabilities	14,270	12,752	27,022	
Commitments and contingencies (see Note 13)				

Stockholders' deficit

Common stock - \$				
	0.0001			
	1	—	1	
par value per share;		(		
	93,702	21,480	72,222	
Additional paid-in capital	(	)		4
	104,587	8,989	95,598	
Accumulated deficit	(	(	)	5
	10,884	12,491	23,375	
Total stockholders' deficit	)	)	)	
	3,386	261	3,647	
Total liabilities and stockholders' deficit	\$ <u>                    </u>	\$ <u>                    </u>	\$ <u>                    </u>	

June, 30 2023				
	As Previously Reported	Restatement Impacts	As Restated	Ref
<b>ASSETS</b>				
Current assets				
Cash	\$ 13	\$ —	\$ 13	
Other receivables	—	—	—	
Prepaid expenses	2,319	1,099	1,220	1,6
Total current assets	2,332	1,099	1,233	
Forward option-prepaid forward contracts, net	—	—	—	
Other assets	2	1,360	1,362	6
Total assets	\$ 2,334	\$ 261	\$ 2,595	
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>				
Current liabilities				
Accounts payable	\$ 4,355	\$ —	\$ 4,355	
Accrued expenses	1,095	261	1,356	1
Contingent upfront payment for license agreement	100	—	100	
Notes payable, net of deferred financing costs	5,907	—	5,907	
Convertible notes, current portion	2,230	—	2,230	
Liability classified warrants	95	308	403	2
Total current liabilities	13,782	569	14,351	
Total liabilities	13,782	569	14,351	
Commitments and contingencies (see Note 13)				
Stockholders' deficit				
Common stock - \$				
0.0001				
par value per share;	2	—	2	

		(		
	96,806	10,519	86,287	4
Additional paid-in capital	(	)	(	
	108,256	10,211	98,045	5
Accumulated deficit	(	)	(	
	11,448	308	11,756	
Total stockholders' deficit	(	)	(	
	2,334	261	2,595	
Total liabilities and stockholders' deficit	\$ <u>                    </u>	\$ <u>                    </u>	\$ <u>                    </u>	

September, 30 2023				
	As Previously Reported	Restatement Impacts	As Restated	Ref
<b>ASSETS</b>				
Current assets				
Cash	\$ 73	\$ —	\$ 73	
Other receivables	—	—	—	
Prepaid expenses	2,172	1,020	1,152	1,6
Total current assets	2,245	1,020	1,225	
Other assets	2	1,281	1,283	6
Total assets	\$ 2,247	\$ 261	\$ 2,508	
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>				
Current liabilities				
Accounts payable	\$ 5,042	\$ —	\$ 5,042	
Accrued expenses	1,481	267	1,748	1
Contingent upfront payment for license agreement	100	—	100	
Convertible notes, current portion	4,405	—	4,405	
Liability classified warrants	1,400	108	1,508	2
Total current liabilities	12,428	375	12,803	
Notes payable, net of deferred financing costs	5,722	-	5,722	
Total liabilities	18,150	375	18,525	
Commitments and contingencies (see Note 13)				
Stockholders' deficit				
Common stock - \$				
0.0001				
par value per share;	3	—	3	

		(		
	99,776	10,519	89,257	
Additional paid-in capital		)		4
	(	(		
	115,682	10,405	105,277	
Accumulated deficit	)	)	)	5
	(	(	(	
	15,903	114	16,017	
Total stockholders' deficit	)	)	)	
		261		
	2,247		2,508	
Total liabilities and stockholders' deficit	\$	\$	\$	

*Tickmark explanations for the reconciliation of the original to the restated quarterly balance sheets for 2023:*

1. Accrual for certain unpaid demand deposits relating to a clinical trial services agreement not recognized at March 31, 2023, June 30, 2023, or September 30, 2023.
2. Recognition of the fair value of certain warrants which were originally classified as equity at the October 28, 2022, Merger, but which upon further consideration were determined to be liability classified.
3. Impacting the balance sheet at March 31, 2023, only, this is comprised of the following: (i) recognition of the stand-alone fair prepaid forward purchase agreement derivative liability related to certain settlement features, which originally were netted with an note receivable asset that was later to be determined to be a subscription receivable. However, certain embedded features related to the prepaid forward purchase agreement, including (i) a forward purchase agreement to purchase remaining unsold shares of the Company's stock for \$

10.37  
per share, and (ii) certain additional settlement features that require the Company to pay an addition \$

2.50  
per remaining unsold shares or additional cash consideration in the event the Company's common stock is delisted.



4. Impact from accumulative combination of (i) derecognition of the asset portion of the prepaid forward purchase agreement into equity, offset by (ii) recognition as a liability certain warrants of the Company that were initially classified into equity for all periods since October 28, 2022.

5. Accumulative impact to the Company's accumulated deficit as a result of all of the above adjustments since October 28, 2022 through to each reporting period balance sheet date.

