As filed with the Securities and Exchange Commission on June 16, 2025

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SeaStar Medical Holding Corporation
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**3841**	**85-3681132**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.

3513 Brighton Blvd, Suite 410
Denver, CO 80216
(844) 427-8100

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Eric Schlorff
Chief Executive Officer
3513 Brighton Blvd, Suite 410
Denver, CO 80216

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

Joshua Erekson
Daniel Lyman
Dorsey & Whitney LLP
111 South Main Street, Suite 2100
Salt Lake City, UT 84111
(801) 933-7360

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS (Subject to Completion) **Dated June 16, 2025**

Up to 4,237,288 Shares of Common Stock and accompanying Warrants to Purchase Up to 4,237,288 Shares of Common Stock

or

Up to 4,237,288 Pre-Funded Warrants to Purchase Up to 4,237,288 Shares of Common Stock and accompanying Warrants to Purchase Up to 4,237,288 Shares of Common Stock

Up to 296,610 Placement Agent Warrants to Purchase Up to 296,610 Shares of Common Stock

Up to 4,533,898 Shares of Common Stock Issuable Upon Exercise of the Warrants, Pre-Funded Warrants and Placement Agent Warrants

SeaStar Medical Holding Corporation

We are offering up to 4,237,288 shares of common stock, par value $0.0001 per share (the "Common Stock"), together with warrants to purchase up to shares of common stock (the "Warrants"), pursuant to this prospectus. The assumed combined public offering price for each share of Common Stock, together with an accompanying Warrant to purchase one share of Common Stock, is $1.18, which is equal to the last reported sale price of our Common Stock on The Nasdaq Capital Market on June 13, 2025. The shares of Common Stock and Warrants will be separately issued, but the shares of Common Stock and Warrants will be issued to purchasers in the ratio of one to one. Each Warrant will have an exercise price of $1.18 per share, will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (the "Warrant Stockholder Approval"), provided however, if the Pricing Conditions (as defined below) are met, the Warrant Stockholder Approval will not be required and the Warrants will be exercisable upon issuance (the "Initial Exercise Date"). The Warrants will expire on the anniversary of the Initial Exercise Date. As used herein "Pricing Conditions" means that the combined public offering price per share and accompanying Warrant is such that the Warrant Stockholder Approval is not required under the rules of The Nasdaq Stock Market LLC ("Nasdaq") because either (i) the offering is an at-the-market offering under Nasdaq rules and such price equals or exceeds the sum of (a) the applicable "Minimum Price" per share under Nasdaq Rule 5635(d) plus (b) $0.125 per whole share of Common Stock underlying the Warrants or (ii) the offering is a discounted public offering where the pricing and discount (including attributing a value of $0.125 per whole share of Common Stock underlying the Warrants) meet the pricing requirements under Nasdaq's rules.

We are also offering up to 4,237,288 pre-funded warrants (the "Pre-Funded Warrants") to those purchasers whose purchase of shares of Common Stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering in lieu of the shares of our Common Stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Pre-Funded Warrant will be exercisable for one share of Common Stock at an exercise price of $0.001 per share. Each Pre-Funded Warrant is being issued together with the same Warrants described above being issued with each share of Common Stock. The assumed combined public offering price for each such Pre-Funded Warrant, together with an accompanying Warrant to purchase one share of Common Stock, is $1.1799, which is equal to the last reported sale price of our Common Stock on The Nasdaq Capital Market on June 13, 2025, minus $0.0001, the exercise price of the Pre-Funded Warrants. Each Pre-Funded Warrant will be exercisable upon issuance and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Pre-Funded Warrants and accompanying Warrants are immediately separable and will be issued separately in this offering, but the Pre-Funded Warrants and Warrants will be issued to purchasers in the ratio of one to one. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants, Pre-Funded Warrants and Placement Agent Warrants (as defined herein). For each Pre-Funded Warrant sold, the number of shares of Common Stock sold will be reduced on a one-for-one basis.

There is no established public trading market for the Warrants or the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Warrants or the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants and the Pre-Funded Warrants will be limited.

This offering will terminate on , 2025, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share of Common Stock (or Pre-Funded Warrant in lieu thereof) and accompanying Warrants will be fixed for the duration of this offering.

We have engaged (the "Placement Agent"), to act as our exclusive placement agent in connection with this offering. The Placement Agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The Placement Agent is not purchasing or selling any of the securities we are offering and the Placement Agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the Placement Agent the Placement Agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no minimum number of securities or amount of proceeds required as a condition to closing in this offering. In addition, because there is no escrow trust or similar arrangement and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. We will bear all costs associated with the offering. See "Plan of Distribution" on page 42 of this prospectus for more information regarding these arrangements.

The assumed combined offering price used throughout this prospectus has been included for illustration purposes only, and may not be indicative of the final offering price. The actual combined public offering price per share of Common Stock and accompanying Warrant and the combined public offering price per Pre-Funded Warrant and accompanying Warrant we are offering and the exercise price and other terms of the Warrants will be negotiated between us and the purchasers, in consultation with the Placement Agent based on the trading of our Common Stock prior to this offering, among other factors. Other factors considered in determining the offering price of the securities we are offering and the exercise price and other terms of the Warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant. The combined public offering price per share of Common Stock and accompanying Warrant and the combined public offering price per Pre-Funded Warrant and accompanying Warrant may be at a discount to the current market price of our Common Stock. Therefore, the recent market price used throughout this prospectus may differ substantially from the combined public offering price.

You should read this prospectus, together with additional information described under the heading "Where You Can Find More Information" carefully before you invest in any of our securities.

	Per Share and Accompanying Warrant	Per Pre-Funded Warrant and Accompanying Warrant	Total
Combined public offering price			
Placement Agent fees(1)			
Proceeds to us, before expenses(2)			

(1) Represents a cash fee equal to % of the aggregate gross proceeds raised in this offering. In addition, we have also agreed to pay the Placement Agent a management fee equal to % of the aggregate gross proceeds raised in this offering and to reimburse the Placement Agent for its non-accountable expenses in the amount of $, for its legal fees and expenses and other out-of-pocket expenses in an amount of $, and for its clearing expenses in the amount of $. In addition, we have agreed to issue to the Placement Agent, or its designees, warrants (the "Placement Agent Warrants") as compensation in connection with this offering to purchase a number of shares of our Common Stock equal to % of the aggregate number of shares of Common Stock and Pre-Funded Warrants being offered at an exercise price equal to % of the combined public offering price per share of Common Stock and accompanying Warrant. See "Plan of Distribution" for a description of the compensation to be received by the Placement Agent.

(2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual offering amount, Placement Agent fees, estimated expenses and net proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. The amount of the proceeds to us presented in this table does not give effect to any exercise of the Warrants or Placement Agent Warrants offered hereby.

We are a “smaller reporting company” under the federal securities laws and, as such, are subject to reduced public company reporting requirements. See “Implications of Being a Smaller Reporting Company.”

We are an “emerging growth company” under the federal securities laws and, as such, are subject to reduced public company reporting requirements. See “Implications of Being an Emerging Growth Company.”

Our Common Stock and warrants exercisable for one share of Common Stock for $11.50 per share (the “Listed Warrants”) are traded on the Nasdaq Stock Market under the symbols “ICU” and “ICUCW,” respectively. On May 20, 2025, the closing price of our Common Stock was $1.285 per share, and the closing price of our Listed Warrants, was $0.0329 per warrant.

On June 7, 2024, we effected a 1-for-25 reverse stock split of the Common Stock (the “Reverse Split”) of our issued and outstanding shares of Common Stock, and our shares of Common Stock began trading on a split-adjusted basis on the Nasdaq Capital Market on June 10, 2024 under the same symbol “ICU”. All of our stock options and warrants outstanding immediately prior to the Reverse Split were proportionally adjusted except for the Listed Warrants and the private placement warrants that were issued as part of the SPAC transaction, which total 16,788,000 outstanding warrants in the aggregate (the “Unadjusted Warrants”). The Unadjusted Warrants retain an $11.50 exercise price each and require the exercise of 25 warrants to purchase one share of Common Stock. Unless otherwise indicated, all other share and per share prices in this prospectus have been adjusted to reflect the Reverse Split.

On June 24, 2024, we received a written notification from the Listing Qualifications staff of Nasdaq that we were not in compliance with the requirement to maintain a minimum market value of listed securities of $35 million (the “MVLS Requirement”), as set forth in Nasdaq Listing Rule 5550(b)(2) (the “MVLS Rule”), because the market value of our listed securities (the “Securities”) had been below $35 million for 30 consecutive business days. We had an initial 180 days, or until December 23, 2024, to regain compliance with the MVLS Requirement.

On December 24, 2024, we received written notification (the “Notification”) from Nasdaq stating that we had not regained compliance with the MVLS Requirement. Pursuant to the Notification, the Securities were subject to delisting from Nasdaq on January 3, 2025, unless we requested a hearing before the Nasdaq Hearings Panel (the “Panel”) by December 31, 2024.

On March 11, 2025, we received a decision letter (the “Letter”) from the Panel, granting our request to continue its listing on Nasdaq, subject to certain conditions. The Panel’s decision provides us with an exception until June 22, 2025, to demonstrate compliance with the MVLS Requirement.

Investing in our securities involves a high degree of risk. You should read “Risk Factors” beginning on page 6 of this prospectus, and under similar headings in the documents incorporated by reference in this prospectus, as well as in any amendments or supplements to this prospectus, to read about factors to consider before purchasing our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Delivery of the securities to the purchasers is expected to be made on or about , 2025, subject to the satisfaction of customary closing conditions.

The date of this prospectus is , 2025.

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ABOUT THIS PROSPECTUS

We have not, and the Placement Agent has not, authorized anyone to provide you with information different from that contained in this prospectus or any accompanying prospectus supplement or free writing prospectus, and neither we nor the Placement Agent take any responsibility for any other information that others may give you. We and the Placement Agent are offering to sell these securities and seeking offers to buy these securities only in jurisdictions where offers and sales are permitted. This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate.

You should not assume that the information contained in this prospectus or any prospectus supplement or free writing prospectus is accurate as of any date other than the date on the front cover of those documents, regardless of the time of delivery of this prospectus or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

This prospectus relates to the offering of our Common Stock. Before buying any of our Common Stock, you should carefully read this prospectus, any supplement to this prospectus, and the additional information under the heading "Where You Can Find More Information." These documents contain important information that you should consider when making your investment decision. Unless the context indicates otherwise, references to the "Company," "we," "us" and "our" refer to the business of SeaStar Medical Holding Corporation, a Delaware corporation, and its consolidated subsidiaries following the Business Combination. "LMAO" refers to LMF Acquisition Opportunities, Inc. prior to the Business Combination.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Exchange Act of 1934, as amended (the "Exchange Act"). These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in the sections titled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Any statements in this prospectus about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. Within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, these forward-looking statements may include, but are not limited to, statements regarding:

- our future capital requirements and sources and uses of cash;
- our ability to obtain funding or raise capital for our operations and future growth;
- any delays or challenges in obtaining U.S. Food and Drug Administration approval of our SCD product candidates;
- economic downturns and the possibility of rapid change in the highly competitive industry in which we operate;
- the ability to develop and commercialize our products or services following regulatory approval of our product candidates;
- the failure of third-party suppliers and manufacturers to fully and timely meet their obligations;
- product liability or regulatory lawsuits or proceedings relating to our products and services;
- inability to secure or protect our intellectual property;
- dispute or deterioration of relationship with our major partners and collaborators;
- the ability to maintain the listing of our Common Stock on the Nasdaq Capital Market;
- the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition, and the ability to grow and manage growth profitably; and
- other risks and uncertainties indicated in this prospectus, including those under "Risk Factors" herein, and other filings that have been made or will be made with the SEC.

In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expects," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "will," "would" or the negative or plural of those terms, and similar expressions intended to identify statements about the future, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that may be important to you. To understand this offering fully, you should read this entire prospectus and, the registration statement of which this prospectus is a part carefully, including the information set forth under the heading "Risk Factors" and our financial statements.

Business Summary

Company Overview

We are a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. Our Selective Cytopheretic Device ("SCD"), is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body. It has broad potential applications for patients suffering from both acute and chronic kidney disease as well as cardiovascular and other serious inflammatory diseases.

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

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

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

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

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

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

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

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 150 patients reduced mortality rates by 50%, and, of those patients who survive 60 days, none have required dialysis.

On October 28, 2022, we completed a business combination with LMAO, pursuant to that certain Agreement and Plan of Merger, dated as of April 21, 2022 (the "Merger Agreement"), by and among LMAO, LMF Merger Sub, Inc., a Delaware corporation and direct wholly owned subsidiary of LMAO ("Merger Sub"), and SeaStar Medical, Inc., a Delaware corporation ("SeaStar Medical, Inc."). As contemplated by the Merger Agreement, SeaStar Medical, Inc. merged with and into Merger Sub, with SeaStar Medical, Inc. continuing as the surviving entity in the merger as a wholly owned subsidiary of LMAO (the "Business Combination"). In connection with the closing of the Business Combination, LMAO changed its name to "SeaStar Medical Holding Corporation."