6. Reclass of certain prepaid insurance contracts with terms in excess of one year from the balance sheet date.

**Consolidated Statements of Operations for the Three Months Ended March 31, 2023, Three-and Six-Months Ended June 30, 2023, and Three- and Nine-Months Ended September 30, 2023**

The following tables present a reconciliation of the Company's consolidated statements of operations as previously reported to the restated amounts for the following periods:

- Three-months ended March 30, 2023
- Three- and six-months ended June 30, 2023
- Three- and nine-months ended September 30, 2023

	Three Months Ended March 31, 2023			Ref
	As Previously Reported	Restatement Impacts	As Restated	
Operating expenses			(	
Research and development	\$ 1,784	\$ 54 )	\$ 1,730	1
General and administrative	2,797	54	2,851	1
Total operating expenses	4,581	—	4,581	
	(		(	
Loss from operations	4,581 )	—	4,581 )	
Other income (expense), net	(		(	
Interest expense	433 )	—	433 )	
	100	—	100	
Change in fair value of convertible notes	(	(	(	
Change in fair value of forward purchase agreement derivative liability	1,654 )	564 )	2,218 )	2
	—	36	36	
Change in fair value of liability classified warrants				3
		(		
Gain (loss) on sale of recycled shares	1,306 )	1,306 )	-	4
	(	(	(	
Total other income (expense), net	681 )	1,834 )	2,515 )	
	(	(	(	
Loss before provision for income taxes	5,262 )	1,834 )	7,096 )	
	—	—	—	
Provision for income taxes				

	(	(	(
	5,262	1,834	7,096
Net loss	\$ <u>          </u> )	\$ <u>          </u> )	\$ <u>          </u> )
	(	(	(
	0.40	0.14	0.54
Net loss per share of common stock, basic and diluted	\$ <u>          </u> )	\$ <u>          </u> )	\$ <u>          </u> )

	13,025,852	13,025,852	13,025,852
Weighted-average shares outstanding, basic and diluted (1)	<u>                    </u>	<u>                    </u>	<u>                    </u>

(1) Retrospectively restated to give effect to the reverse recapitalization

	Three Months Ended June 30, 2023			Ref
	As Previously Reported	Restatement Impacts	As Restated	
Operating expenses			(	
Research and development	\$ 2,007	\$ 26	\$ 1,981	1
General and administrative	1,743	26	1,769	1
Total operating expenses	3,750	—	3,750	
	(		(	
Loss from operations	3,750	—	3,750	
	)		)	
Other income (expense), net				
	(		(	
Interest expense	225	—	225	
	)		)	
	(		(	
Change in fair value of convertible notes	100	—	100	
	)		)	
	(		(	
Change in fair value of forward purchase agreement derivative liability	69	979	910	2
	)			
	480	243	723	3
Change in fair value of liability classified warrants				
Total other income (expense), net	86	1,222	1,308	
	(		(	
Loss before provision for income taxes	3,664	1,222	2,442	
	)		)	
	5	—	5	
Provision for income taxes				
	(		(	
Net loss	\$ 3,669	\$ 1,222	\$ 2,447	
	)		)	
	(		(	
	0.25	0.08	0.16	
Net loss per share of common stock, basic and diluted	\$ )	\$ )	\$ )	
Weighted-average shares outstanding, basic and diluted (1)	14,932,866	14,932,866	14,932,866	

(1) Retrospectively restated to give effect to the reverse recapitalization



	Six Months Ended June 30, 2023			Ref
	As Previously Reported	Restatement Impacts	As Restated	
Operating expenses			(	
Research and development	\$ 3,791	\$ 80	\$ 3,711	1
General and administrative	4,540	80	4,620	1
Total operating expenses	8,331	—	8,331	
	(		(	
Loss from operations	8,331	—	8,331	
	)		)	
Other income (expense), net				
	(		(	
Interest expense	658	—	658	
	)		)	
	(		(	
Change in fair value of forward purchase agreement derivative liability	1,723	415	1,308	2
	)		)	
Change in fair value of liability classified warrants	480	279	759	3
			(	
Gain (loss) on sale of recycled shares	1,306	1,306	—	4
	)	)		
	(	(	(	
Total other income (expense), net	595	612	1,207	
	)	)	)	
	(	(	(	
Loss before provision for income taxes	8,926	612	9,538	
	)	)	)	
Provision for income taxes	5	-	5	
			(	
	(	(	(	
Net loss	8,931	612	9,543	
	)	)	)	
	(	(	(	
	0.64	0.04	0.68	
Net loss per share of common stock, basic and diluted	\$ )	\$ )	\$ )	
Weighted-average shares outstanding, basic and diluted (1)	13,984,625	13,984,625	13,984,625	

(1) Retrospectively restated to give effect to the reverse recapitalization



	Three Months Ended September 30, 2023			Ref
	As Previously Reported	Restatement Impacts	As Restated	
Operating expenses			(	
Research and development	\$ 1,107	\$ 20	\$ 1,087	1
General and administrative	1,829	26	1,855	1
Total operating expenses	2,936	6	2,942	
	(	(	(	
Loss from operations	2,936	6	2,942	
	)	)	)	
Other income (expense), net				
	(		(	
Interest expense	224	—	224	
	)		)	
	(		(	
Change in fair value of convertible notes	291	—	291	
	)		)	
Change in fair value of liability classified warrants	825	200	1,025	4
	(		(	
Loss on extinguishment of convertible notes	4,949	—	4,949	
	)		)	
Other income	149	—	149	
	(		(	
Total other income (expense), net	4,490	200	4,290	
	)		)	
	(		(	
Loss before provision for income taxes	7,426	194	7,232	
	)		)	
Provision for income taxes	—	—	—	
	(		(	
Net loss	\$ 7,426	\$ 194	\$ 7,232	
	)		)	
	(		(	
Net loss per share of common stock, basic and diluted	\$ 0.37	\$ 0.01	\$ 0.36	
	)		)	
Weighted-average shares outstanding, basic and diluted (1)	20,048,473	20,048,473	20,048,473	

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	As Previously Reported	Nine Months Ended September 30, 2023 Restatement Impacts	As Restated	Ref
Operating expenses				
		(		
Research and development	\$ 4,898	\$ 100 )	\$ 4,798	1
General and administrative	6,369	106	6,475	1
Total operating expenses	11,267	6	11,273	
	(	(	(	
Loss from operations	11,267 )	6 )	11,273 )	
Other income (expense), net				
	(		(	
Interest expense	882 )	-	882 )	
	(		(	
Change in fair value of convertible notes	291 )	-	291 )	
	(		(	
Change in fair value of forward option-prepaid forward contracts	1,723 )	415	1,308 )	2
	1,305	479	1,784	3
Change in fair value of warrants liability	(		(	
Loss on extinguishment of convertible notes	4,949 )	—	4,949 )	
	(		(	
Gain (loss) on sale of recycled shares	1,306 )	1,306 )	-	4
Other income	149	—	149	
	(	(	(	
Total other income (expense), net	5,085 )	412 )	5,497 )	
	(	(	(	
Loss before provision for income taxes	16,352 )	418 )	16,770 )	
	5	—	5	
Provision for income taxes				
	(	(	(	
Net loss	\$ 16,357 )	\$ 418 )	\$ 16,775 )	
	(	(	(	
	1.02	0.03	1.05	
Net loss per share of common stock, basic and diluted	\$ )	\$ )	\$ )	

	16,028,118	16,028,118	16,028,118
Weighted-average shares outstanding, basic and diluted (1)	<u>                    </u>	<u>                    </u>	<u>                    </u>

(1) Retrospectively restated to give effect to the reverse recapitalization

*Tickmark Explanations for the reconciliation from the original to the restatement quarterly statements of operations for interim periods previously reported in the fiscal year 2023.*

1. Presentation reclass of legal fees previously presented as components of research and development into general and administrative to conform with US GAAP.

2. Result of the derecognition of the asset components to the prepaid forward purchase agreement, which was originally accounted for akin to a note receivable. However, upon further analysis, the nature of the receivable was more akin to a subscription receivable, and accordingly, recognized to equity at the October 28, 2022, Merger date. Result of the decline in fair value of the prepaid forward purchase option derivative liability. Certain embedded features related to the prepaid forward purchase agreement, including (i) a forward purchase agreement to purchase remaining unsold shares of the Company's stock for \$

10.37

per share, and (ii) certain additional settlement features that require the Company to pay an addition \$

2.50

per remaining unsold shares or additional cash consideration in the event the Company's common stock is delisted.

3. Result of the decline in the warrants derivative liability for the Company's Private Placement Warrants and PIPE Warrants (see Footnote 11), that were originally classified as components of equity. However, once it was determined that these warrants required liability classification, the warrants were required to be remeasured at each reporting period date, and the changes in fair value recognized as a component of earnings.

4. Related to the determination that the asset portion of the prepaid forward purchase agreement was more akin to a subscription receivable for an issuer's own equity, any proceeds from the sale of the Recycled Shares under the prepaid forward purchase agreement can not result in any gain or loss. Any proceeds received by the Company for the sale of these shares should be accounted for akin to the accounting for any sale of the Company's shares in an offering or other issuance, with the proceeds merely recognized to additional paid-in-capital.

***Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2023, Six-Months Ended June 30, 2023, and Nine-Months Ended September 30, 2023***

The following tables present a reconciliation of the Company's consolidated statements of cash flows as previously reported to the restated amounts for the following periods:

- Three-months ended March 30, 2023
- Six-months ended June 30, 2023
- Nine-months ended September 30, 2023

No adjustments to supplemental cash flow information was impacted by these adjustments, and accordingly, were omitted to reduce complexity of this disclosure

	Three Months Ended March 31, 2023			Ref
	As Previously Reported	Restatement Impacts	As Restated	
Cash flows from operating activities				
Net loss	(	(	(	
	5,262	1,834	7,096	
	\$ )	\$ )	\$ )	1
Adjustments to reconcile net loss to net cash used in operating activities				
Amortization of deferred financing costs	4	—	4	
Change in the fair value of the forward purchase agreement derivative liability	1,654	564	2,218	2
Change in fair value of liability classified warrants	—	(	(	
	36	36	36	
	)	)	)	3
Change in fair value of convertible notes	(	(	(	
	100	—	100	
	)		)	
(Gain) loss on sale of recycled shares	(			
	1,306	1,306	—	
	)			4
Stock-based compensation	505	—	505	
Changes in operating assets and liabilities				
Other receivables	12	—	12	
Prepaid expenses and other	318	—	318	
Accounts payable	1,095	—	1,095	
Accrued expenses	786	—	786	
Net cash used in operating activities	(	(	(	
	2,294	—	2,294	
	)		)	
Cash flows from financing activities				
Proceeds from issuance of convertible notes	3,000	—	3,000	
Payment of convertible notes	(	(	(	
	10	—	10	
	)		)	
Proceeds from issuance of shares	1,108	—	1,108	

Payment of commitment fee - equity line of credit	(		(
	500	—	500
	)		)
Proceeds from sale of recycled shares			
	1,870	—	1,870
Proceeds from notes payable			
	100	—	100
Payment of notes payable	(		(
	2,596	—	2,596
	)		)
Net cash provided by financing activities			
	2,972	—	2,972
Net increase (decrease) in cash			
	678	—	678
Cash, beginning of period			
	47	—	47
Cash, end of period	\$	\$	\$
	725	—	725
	<u>          </u>	<u>          </u>	<u>          </u>