Corporate Information

Our principal executive offices are located at 3513 Brighton Boulevard, Suite 410, Denver, Colorado 80216, and our phone number is 844-427-8100.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company," meaning that the market value of our Common Stock held by non-affiliates is less than $250.0 million measured on the last business day of our most recent second fiscal quarter or our annual revenue was less than $100.0 million during the most recent completed fiscal year and the market value of our Common Stock held by non-affiliates was less than $700.0 million measured on the last business day of our most recent second fiscal quarter. Accordingly, we may provide less public disclosure than larger public companies, including the inclusion of only two years of audited financial statements and only two years of management's discussion and analysis of financial condition and results of operations disclosure. As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not applicable to emerging growth companies. These exemptions include:

- reduced disclosure about our executive compensation arrangements;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of reduced reporting requirements in this prospectus and may continue to do so until such time that we are no longer an emerging growth company. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (b) the last day of our first fiscal year following the fifth anniversary of the closing of the Business Combination, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards.

Recent Developments

Nasdaq Listing

On June 24, 2024, we received a written notification from the Listing Qualifications staff of Nasdaq that we were not in compliance with the requirement to maintain a minimum market value of listed securities of $35 million, as set forth in the MVLS Rule, because the market value of our listed securities had been below $35 million for 30 consecutive business days. We had an initial 180 days, or until December 23, 2024, to regain compliance with the MVLS Requirement.

On December 24, 2024, we received the Notification from Nasdaq stating that we had not regained compliance with the MVLS Requirement. Pursuant to the Notification, the Securities were subject to delisting from Nasdaq on January 3, 2025, unless we requested a hearing before the Panel by December 31, 2024.

On March 11, 2025, we received the Letter from the Panel, granting our request to continue its listing on Nasdaq, subject to certain conditions. The Panel's decision provides us with an exception until June 22, 2025, to demonstrate compliance with the MVLS Requirement.

Bonus Release Agreements

On June 6, 2025, in order to support us in our efforts to reduce liabilities, and pursuant to confidential bonus release agreements, our Chief Executive Officer, Mr. Eric Schlorff, and our Chief Medical Officer, Dr. Kevin Chung, each agreed to waive receipt of their earned bonuses for our 2023 and 2024 fiscal years, otherwise payable and earned under each of their employment agreements.

THE OFFERING

Securities we are offering	Up to 4,237,288 shares of Common Stock and accompanying Warrants to purchase up to 4,237,288 shares of Common Stock, or Pre-Funded Warrants to purchase up to 4,237,288 shares of Common Stock and accompanying Warrants to purchase shares up to 4,237,288 shares of Common Stock. The shares of Common Stock, or Pre-Funded Warrants, and in each case the accompanying Warrants will be separately transferable immediately upon issuance, but the shares of Common Stock, or Pre-Funded Warrants, and in each case the accompanying Warrants will be issued to purchasers in the ratio of one to one. There is no established trading market for the Warrants or the Pre-Funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants or the Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Warrants and Pre-Funded Warrants will be limited.
Description of Warrants:	Each Warrant is exercisable for one share of Common Stock, will have an exercise price of $1.18 per share, and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon the Initial Exercise Date. The Warrants will expire on the anniversary of the Initial Exercise Date. To better understand the terms of the Warrants, you should carefully read the "Description of Securities We Are Offering" section of this prospectus. You should also read the forms of Warrants, which will be filed as exhibits to the registration statement that includes this prospectus. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants.
Description of Pre-Funded Warrants:	If the issuance of shares of our Common Stock to a purchaser in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering, then such purchaser may purchase, if they so choose, in lieu of the shares of our Common Stock that would result in such excess ownership, a Pre-Funded Warrant to purchase shares of our Common Stock for a purchase price per share of Common Stock subject to such Pre-Funded Warrant equal to the per share combined public offering price for the Common Stock to be sold in this offering less $0.0001. Each Pre-Funded Warrant will have an exercise price of $0.0001 per share, will be exercisable upon issuance and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. Purchasers of Pre-Funded Warrants will also receive accompanying Warrants as if such purchasers were buying shares of our Common Stock in this offering. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of these Pre-Funded Warrants. To better understand the terms of the Pre-Funded Warrants, you should carefully read the "Description of Securities We Are Offering" section of this prospectus. You should also read the form of Pre-Funded Warrant, which will be filed as an exhibit to the registration statement that includes this prospectus.
Description of Placement Agent Warrants	We have also agreed to issue to the Placement Agent or its designees as compensation in connection with this offering, the Placement Agent Warrants to purchase up to 296,610 shares of Common Stock. The Placement Agent Warrants will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, such Placement Agent Warrants will be exercisable upon issuance and will have substantially the same terms as the Warrants, except that the Placement Agent Warrants will have an exercise price of $1.475 per share (representing 125% of the combined public offering price per share of Common Stock and accompanying Warrants) and a termination date that will be 5 years from the commencement of the sales pursuant to this offering. See "Plan of Distribution" below. To better understand the terms of the Placement Agent Warrants, you should carefully read the descriptions of the Placement Agent Warrants in the "Description of Securities We Are Offering" and "Plan of Distribution" sections of this prospectus. You should also read the form of Placement Agent Warrant, which will be filed as an exhibit to the registration

statement that includes this prospectus. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Placement Agent Warrant.

Common Stock outstanding immediately prior to this offering	11,203,752 shares of Common Stock
Common Stock to be outstanding after this offering	15,441,040 shares of Common Stock, assuming no sale of Pre-Funded Warrants in this offering and no exercise of the Warrants or Placement Agent Warrants being issued in this offering and an assumed combined public offering price of $1.24 per share and accompanying Warrant, which is equal to the last reported sale price per share of our common stock on The Nasdaq Capital Market on June 12, 2025.
Use of proceeds	We estimate that the net proceeds of this offering based upon an assumed combined public offering price of $1.18 per share of Common Stock and accompanying Warrants, which was the closing price of our Common Stock on Nasdaq on June 13, 2025, after deducting Placement Agent fees and estimated offering expenses, will be approximately $ million, assuming no sale of the Pre-Funded Warrants offered hereby and no exercise of the Warrants and Placement Agent Warrants. We currently intend to use the net proceeds from this offering for working capital, product candidate development activities and general corporate purposes. See "Use of Proceeds."
Lock Up Agreements	The Company and our directors and officers have agreed with the Placement Agent, subject to certain exceptions, not to sell, transfer or dispose of, directly or indirectly, any of our Common Stock or securities convertible into or exercisable or exchangeable for our Common Stock for a period of sixty (60) days after the closing of this offering. See "Plan of Distribution" for more information.
Risk Factors	Investment in our Common Stock involves a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus, as well as the other information included in this prospectus, for a discussion of risks you should carefully consider before investing in our Common Stock.
Nasdaq Capital Market symbol	Our Common Stock and Listed Warrants are listed for trading on Nasdaq under the symbols "ICU" and "ICUCW," respectively.

The number of shares of our Common Stock outstanding prior to and after this offering in the table above is based on 11,203,752 shares of our Common Stock outstanding as of June 12, 2025, and excludes (in each case as of June 12 , 2025):

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- 21,931 shares of Common Stock issuable upon the exercise of stock options, with a weighted-average exercise price of $45.32 per share;
- 321,750 shares of Common Stock issuable upon the settlement of outstanding restricted stock units;
- 6,136,300 shares of Common Stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of $36.64 per share; and
- 147,751 additional shares of Common Stock reserved for future issuance under our 2022 Omnibus Equity Incentive Plan.

RISK FACTORS

An investment in our Common Stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below. The impacts of the contingencies contemplated by these risks could materially adversely affect our business, financial condition or results of operations. The risks described in these documents are not the only ones we face, but those that we consider to be material. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and financial condition. Please also read carefully the section titled "Cautionary Note Regarding Forward-Looking Statements," where we describe additional uncertainties associated with our business and the forward-looking statements included in this prospectus.

Risk Factor Summary

- You will experience immediate dilution in the book value per share of the Common Stock purchased in the offering.
- If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.
- A substantial number of shares of Common Stock may be sold in the market following this offering, which may depress the market price for our Common Stock.
- We have broad discretion to determine how to use the funds raised in this offering, which may not enhance our operating results or the price of our Common Stock.
- The holders of Warrants and Pre-Funded Warrants purchased in this offering will have no rights as common stockholders until such warrants' exercise, except as set forth in the Warrants and Pre-Funded Warrants.
- The Warrants and Pre-Funded Warrants are speculative in nature.
- This is a reasonable best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required to continue our operations.
- We have not generated revenue sufficient for positive operating cash flows, have incurred significant losses since our inception and may continue to incur significant losses for the foreseeable future.
- There is substantial doubt about our ability to continue as a going concern and if we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development program.
- We have a limited operating history.
- We may not be able to use our net operating losses to offset future taxable income.
- We may face challenges in obtaining additional FDA approvals to market our product.
- The United States could change tariff, trade, or tax provisions related to the manufacturing and sales of our products in ways that we currently cannot predict.
- We may not be able to manage our growth effectively.
- Changing priorities within the U.S. government resulting in the loss of government grant funding could adversely impact our future growth plans.
- We will initially depend on revenue generated from a single product.

- We may fail to comply with extensive regulations of United States and foreign regulatory agencies.
- Delays in successfully completing our clinical trials could jeopardize our ability to obtain regulatory approval.
- We have limited experience with large-scale contracts with medical device manufacturers.
- We face intense competition in the medical device industry and our SCD technology may become obsolete.
- We outsource many of our operational and development activities for which we may not have full control.
- A lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.
- Adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our products.
- We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.
- United States legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.
- We are subject to stringent and changing privacy laws, regulations and standards
- Our business operations will be adversely affected if our security measures, or those maintained on our behalf, are compromised, limited or fails.
- We depend on key personnel and our inability to attract and retain qualified personnel could impede our ability to achieve our business objectives.
- Our estimates of market opportunity, industry projections and forecasts of operating and financial results and market growth may prove to be inaccurate.
- We rely upon exclusively licensed patent rights from third parties which are subject to termination or expiration.
- If we are unable to obtain and maintain sufficient patent protection for our products, our ability to commercialize such products successfully may be adversely affected.
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be adversely and materially affected, and our business could be harmed.
- The United States government may exercise certain rights with regard to our inventions, or licensors' inventions, developed using federal government funding.
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
- Our Common Stock may be delisted from Nasdaq if we do not maintain compliance with Nasdaq's continued listing requirements. If our Common Stock is delisted, it could negatively impact us.
- The trading price of our Common Stock has been volatile and is likely to be volatile in the future.
- 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.

Risks Related to this Offering

This offering is being made on a reasonable best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering, which will provide us only limited working capital.

This offering is being made on a reasonable best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering. Assuming that we receive net proceeds of approximately $ million from this offering (assuming an offering with gross proceeds of $3.0 million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will meet our capital needs for the next months under our current business plan. Assuming that we receive net proceeds of approximately $ million from this offering (assuming an offering with gross proceeds of $4.0 million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will satisfy our capital needs for the next months under our current business plan. Assuming that we receive net proceeds of approximately $ million from this offering (assuming an offering with gross proceeds of $5.0 million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will satisfy our capital needs for the next months under our current business plan. Without giving effect to the receipt of any proceeds from this offering, we currently estimate that our existing cash and cash equivalents are sufficient to fund business operations into .

You will experience immediate dilution in the net tangible book value per share of the Common Stock purchased in the offering.

Since the effective public offering price of our Common Stock in this offering is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding Common Stock outstanding prior to this offering, you will suffer dilution in the book value of the Common Stock you purchase in this offering. After giving effect to the sale of our Common Stock in the aggregate offering amount of $5.0 million at an assumed effective offering price of $1.18 per share of Common Stock (the last reported sale price of our Common Stock on The Nasdaq Capital Market on June 13, 2025), assuming no sale of any Pre-Funded Warrants offered hereby, no exercise of the Warrants or the Placement Agent Warrants, and after deducting the Placement Agent's fees and estimated offering expenses payable by us, you would suffer immediate dilution of $ per share in the pro forma as adjusted net tangible book value of the Common Stock. See "Dilution" for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

We will likely offer and issue additional shares of our Common Stock or other equity or convertible debt securities in order to raise additional capital. Future equity offerings or other equity issuances may be at a price per share that is less than the price per share paid by investors in this offering. Future investors in such offerings may have rights superior to existing stockholders, and the price per share at which we sell additional shares of Common Stock or other equity or convertible debt securities in future transactions may be at a higher or lower price per share than the price per share in this offering.

A substantial number of shares of Common Stock may be sold in the market following this offering, which may depress the market price for our Common Stock.

The securities offered hereby will be freely tradable without restriction or further registration under the Securities Act. Sales of a substantial number of shares of our Common Stock in the public market following this offering, or the perception that such sales could occur, could cause the market price of our Common Stock to decline.

We have broad discretion to determine how to use the funds raised in this offering and may use them in ways that may not enhance our operating results or the price of our Common Stock.

Our management will have broad discretion over the use of net proceeds from this offering, and we could spend the net proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from this offering for general corporate purposes. However, our use of these net proceeds may differ substantially from our current plans. If we do not invest or apply the net proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline. See "Use of Proceeds" for further information on the anticipated use of proceeds.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may limit a stockholder's ability to buy and sell our securities.

Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that "a broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer." This is a significantly higher standard for broker-dealers to recommend securities to retail customers than before under FINRA "suitability rules." FINRA suitability rules do still apply to institutional investors and require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information, and for retail customers determine the investment is in the customer's "best interest" and meet other SEC requirements. Both SEC Regulation Best Interest and FINRA's suitability requirements may make it more difficult for broker-dealers to recommend that their customers buy speculative, low-priced securities. They may affect investing in our Common Stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker-dealers may be willing to make a market in our Common Stock, reducing a stockholder's ability to resell our Common Stock.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including, but not limited to: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for sixty days from closing, subject to certain exceptions; (iii) agreement to not enter into any financings for sixty days from closing, subject to certain exceptions; and (iv) indemnification for breach of contract.

There is no public market for the Warrants and Pre-Funded Warrants being offered in this offering.

There is no established public trading market for the Warrants and Pre-Funded Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or Pre-Funded Warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the Warrants or Pre-Funded Warrants will be limited.

The holders of Warrants and Pre-Funded Warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Warrants or Pre-Funded Warrants and acquire shares of our Common Stock, except as set forth in the Warrants and Pre-Funded Warrants.

Until a holder of Warrants and Pre-Funded Warrants acquires the shares of Common Stock upon exercise of the Warrants and Pre-Funded Warrants, as the case may be, such holder will have no rights with respect to the shares of Common Stock underlying such Warrants and Pre-Funded Warrants, except as set forth in the Warrants and Pre-Funded Warrants. Upon exercise of the Warrants and Pre-Funded Warrants, holders will be entitled to exercise the rights of common stockholders only as to matters for which the record date occurs after the exercise date.

The Warrants and Pre-Funded Warrants are speculative in nature.

The Warrants and Pre-Funded Warrants do not confer any rights of Common Stock ownership on their holders, such as voting rights, but rather merely represent the right to acquire shares of Common Stock at a fixed price for a limited period of time. There can be no assurance that the market price of the Common Stock will ever equal or exceed the exercise price of the Warrants, and consequently, it may not ever be profitable for holders of the Warrants to exercise the Warrants.

This is a reasonable best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required to continue our operations.

The Placement Agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations.

Terms of subsequent financings may adversely impact holders of our securities.

In order to finance our future production plans and working capital needs, we may have to raise funds through the issuance of equity or debt securities. Depending on the type and the terms of any financing we pursue, holders of our securities' rights and the value of their investment in our Common Stock could be reduced. A financing could involve one or more types of securities including Common Stock, convertible debt or warrants to acquire Common Stock. These securities could be issued at or below the then prevailing market price for our Common Stock. We currently have no authorized preferred stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be senior to the rights of holders of our other securities until the debt is paid. Interest on these debt securities would increase financing and interest costs and could negatively our impact our operating results. If the issuance of new securities results in diminished rights to holders of our Common Stock, the market price of our Common Stock could be negatively impacted.

The sale of our Common Stock in ATM offerings may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our Common Stock to decline.

We have used at-the-market, or ATM, offerings to fund a significant portion of our operations in prior years, and we may continue to use ATM offerings to raise additional capital in the future. For example, in 2024, we sold an aggregate of approximately 1.78 million shares of our Common Stock for net proceeds of approximately $4.5 million under our At-the-Market offering program. While sales of shares of our Common Stock in ATM offerings may enable us to raise capital at a lower cost compared with other types of equity financing transactions; such sales may result in dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our Common Stock to decline.

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

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 downgrade our stock or change their opinions of our stock, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

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

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

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

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

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

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

We are an "emerging growth company" as that term is used in the 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 non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved, and exemptions from any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements. 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.

Risks Relating to Our Financial Condition

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

We have incurred significant net losses since our inception and had an accumulated deficit of $143.3 million and $139.6 million as of March 31, 2025 and December 31, 2024, respectively.

We have devoted most of our financial resources to research and development, including clinical trials and non-clinical development activities, and obtaining regulatory approval of our SCD product candidates. Since the completion of the Business Combination, we relied primarily on the sales of securities to fund our operations and are limited as we need to meet certain conditions before such funding becomes available. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. If our product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, it will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenues are also dependent upon the size of the markets outside of the United States, regulatory approval outside of the United States, and our ability to obtain market approval and achieve commercial success.

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

We have not generated any significant revenue and may never be profitable.

Our ability to generate sustainable revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully commercialize our approved pediatric SCD and complete the development, obtain the necessary regulatory approvals of and commercialize our adult SCD. We do not anticipate generating substantial revenue for the foreseeable future. Our ability to generate meaningful future revenue from product sales depends heavily on our success with the following items:

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

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

Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. In the case of our SCD product candidate for the treatment of pediatric AKI, we will be limited in our ability to sell and distribute our 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 us. Even if we successfully expand sales of our products, we may not become profitable and may need to obtain additional funding to continue operations.

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 us.

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

Developing medical device products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we advance our clinical programs. As of March 31, 2025 and December 31, 2024, we had negative working capital of $0.2 million and $3.0 million, respectively. We currently do not have sufficient capital to support our operations and complete our planned regulatory approval process. We will need to secure additional capital to continue our operations, and such funding may not be available on acceptable terms, or at all.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed in its auditors' report on our 2024 financial statements, included in our Annual Report on Form 10-K filed on March 27, 2025, an emphasis of matter paragraph relating to our ability to continue as a "going concern," meaning that our recurring losses from operations and negative cash flows from operations raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty, with the exception that all borrowings are classified as current on the balance sheets.

Even if we receive sufficient capital in the future, we will be required to raise additional funds to support our operations and complete our planned regulatory approval process, and such funding may not be available in sufficient amounts or on acceptable terms to us, or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

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

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

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

In the event we seek to pursue a restructuring, or if we file for relief under the United States Bankruptcy Code, either Chapter 7, Chapter 11 or other proceedings, our operations, our ability to develop and execute our business plan and our continuation as a going concern will be subject to the risks and uncertainties associated with bankruptcy proceedings, including, among others: our ability to execute, confirm and consummate a plan of reorganization; the high costs of bankruptcy proceedings and related fees; our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post-emergence, and our ability to comply with terms and conditions of that financing; our ability to continue our operations in the ordinary course; our ability to maintain our relationships with our customers, business partners, counterparties, employees and other third parties; our ability to obtain, maintain or renew contracts that are critical to our operations on reasonably acceptable terms and conditions; our ability to attract, motivate and retain key employees; the ability of third parties to use certain limited safe harbor provisions to terminate contracts; and the actions and decisions of our stakeholders and other third parties who have interests in our proceedings that may be inconsistent with our operational and strategic plans. Any delays in our proceedings would increase the risks of our being unable to reorganize our business and emerge from any such proceedings and may increase our costs associated with the process or result in prolonged operational disruption for us. Also, we would need the prior approval of a court for transactions outside the ordinary course of business during the course of any such proceedings, which may limit our ability to respond timely to certain events or take advantage of certain opportunities. Because of the risks and uncertainties associated with any such proceedings, we cannot accurately predict or quantify the ultimate impact of events that could occur during any such proceedings. There can be no guarantees that if we seek available protections, we will emerge from protection as a going concern or that holders of our common stock will receive any recovery