	Six Months Ended June 30, 2023			
	As Previously Reported	Restatement Impacts	As Restated	Ref
Cash flows from operating activities				
Net loss	(	(	(	
	8,931	612	9,543	
	\$ )	\$ )	\$ )	1
Adjustments to reconcile net loss to net cash used in operating activities				
Amortization of deferred financing costs	23	—	23	
Change in the fair value of the forward purchase agreement derivative liability	1,723	(	1,308	
		415		2
Change in fair value of liability classified warrants	(	(	(	
	480	279	759	
	)	)	)	3
(Gain) loss on sale of recycled shares	(			
	1,306	1,306	—	
	)			4
Stock-based compensation	1,060	—	1,060	
Changes in operating assets and liabilities				
Other receivables	12	—	12	
Prepaid expenses and other	658	—	658	
Accounts payable	2,428	—	2,428	
Accrued expenses	350	—	350	
Net cash used in operating activities	(		(	
	4,463	—	4,463	
	)		)	
Cash flows from financing activities				
Proceeds from issuance of convertible notes	5,000	—	5,000	
Payment of convertible notes	(		(	
	258	—	258	
	)		)	
Proceeds from issuance of shares	1,163	—	1,163	
Payment of commitment fee - equity line of credit	(		(	
	500	—	500	
	)		)	
Proceeds from sale of recycled shares	1,870	—	1,870	
Proceeds from notes payable	100	—	100	

Payment of notes payable	(		(
	2,946	—	2,946
	)		)
Net cash provided by financing activities			
	4,429	—	4,429
Net increase (decrease) in cash	(		(
	34	—	34
	)		)
Cash, beginning of period			
	47	—	47
Cash, end of period	\$	\$	\$
	13	—	13
	<u>          </u>	<u>          </u>	<u>          </u>
	137		

	Nine Months Ended September 30, 2023			Ref
	As Previously Reported	Restatement Impacts	As Restated	
Cash flows from operating activities				
Net loss	(	(	(	
	16,357	418	16,775	
	\$ )	\$ )	\$ )	1
Adjustments to reconcile net loss to net cash used in operating activities				
Amortization of deferred financing costs	37	—	37	
Change in fair value of convertible notes	291	—	291	
Change in the fair value of the forward purchase agreement derivative liability	1,723	415	1,308	2
Change in fair value of liability classified warrants	(	(	(	
	1,305	479	1,784	3
	)	)	)	
(Gain) loss on sale of recycled shares	(			
	1,306	1,306	—	4
	)			
Loss on extinguishment of convertible notes	4,949	—	4,949	
Stock-based compensation	1,544	—	1,544	
Changes in operating assets and liabilities				
Other receivables	12	—	12	
Prepaid expenses and other	805	—	805	
Accounts payable	3,115	—	3,115	
Accrued expenses	692	6	698	5
Net cash used in operating activities	(		(	
	5,800	—	5,800	
	)		)	
Cash flows from financing activities				
Proceeds from issuance of convertible notes	6,500	—	6,500	
Payment of convertible notes	(		(	
	282	—	282	
	)		)	
Proceeds from issuance of shares	1,283	—	1,283	



Payment of commitment fee - equity line of credit	(		(
	500	—	500
	)		)
Proceeds from sale of recycled shares			
	1,870	—	1,870
Proceeds from notes payable			
	100	—	100
Payment of notes payable	(		(
	3,145	—	3,145
	)		)
Net cash provided by financing activities			
	5,826	-	5,826
Net increase (decrease) in cash	\$	\$	
	26	—	26
		\$	
Cash, beginning of period	\$	\$	\$
	47	—	47
Cash, end of period	\$	\$	\$
	73	—	73
	<u>          </u>	<u>          </u>	<u>          </u>

*Tickmark explanations for the reconciliation of the original to the restated quarterly balance sheets for 2023:*

1. Cumulative impact to the Company's Statement of Operations as a result of all of the adjustments which impacted the Statement of Operations Net Loss for each Statement of Cash Flows Presented.
2. Result of the (i) derecognition of the asset portion of the prepaid forward purchase agreement, which after further consideration, was determined to be a subscription receivable on the Company's own common stock, and (ii) Result of the change in fair value of prepaid forward purchase agreement derivative liability related to settlement features embedded within the agreement for each cash period presented. Accordingly, the asset was derecognized, the original value at the Merger date classified as a component of equity. The prepaid forward purchase agreement was fully settled in June 2023.
3. Result of the decline in the warrants derivative liability for the Company's Private Placement Warrants and PIPE Warrants (see Footnote 11), that were originally classified as components of equity. However, once it was determined that these warrants required liability classification, the warrants were required to be remeasured at each reporting period date, and the changes in fair value recognized as a component of earnings.

4. Related to the determination that the asset portion of the prepaid forward purchase agreement was more akin to a subscription receivable for an issuer's own equity, any proceeds from the sale of the Recycled Shares under the prepaid forward purchase agreement can not result in any gain or loss. Any proceeds received by the Company for the sale of these shares should be accounted for akin to the accounting for any sale of the Company's shares in an offering or other issuance, with the proceeds merely recognized to additional paid-in-capital.