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

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

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

As of December 31, 2024, we had net operating loss (“NOL”) carryforwards for federal and state income tax purposes of $108.2 million and $36.3 million, respectively, which may be available to offset taxable income in the future. Under the Tax Cuts and Jobs Act of 2017, as modified by the Coronavirus Aid, Relief, and Economic Security Act, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80 percent of taxable income. Federal NOLs incurred before 2018 may be carried forward 20 years but are not subject to the taxable income limitation. Under current law, California NOLs generally may be carried forward 20 years (with a limited extension for California NOLs incurred in 2020-2021) without a taxable income limitation. Our federal NOLs include $55.6 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 our 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. We may experience a future ownership change under Section 382 of the Code that could affect our ability to utilize the NOLs to offset our income. We have not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of NOL and research tax credit carryforwards available to offset future taxable income and income tax liabilities in future years may be significantly restricted or eliminated. Further, deferred tax assets associated with such NOLs, and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to legislative or regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our business, results of operations and financial condition.

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

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

In addition, on July 5, 2024, Forrest A K Wells (the "Plaintiff"), a purported stockholder of ours, filed a putative class action complaint in the United States District Court for the State of Colorado (the "Class Action"), alleging that we and our management members made material misstatements or omissions regarding our business and operations, including disclosures relating to FDA approval of our product candidates, allegedly culminating in the restatement of our consolidated financial statements as disclosed in the Form 8-K filed on March 27, 2024. The Class Action asserts claims under Section 10(b) of the Exchange Act against us, our Chief Executive Officer and former Chief Financial Officer (collectively, the "Defendants"), as well as claims under Section 20(a) of the Exchange Act against the Defendants. Among other remedies, the Class Action seeks to recover compensatory and other damages. On March 4, 2025, the Plaintiff filed an amended complaint. We intend to vigorously defend the action.

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

Such lawsuits, and other such lawsuits in the future, could divert our management's attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). In connection with these lawsuits, we may be required to pay material damages, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions, or issue additional shares upon the exercise of certain warrants, which may cause additional dilution. In addition, any such future lawsuits could adversely impact our reputation and/or ability to launch and commercialize our products, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters and any future matters could have a material adverse effect on our business, financial condition, results of operations and cash flow and, consequently, could negatively impact the trading price of our Common Stock.

Risks Related to Our Business Operations

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

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

On November 6, 2024, we received BDD for our patented and cell-directed SCD to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic hemodialysis, also known as chronic dialysis. While we expect the BDD to expedite the clinical development and regulatory review of the SCD program for use in this patient population, there is no guarantee that we will be able to expedite the clinical development or obtain regulatory approval.

While we recently obtained approval from the FDA to conduct the AKI adult pivotal trial for SCD, there is no guarantee that we 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 we are able to generate positive results from this trial, the FDA and other regulatory agencies may require us to conduct additional trials to support the study or disagree with the design of the trial and request changes or improvements to such design. We are also subject to numerous other risks relating to the regulatory approval process, which include but are not limited to:

- an inability to secure and obtain support and references from collaborators and suppliers required by the FDA;
- a disagreement with the FDA regarding the design of the trial, including the number of clinical study subjects and other data, which may require us to conduct additional testing or increase the size and complexity of our pivotal study;
- a failure to obtain a sufficient supply of cartridges to conduct our 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 we obtain 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 our future products could prevent us 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 us, could dissuade some physicians from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

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

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

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

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

Our business benefits from free trade agreements, and we also rely on various U.S. corporate tax provisions related to international commerce as we develop, market and sell our products within the U.S. and globally. The U.S. presidential administration has instituted or proposed changes in trade policies that include the imposition of higher tariffs on imports into the U.S., economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the U.S. and other countries where we conduct business. The new tariffs and other changes in U.S. trade policy could trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing trade sanctions on certain U.S. goods. The U.S. presidential administration has indicated a focus on policy reforms that discourage corporations from outsourcing manufacturing and production activities to foreign jurisdictions, including through tariffs or penalties on goods manufactured outside the U.S., which may require us to change the way we conduct business. These changes in U.S. and foreign laws and policies have the potential to adversely impact the U.S. economy or certain sectors thereof, our industry and the demand for our products, and as a result, could have a material adverse effect on our business, financial condition and results of operations. As of March 27, 2025, we do not import materials from Canada or China, but we do source tubing sets from Medtronic that is manufactured in Mexico. Tariffs and other trade restrictions could adversely affect our ability to obtain such materials on a timely basis or cause such components to become more expensive, which could adversely affect our business.

Proposed legislation in the U.S. Congress, including changes in U.S. tax law, may adversely impact us and the value of our shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares.

Changes to U.S. tax laws (which changes may have retroactive application) could adversely affect us or holders of our shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares. In recent years, many changes to U.S. federal income tax laws have been proposed and made, and additional changes to U.S. federal income tax laws are likely to continue to occur in the future.

The U.S. Congress is currently considering numerous items of legislation which may be enacted prospectively or with retroactive effect, which legislation could adversely impact our financial performance and the value of our shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares. Additionally, states in which we operate or own assets may impose new or increased taxes. If enacted, most of the proposals would be effective for the current or later years. The proposed legislation remains subject to change, and its impact on us and purchasers of our shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares is uncertain

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

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

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

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

We 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.

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

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

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

- the FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied;
- the FDA may require additional testing for safety and effectiveness;
- the FDA may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them;

- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- the FDA may change its approval policies and/or adopt new regulations.
- Failure to comply with these or other regulatory requirements of the FDA may subject us to administrative or judicially imposed sanctions, 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 production.

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

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

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

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

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

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

We believe we have sufficient access to the SCD inventory to conduct our current and near future clinical trials and commercial needs, but it is possible that the need for our SCD could increase which may require us to acquire more cartridges than we are currently able to purchase under our agreement with our supplier, and we may not be able to negotiate a new supply agreement successfully. If we are unable to find alternative sources of supply in a timely manner, any such delay could limit our ability to meet demand for the SCD and delay our ongoing clinical trials or limit our sales of QUELIMMUNE, which would have a material adverse impact on our business, results of operations and financial condition.

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

We have limited experience in identifying and working with large-scale contracts with medical device manufacturers.

To achieve the levels of production necessary to commercialize our SCD and any other future products, we 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. We have limited experience coordinating and overseeing the manufacturing of medical device products on a large-scale. Manufacturing and control problems could arise as we attempt to commercialize our products and manufacturing may not be completed in a timely manner or at a commercially reasonable cost. In addition, we may not be able to adequately finance the manufacturing and distribution of our products on terms acceptable to us, if at all. If we cannot successfully oversee and finance the manufacturing of our products after receiving regulatory approval, we may not generate sufficient revenue to become profitable.

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

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

- the availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other supplier;

- our ability to comply with new regulatory requirements and cGMP;

- potential facility contamination by microorganisms or viruses;
- updating of our manufacturing specifications;
- product quality success rates and yields; and
- global viruses and pandemics.

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

Our SCD technology may become obsolete.

Our SCD product candidates may become obsolete prior to commercialization by new scientific or technological developments, or by others with new treatment modalities that are more efficacious and/or more economical than our products. Any one of our competitors could develop a more effective product which would render our technology obsolete. In addition, it is possible that competitors may use similar technologies, equipment or devices, including using certain "off-the-shelf" cartridges 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 our SCD product candidates to become obsolete. For example, the SCD relies on the existing footprint of CRRT pump systems in ICUs, as well as the growing use and adoption of regional citrate as an anticoagulant. Further developments in these areas could require us to reconfigure our SCD product candidates, which may not be commercially feasible, or cause them to become obsolete. Lastly, our ability to achieve significant and sustained growth in our key target markets will depend upon our success in hospital penetration, utilization, publication, our SCD's reimbursement status and medical education. Our products may not remain competitive with products based on new technologies. If we fail to sell products that satisfy our customers' demands or respond effectively to new product announcements by our competitors, then market acceptance of our products could be reduced and our business, results of operations and financial condition could be adversely affected.

We face intense competition in the medical device industry.

We compete with numerous United States and foreign companies in the medical device industry, and many of our competitors have greater financial, personnel, operational and research and development resources than us. We believe 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. Our commercial opportunities will be reduced or eliminated if our competitors develop and market products for any of the diseases we target that:

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

Even if we successfully develop the SCD and any other future products and obtain FDA and other regulatory approvals necessary for commercializing them, our products may not compete effectively with other products. Researchers are continually learning more about diseases, which may lead to new technologies for treatment. Our competitors may succeed in developing and marketing products that are either more effective than those that we may develop or that are marketed before any of our products. Our competitors include fully integrated pharmaceutical and medical device companies and biotechnology companies, universities, and public and private research institutions. Many of the organizations competing with us 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 our competitors develop more effective treatments for infectious disease or hyperinflammation or bring those treatments to market before we can commercialize the SCD for such uses, we may be unable to obtain any market traction for our products, or the diseases we seek to treat may be substantially addressed by competing treatments. If we are unable to successfully compete against larger companies in the pharmaceutical industry, we may never generate significant revenue or be profitable.

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

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

We outsource many of our operational and development activities for which we may not have full control.

We rely on third-party consultants, vendors and distributors to manage and implement much of the day-to-day responsibilities of conducting clinical trials and manufacturing and distribution of our current products and product candidates. Accordingly, we are and will continue to be dependent on the timeliness and effectiveness of the efforts of these third parties. Our dependence on third parties includes key suppliers and third-party service providers supporting the development, manufacturing, distribution and regulatory approval of our SCD, as well as support for our information technology systems and other infrastructure. While our management team oversees these vendors, the failure of any of these third parties to meet their contractual, regulatory, and other obligations, or the development of factors that materially disrupt the performance of these third parties, could have a material adverse effect on our business, results of operations and financial condition.

For example, in December 2022, we entered into the Distribution Agreement with 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. In the event of a material breach if such breach is not cured within ninety (90) days after written notice, we have the right to terminate the Distribution Agreement in accordance with the terms set forth in the Distribution Agreement. The Distribution Agreement with Nuwellis was terminated as of December 31, 2024.

A lack of third-party coverage and reimbursement for our 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 our products under development be approved for commercialization by the FDA, reimbursement may not be available in the United States or other countries or, even if approved, the amount of reimbursement may not be sufficient to allow sales of our future products, including the SCD, on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. These assessments are outside our control, and any such evaluations may not be conducted or have a favorable outcome.

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

Adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our 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. Additionally, executive orders have directed governmental agencies to review and reconsider policies that affect healthcare access and reimbursement, which could lead to further changes impacting our business.

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 our products from governmental payors. Furthermore, commercial payors such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products. Therefore, it is possible that our products or the procedures or patient care performed using our products will not be reimbursed at a cost-effective level.

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

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

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

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

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

We intend to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of our SCD or any future product candidates that we may develop, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We do not have the required financial and human resources to carry out on our own all the pre-clinical and clinical development for our SCD product candidate or any other or future product candidates that we may develop, and do not have the capability and resources to manufacture, market or sell our SCD product candidate or any future product candidates that we may develop. Our business model calls for the partial or full outsourcing of the clinical development, manufacturing, sales, and marketing of our product candidates in order to reduce our capital and infrastructure costs as a means of potentially improving our financial position. Our success will depend on the performance of these outsourced providers. If these providers fail to perform adequately, our development of product candidates may be delayed and any delay in the development of our product candidates may have a material and adverse effect on our business, results of operations and financial condition.

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

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

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

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

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

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

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

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

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

- increase our compliance and operational costs;
- expose us to regulatory scrutiny, actions, fines and penalties;
- result in reputational harm; interrupt or stop our clinical trials;
- result in litigation and liability; result in an inability to process personal data or to operate in certain jurisdictions; or
- harm our business operations or financial results or otherwise result in a material harm to our 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, we may be required to incur material costs, divert management attention, and change our business operations, including our clinical trials, in an effort to comply, which could materially adversely affect our 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 our business activities depending on how they are interpreted.

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

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in their design or manufacture. For the FDA, the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may, 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 our products would divert managerial and financial resources and have an adverse effect on our reputation, business, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands.

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

Our business is subject to risks arising from future pandemics.

Worldwide pandemics have presented substantial public health and economic challenges and has affected our 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 our SCD product candidate. We may experience disruptions that could severely impact our business, clinical trials, and manufacturing and supply chains, including:

- further delays or difficulties in enrolling patients in our 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 our 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 our product candidates from our 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 our 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 our 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 us to change the ways in which our 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 our ability to raise additional capital on a timely basis or at all.

The extent to which a future pandemic may impact our business, including our 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.

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

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

- whether we can obtain sufficient capital to develop and commercialize our SCD product candidate and grow our business;
- whether we can manage relationships with key suppliers;
- the ability to obtain necessary regulatory approvals;
- demand for our products;
- the timing and costs of new and existing marketing and promotional efforts;
- competition, including from established and future competitors;
- our ability to retain existing key management, to integrate recent hires and to attract, retain and motivate qualified personnel;
- the overall strength and stability of the economies in the markets in which 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 our control, could materially and adversely affect our business, results of operations and financial condition.