5. To reflect certain unaccrued marketing fees as of September 30, 2023.

***Consolidated Statements of Changes in Stockholders' Deficit for the each of the three-months ended March 31, 2023, June 30, 2023, and September 30, 2023***

The following tables present a reconciliation of the Company's consolidated statements of cash flows as previously reported to the restated amounts for the following periods:

- Three-months ended March 30, 2023
- Three-months ended June 30, 2023
- Three-months ended September 30, 2023

(amounts in thousands, except per share amounts)	Ref	Common Shares		Stockholders' Deficit	Accumulated	Stockholders'
		Shares (1)	Amount	Additional Paid-In Capital	Deficit	Deficit
					(	(
<b>Balance - January 1, 2023 (As Restated)</b>		<b>12,699,668</b>	<b>1</b>	<b>67,739</b>	<b>88,502</b>	<b>20,762</b>
			\$		)	)
Issuance of shares - equity line of credit		378,006	—	1,108	—	1,108
Issuance of shares - commitment fee for equity line of credit		218,842	—	1,000	—	1,000
Issuance of shares - prepaid forward contracts (As Revised)	1,2	—	—	1,870	—	1,870
Stock-based compensation		—	—	505	—	505
Net loss (As Revised)	4	—	—	—	7,096	7,096
				\$	(	(
<b>Balance - March 31, 2023 (As Restated)</b>		<b>13,296,516</b>	<b>1</b>	<b>72,222</b>	<b>95,598</b>	<b>23,375</b>
			\$		)	)
Issuance of shares - equity line of credit		26,996	—	55	—	55
Issuance of shares - conversion of convertible notes		3,088,167	1	1,936	—	1,937
Issuance of shares - vesting of RSUs		153,405	—	—	—	—
Issuance of shares - prepaid forward contracts		1,096,972	—	—	—	-
Forward Purchase Agreement Derivative Liability	3	—	—	11,519	—	11,519
Stock-based compensation		459,185	—	555	—	555
Net loss (As Revised)	4	—	—	—	2,447	2,447
				\$	(	(
<b>Balance - June 30, 2023 (As Restated)</b>		<b>18,121,241</b>	<b>2</b>	<b>86,287</b>	<b>98,045</b>	<b>11,756</b>
			\$		)	)

	234,579		120		120
Issuance of shares - equity line of credit		—		—	
Issuance of shares - commitment fee for equity line of credit	—	—	—	—	—
Issuance of shares - conversion of convertible notes	8,432,517	1	2,410	—	2,411
Issuance of shares - exercise of warrants	—	—	—	—	—
Issuance of shares - vesting of RSUs	32,839	—	—	—	—
Issuance of shares - prepaid forward contracts	—	—	—	—	—
Stock-based compensation	379,914	—	440	—	440
				(	(
Net loss (As Revised)	4	—	-	7,232	7,232
			\$	\$(	\$(
<b>Balance - September 30, 2023 (As Restated)</b>	<b>27,201,090</b>	<b>3</b>	<b>89,257</b>	<b>105,277</b>	<b>16,017</b>
				)	)

*Tickmark explanations for the reconciliation of the original to the restated quarterly **statements of stockholders deficit** are as follows:*

1. Includes the reversal of the gain on sale of recycled shares, and classify proceeds as merely increase in additional paid-in-capital

2. Includes the reversal of the final derecognition of the prepaid forward purchase agreement asset, which was adjusted to reflect that the receivable component of the agreement reflected a subscription receivables on the Company's own equity.
3. Recognition of subscription receivable in the form of the prepaid forward purchase agreement. The prepayment is considered under US GAAP, to be effectively a loan to shareholders, while the related forward purchase agreement and any related obligations are accounted for separately
4. Cumulative impact to the Company's Statement of Operations as a result of all of the adjustments which impacted the Statement of Operations for each Statement of Cash Flows Presented.

**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, including our Chief Executive Officer and Chief Financial Officer, have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2023 and based on this evaluation, have concluded that, as a result of the material weaknesses in internal control over financial reporting as described below, our disclosure controls and procedures were not effective as of December 31, 2023.

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. The management of the Company has 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. 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.

As discussed elsewhere in this report, we completed the Business Combination on October 28, 2022. Prior to the Business Combination, the Predecessor was a private company and therefore its controls were not required to be designed or maintained in accordance with Rules 13a-15 and 15d-15 under the Exchange Act. The design and implementation of internal control over financial reporting for the Company post-Business Combination has required

and will continue to require significant time and resources from management and other personnel. Because of this, the design and ongoing development of our framework for implementation and evaluation of internal control over financial reporting is in its preliminary stages. As a result, management was unable, without incurring unreasonable effort or expense to conduct an assessment of our internal control over financial reporting as of December 31, 2023. Accordingly, we are excluding management's report on internal control over financial reporting pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations.

#### *Identification of Material Weaknesses*

In the course of preparing the consolidated financial statements that are included in this Annual Report, the Company has identified material weaknesses in its internal controls over financial reporting as of December 31, 2023, which relates to a deficiency in the design and operation of its financial accounting and reporting controls (See Note 3 and Note 19). A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, the Company identified deficiencies in internal controls over financial reporting which were determined to rise to the level of material weakness. The Company has strengthened its accounting team with the addition of an experienced Controller and Chief Financial Officer, and has identified additional accounting resources that are expected to help to remediate the material weaknesses. The Company will also continue to review the overall internal control environment as we develop the requisite internal control framework.

#### ***Changes in Internal Control over Financial Reporting***

Except as noted above, 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 period ended December 31, 2023 and 2022, respectively, 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 Company's 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 Company's fiscal year ended December 31, 2023.

We have adopted a Code of Ethics that applies to all officers, directors, and employees in connection with their work for us. The full text of our Code of Ethics is posted on the investor relations page of our website at <https://investors.seastarmedical.com/governance/governance-documents/default.aspx>.

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 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 by reference to the Company's 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 Company's fiscal year ended December 31, 2023.

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

The information required under this item is incorporated by reference to the Company's 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 Company's fiscal year ended December 31, 2023.

#### **Item 13. Certain Relationships and Related Transactions, And Director Independence.**

The information required under this item is incorporated by reference to the Company's 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 Company's fiscal year ended December 31, 2023.

#### **Item 14. Principal Accounting Fees and Services.**

The information required under this item is incorporated by reference to the Company's 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 Company's fiscal year ended December 31, 2023.

## **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 F-1 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
1.1	<a href="#"><u>Placement Agency Agreement, dated January 26, 2024, by and among the Company and Maxim Group LLC (incorporated by reference to Exhibit 1.1 of Form 8-K dated January 30, 2024).</u></a>
2.1†	<a href="#"><u>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).</u></a>
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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).</u></a>
3.3	<a href="#"><u>Amended and Restated Bylaws of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.2 to Form 8-K filed by the registrant on November 4, 2022).</u></a>
4.1	<a href="#"><u>Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the registrant on November 4, 2022).</u></a>
4.2	<a href="#"><u>Specimen Warrant Certificate (included in Exhibit 4.3).</u></a>
4.3	<a href="#"><u>Warrant Agreement, dated January 25, 2021, between LMAO and Continental Stock Transfer &amp; Trust Company (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the registrant on January 28, 2021).</u></a>
4.4	<a href="#"><u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the registrant on March 16, 2023).</u></a>
4.5	<a href="#"><u>Description of Securities (included under "Description of Securities" in Form S-1 filed by the registrant on January 20, 2023).</u></a>
4.6	<a href="#"><u>Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of Form 8-K dated January 30, 2024).</u></a>
4.7	<a href="#"><u>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).</u></a>
4.8	<a href="#"><u>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).</u></a>
10.1	<a href="#"><u>Amended and Restated Registration Rights Agreement, dated as of April 21, 2022, by and among LMAO, SeaStar Medical, Inc., and certain stockholders of SeaStar Medical, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the registrant on April 26, 2022).</u></a>
10.2	<a href="#"><u>Investment Management Trust Agreement, dated January 25, 2021, between LMAO and Continental Stock Transfer &amp; Trust Company, as trustee (incorporated by reference to Exhibit 10.2 to Form 8-K filed by the registrant on January 28, 2021).</u></a>
10.3	<a href="#"><u>Registration Rights Agreement, dated as of January 25, 2021, by and among LMF Acquisition Opportunities, Inc., SeaStar Medical, Inc., and certain stockholders of SeaStar Medical, Inc. (incorporated by reference to Exhibit 10.3 to Form 8-K filed by the registrant on January 28, 2021).</u></a>
10.4	<a href="#"><u>SeaStar Medical Holding Corporation 2022 Omnibus Incentive Plan (incorporated by reference to Annex D of Form S-4 filed by the registrant on May 16, 2022).</u></a>
10.5	<a href="#"><u>SeaStar Medical Holding Corporation 2022 Employee Stock Purchase Plan (incorporated by reference to Annex E of Form S-4 filed by the registrant on May 16, 2022).</u></a>
10.6	<a href="#"><u>Promissory Note, dated effective as of March 1, 2022, between LMFAO Sponsor LLC and LMAO (previously filed as Exhibit 10.1 to Form 10-Q filed by LMAO to the SEC on May 19, 2022).</u></a>
10.7	<a href="#"><u>Amended and Restated Promissory Note, dated July 28, 2022, issued by LMAO to LMFAO Sponsor, LLC (previously filed as Exhibit 10.1 to Form 8-K filed by LMAO with the SEC on August 1, 2022).</u></a>
10.8	<a href="#"><u>Form of Subscription Agreement, dated August 23, 2022, between LMAO, SeaStar Medical, Inc. and certain investors (incorporated by reference to Exhibit 10.29 to Form S-4/A filed by the registrant on August 24, 2022).</u></a>

- 10.09 [Credit Agreement, between SeaStar Medical, Inc. and LM Funding America, Inc., dated September 9, 2022 \(incorporated by reference to Exhibit 10.34 to Form S-4/A filed by the registrant on September 13, 2022\).](#)
- 10.10 [Amendment No. 1 to Amended and Restated Registration Rights Agreement and Waiver of Lock-up Period, dated October 25, 2022, by and among LMAO and the investors listed on the signature pages thereto \(incorporated by reference to Exhibit 10.12 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.11 [Letter Agreement, dated October 28, 2022, by and among LMAO, SeaStar Medical, Inc., and Tumim Stone Capital LLC \(incorporated by reference to Exhibit 10.13 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.12 [Director Nomination Agreement, dated as of October 28, 2022, by and among LMFAO Sponsor LLC and LMAO \(incorporated by reference to Exhibit 10.14 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.13 [First Amendment to Credit Agreement, dated October 28, 2022, by and between SeaStar Medical, Inc. and LM Funding America, Inc. \(incorporated by reference to Exhibit 10.15 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.14 [Amended and Restated Promissory Note, dated October 28, 2022, issued by SeaStar Medical, Inc. to LM Funding America, Inc. \(incorporated by reference to Exhibit 10.16 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.15 [Security Agreement, dated October 28, 2022, issued by SeaStar Medical, Inc. and SeaStar Medical Holding Corporation to LM Funding America, Inc. \(incorporated by reference to Exhibit 10.17 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.16 [Guaranty, dated October 28, 2022, issued by SeaStar Medical Holding Corporation to LM Funding America, Inc. \(incorporated by reference to Exhibit 10.18 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.17 [Consolidated Amended and Restated Promissory Note, dated October 28, 2022, issued by SeaStar Medical Holding Corporation to LMFAO Sponsor, LLC \(incorporated by reference to Exhibit 10.19 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.18 [Security Agreement, dated October 28, 2022, issued by SeaStar Medical, Inc. and SeaStar Medical Holding Corporation to LMFAO Sponsor, LLC \(incorporated by reference to Exhibit 10.20 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.19 [Guaranty, dated October 28, 2022, issued by SeaStar Medical, Inc. to LMFAO Sponsor, LLC \(incorporated by reference to Exhibit 10.21 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.20 [Promissory Note, dated October 28, 2022, issued by SeaStar Medical Holding Corporation to Maxim Group LLC \(incorporated by reference to Exhibit 10.22 to Form 8-K filed by the registrant on November 4, 2022\).](#)
- 10.21 [Intercreditor Agreement, dated October 28, 2022, by and among Maxim Group LLC, LM Funding America, Inc., LMFAO Sponsor, LLC, SeaStar Medical, Inc. and SeaStar Medical Holding Corporation \(incorporated by reference to Exhibit 10.23 to Form 8-K filed by the Company with the registrant on November 4, 2022\).](#)
- 10.22 [Confirmation for Prepaid Forward Transaction, dated October 26, 2022, by and among LMF Acquisition Opportunities, Inc., SeaStar Medical, Inc. and HB Strategies LLC \(incorporated by reference to Exhibit 10.1 to Form 8-K filed by the registrant on October 27, 2022\).](#)
- 10.23 [Confirmation for Prepaid Forward Transaction, dated October 17, 2022, by and among LMF Acquisition Opportunities, Inc., SeaStar Medical, Inc. and Vellar Opportunity Fund SPV LLC—Series 4 \(incorporated by reference to Exhibit 10.1 to Form 8-K filed by the registrant on October 17, 2022\).](#)
- 10.24 [Securities Purchase Agreement, dated as of March 15, 2023, by and among SeaStar Medical Holding Corporation and 3i, LP \(incorporated by reference to Exhibit 10.1 to Form 8-K filed by the registrant on March 16, 2023\).](#)
- 10.25 [Registration Rights Agreement, dated as of March 15, 2023, by and among SeaStar Medical Holding Corporation and 3i, LP \(incorporated by reference to Exhibit 10.2 to Form 8-K filed by the registrant on March 16, 2023\).](#)
- 10.26 [Form of Senior Unsecured Convertible Note \(incorporated by reference to Exhibit 10.3 to Form 8-K filed by the registrant on March 16, 2023\).](#)

10.27	<a href="#"><u>Share Issuance and Settlement Agreement, dated as of June 6, 2023, by and between SeaStar Medical Holding Corporation and Vellar Opportunity Fund SPV LLC – Series 4 (incorporated by reference to Exhibit 10.1 to Form 10-Q filed August 14, 2023).</u></a>
10.28	<a href="#"><u>First Amendment to Securities Purchase Agreement, dated August 7, 2023, by and between the Company and 3i, LP (incorporated by reference to Exhibit 10.1 to Form 8-K filed August 7, 2023).</u></a>
10.29	<a href="#"><u>First Amendment to Registration Rights Agreement, dated August 7, 2023, by and between the Company and 3i, LP (incorporated by reference to Exhibit 10.2 to Form 8-K filed August 7, 2023).</u></a>
10.30	<a href="#"><u>Letter Agreement, dated August 7, 2023, by and between the Company and 3i, LP (incorporated by reference to Exhibit 10.3 to Form 8-K filed August 7, 2023).</u></a>
10.31	<a href="#"><u>Third Amendment, Consent and Waiver Agreement, dated August 7, 2023, by and between the Company and Maxim Group LLC (incorporated by reference to Exhibit 10.4 to Form 8-K filed August 7, 2023).</u></a>
10.32	<a href="#"><u>Third Amendment, Consent and Waiver Agreement, dated August 7, 2023, by and between the Company and LM Funding America, Inc. (incorporated by reference to Exhibit 10.5 to Form 8-K filed August 7, 2023).</u></a>
10.33	<a href="#"><u>Third Amendment, Consent and Waiver Agreement, dated August 7, 2023, by and between the Company and LMFAO Sponsor, LLC (incorporated by reference to Exhibit 10.6 to Form 8-K filed August 7, 2023).</u></a>
10.34	<a href="#"><u>Letter Agreement, dated August 30, 2023, by and between the Company and 3i, LP (incorporated by reference to Exhibit 10.1 to Form 8-K filed August 30, 2023).</u></a>
10.35+	<a href="#"><u>Employment Agreement, dated January 10, 2024, by and between the Company and David Green (incorporated by reference to Exhibit 10.1 to Form 8-K dated January 11, 2024).</u></a>
10.36	<a href="#"><u>Form of Securities Purchase Agreement, by and among the Company and the parties thereto (incorporated by reference to Exhibit 10.1 of Form 8-K filed January 30, 2024).</u></a>
10.37√	<a href="#"><u>License and Distribution Agreement, dated December 27, 2022, by and between the Company and NuWellis, Inc. (incorporated by reference to Exhibit 10.63 of Form 10-K filed by Nuwellis, Inc. on March 3, 2023).</u></a>
10.38**√	<a href="#"><u>Amendment No. 1 to the License and Distribution Agreement, dated December 29, 2023, by and between the Company and Nuwellis, Inc.</u></a>
21.1	<a href="#"><u>List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Form 8-K filed by the registrant on November 4, 2022).</u></a>
23.1**	<a href="#"><u>Consent of Independent Registered Public Accounting Firm of SeaStar Medical Holding Corporation for fiscal year-ended December 31, 2022</u></a>
23.2**	<a href="#"><u>Consent of Independent Registered Public Accounting Firm of SeaStar Medical Holding Corporation for fiscal year-ended December 31, 2023</u></a>
24.1**	<a href="#"><u>Power of Attorney (included on the signature page hereto).</u></a>
31.1**	<a href="#"><u>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.</u></a>
31.2**	<a href="#"><u>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.</u></a>
32.1**	<a href="#"><u>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.</u></a>
32.2**	<a href="#"><u>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.</u></a>
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

√ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

**ITEM 16. FORM 10-K SUMMARY.**

None.

### SIGNATURES

Pursuant to the requirements of 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: April 16, 2024

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

Date: April 16, 2024

By: /s/ David Green  
David Green  
Chief Financial Officer  
(Principal Financial and Accounting 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 Act of 1933, 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)	April 16, 2024
<u>/s/ David Green</u> David Green	Chief Financial Officer (Principal Financial and Accounting Officer)	April 16, 2024
<u>/s/ Rick Barnett</u> Rick Barnett	Chairman of the Board of Directors	April 16, 2024
<u>/s/ Kenneth Van Heel</u> Kenneth Van Heel	Director	April 16, 2024
<u>/s/ Andres Lobo</u> Andres Lobo	Director	April 16, 2024
<u>/s/ Allan Collins</u> Allan Collins	Director	April 16, 2024
<u>/s/ Bruce Rodgers</u> Bruce Rodgers	Director	April 16, 2024
<u>/s/ Richard Russell</u> Richard Russell	Director	April 16, 2024

**AMENDMENT NO. 1 TO LICENSE AND DISTRIBUTION AGREEMENT**

This **AMENDMENT NO. 1 TO LICENSE AND DISTRIBUTION AGREEMENT** ("**Amendment**") is effective as of December 29, 2023 ("**Amendment Effective Date**") between SeaStar Medical Holding Corporation, a Delaware corporation, with a place of business at 3513 Brighton Blvd, Suite 410, Denver, Colorado 80216 ("**Supplier**") and Nuwellis, Inc., a Delaware corporation, with a place of business at 12988 Valley View Road, Eden Prairie, Minnesota 55344 ("**Distributor**"). Supplier or Distributor may hereinafter be referred to as a "**Party**" or collectively as "**Parties**".

**WHEREAS**, Supplier and Distributor are parties to a LICENSE AND DISTRIBUTION AGREEMENT ("**Agreement**") effective as of December 27, 2022 ("**Agreement Effective Date**").

**WHEREAS**, the Parties desire to amend the Agreement as set forth herein and Section 20.3 of the Agreement requiring any amendment to be reduced to writing and signed by the respective authorized officers of the Parties, which requirements, the Parties acknowledge and agree, this Amendment satisfies.

**NOW, THEREFORE**, for good and valuable consideration contained in this Amendment and the relationship between the Parties that this Amendment will further facilitate, the exchange, receipt and sufficiency of which are acknowledged, the Parties agree as follows:

1. The second sentence of Section 4.1 of the Agreement is hereby deleted in its entirety.
2. The first sentence of Section 4.4 of the Agreement is hereby deleted in its entirety and replaced with the following:

**"Milestone Payments.** In addition to the other payments contemplated by the terms and conditions of this Agreement, Distributor shall pay Supplier the following milestone payments set forth below on the later to occur of (i) [\*\*] after achievement of the corresponding milestone events or [\*\*] (such date of payment, the "Payment Date)..

3. Each Party hereby represents and warrants to the other Party that the Agreement, as hereby amended, constitutes the legal, valid and binding obligation of such Party and is enforceable against such Party in accordance with its terms, subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law). The Parties agree that the Agreement, as specifically amended by this Amendment, continues to remain in full force and effect. Defined terms used herein but not defined herein will have the meaning set forth in the Agreement.

4. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware as applicable to contracts made and to be performed in that state, without regard to conflicts of laws principles, suit to enforce the interpretation or application of this Amendment shall be brought within a court of competent jurisdiction, state or federal, located within the State of Delaware. The Parties expressly disclaim application of or reference to the United Nations Convention on Contracts for the International Sale of Goods.

*[Signature page follows]*

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IN WITNESS WHEREOF, this Amendment has been executed and delivered by the Parties by their duly authorized officers as of the Amendment Effective Date.

**SeaStar Medical Holding Corporation Nuwellis, Inc.**

By           /s/ Eric Schlorff  
Name:     Eric Schlorff  
Title      Chief Executive Officer

By:       /s/ Nestor Jaramillo, Jr.  
Name     Nestor Jaramillo, Jr.  
Title     President & CEO

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the registration statements (No. 333-276978 and 333-270070) on Form S-8 and (No. 333-276675, 333-275968, and 333-275844) on Form S-3 of our report dated March 30, 2023, except for the effects of the restatement discussed in Note 3 (not presented herein) for which the date is April 16, 2024, relating to the consolidated financial statements (as restated), which appears in this Form 10-K.

/s/ Armanino<sup>LLP</sup>  
Bellevue, Washington

April 16, 2024

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## 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 and 333-275844 and Form S-8 Nos. 333-276978 and 333-270070 of SeaStar Medical Holding Corporation (the "Company") of our report dated April 16, 2024, 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 year ended December 31, 2023, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey  
April 16, 2024

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**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: April 16, 2024

/s/ Eric Schlorff

Eric Schlorff  
Chief Executive Officer

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

I, Caryl Baron, 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: April 16, 2024

/s/ David Green

David Green

Chief Financial Officer

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**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, 2023 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: April 16, 2024

/s/ Eric Schlorff

Eric Schlorff

Chief Executive Officer

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

I, Caryl Baron, Interim 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, 2023 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: April 16, 2024

/s/ David Green

David Green

Chief Financial Officer

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