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

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

Risks Relating to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Grounds for a validity challenge could be an alleged failure to meet one or more statutory requirements for patentability, 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 we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention at issue. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those other parties and other competitors, which may curtail or preclude our ability to exclude third parties from selling similar products. Any of these occurrences could adversely and materially affect our business, results of operations and financial condition.

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

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

Although we believe that we have conducted our 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, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware of during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose some or all of the patent protection for one or more of our products. Such a loss of patent protection could have a material adverse impact on its business, results of operations and financial condition. Further, intellectual property litigation could lead to unfavorable publicity that could harm our reputation.

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

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

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

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

We have also entered into non-disclosure and confidentiality agreements with all of our employees, advisors, consultants, contract manufacturers, clinical investigators and other third parties involved in the development and commercialization of our technology in order to protect our intellectual property and other proprietary technologies some of which may not be amenable to patent protection. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. For example, trade secrets and confidential know-how can be difficult to maintain as confidential. Although we use reasonable efforts to protect our trade secrets, any party with whom we have executed a confidentiality agreement could breach that agreement and disclose our confidential information.

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

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

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

New technology may lead to our competitors developing superior products which would reduce demand for our products regardless of any patent protection we may have.

Research into technologies similar to our technologies is proceeding at a rapid pace, and companies and research institutions are actively engaged in the development of products similar to our products. These new technologies may, if successfully developed, offer significant performance or price advantages when compared with our technologies. Our existing patents or our 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 our inventions, or licensors' inventions, developed using federal government funding.

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

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

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

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

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

As is the case with other medical device companies, our 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 partes 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 us to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our 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 our ability to enforce our 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 our ability to obtain new patents or to enforce our existing and future patents.

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

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

- others may be able to make products that are the same as or similar to our products but that are not covered by the claims of patents that we own or have rights to;

- we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;

- we or our licensors or any future strategic partners might not have been the first to file patent applications covering the inventions in our patents or applications;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- our pending patent rights may not lead to issued patents, or the patents, if granted, may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- third parties manufacturing or testing our products or technologies could use the intellectual property of others without obtaining proper licenses;

- we may not develop additional technologies that are patentable; and

- third parties may allege that our development and commercialization of our products infringes their intellectual property rights, and the outcome of any related litigation may have an adverse effect on our business, results of operations and financial condition.

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

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

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Accordingly, we have not and in the future may not file for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant, or to not pay maintenance fees on granted patents in certain jurisdictions. 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 our technologies to develop their own products in jurisdictions where we have not obtained patent protection and, further, may export otherwise infringing products to territories where we have patent protection, but where patent enforcement is not as strong as that in the United States. These products may also compete with our products in jurisdictions where we do not have any issued or licensed patents or where our patent or other intellectual property rights are not effective or sufficient to prevent these products from competing with us.

Additionally, some countries do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights in these countries. 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 we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, results of operations and financial condition may be adversely affected. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection. Furthermore, they may export otherwise infringing products to jurisdictions where we have patent protection, if our ability to enforce our patents to stop the infringing activities in those jurisdictions is inadequate.

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

Risks Related to Being a Public Company

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

We are building experience operating as a United States public company, of which, our executive officers have limited experience in managing a United States public company, which makes their ability to comply with applicable laws, rules, and regulations uncertain. Our failure to comply with all laws, rules and regulations applicable to United States public companies could subject us and our management to regulatory scrutiny or sanction, which could harm our reputation and share price. Although we are developing and implementing governance, compliance, risk management and control framework and culture required for a public company, we may not be able to meet the requisite standards expected by the SEC and/or our investors. We 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, we incur significant legal, accounting, insurance, compliance, and other expenses. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. Compliance with reporting, internal control over financial reporting and corporate governance obligations may require members of our management and our finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled.

If we fail to adequately implement the required governance and control framework, we 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 our reputation, and cause the market price of our securities to decline. Other challenges in complying with these regulatory requirements may arise because we may not be able to complete our evaluation of compliance and any required remediation in a timely fashion. Furthermore, any current or future controls may be considered as inadequate due to changes or increased complexity in regulations, our operating environment or other reasons.

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

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

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

For example, on June 24, 2024, we received a written notification from the Listing Qualifications staff of Nasdaq that we were not in compliance with the requirement to maintain a minimum market value of listed securities of $35 million, as set forth in the MVLS Rule, because the market value of our Securities had been below $35 million for 30 consecutive business days. We had an initial 180 days, or until December 23, 2024, to regain compliance with the MVLS Requirement.

On December 24, 2024, we received the Notification from Nasdaq stating that we had not regained compliance with the Rule. Pursuant to the Notification, the Securities were subject to delisting from Nasdaq on January 3, 2025, unless we requested a hearing before the Panel by December 31, 2024.

We requested a hearing before the Panel by December 31, 2024. As disclosed to Form 8-K on March 13, 2025, on March 11, 2025, we received the "Letter from the Panel", granting our request to continue listing our Common Stock on Nasdaq, subject to certain conditions. The Panel's decision provides us with an exception until June 22, 2025, to demonstrate compliance with the MVLS Rule, which requires a Market Value of Listed Securities of at least $35 million. The Panel reviewed our compliance plan, which includes the continuation of fundraising efforts that began in 2024 and strategies for achieving long-term compliance with the MVLS Rule. As part of the conditions outlined in the Panel's decision, we are required to, on or before June 22, 2025:

- file a public disclosure describing the transactions undertaken to increase our equity and providing an indication of our equity following those transactions, and

- provide the Panel with an update on our fundraising plans and updated income projections for the next 12 months, with all underlying assumptions clearly stated.

We are taking steps to address the conditions outlined.

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

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

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

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

As previously disclosed, our management identified material weaknesses in our internal controls over financial reporting, which relate to a deficiency in the design and operation of our 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 U.S. GAAP.

In response to the material weaknesses, we have identified and documented all relevant processes, conducted a corporate-wide risk assessment to address emerging risks, and implemented new entity-level, process-level, and monitoring controls. Additionally, we upgraded IT systems and general controls to mitigate segregation of duty risks.

As a result of these efforts, our management concluded that, as of December 31, 2024, the material weaknesses has been remediated. While these material weaknesses have been remediated, other weaknesses in our disclosure controls and procedures and internal control over financial reporting may be discovered in the future.

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

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

Our management and other personnel will need to devote a substantial amount of time to compliance initiatives applicable to public companies, including compliance with Section 404 and the evaluation of the effectiveness of our internal controls over financial reporting within the prescribed timeframe. We cannot assure you that there will not be additional material weaknesses in our internal control over financial reporting now or in the future and we may discover additional deficiencies in existing systems and controls that we may not be able to remediate in an efficient or timely manner. In the event that we identify additional deficiencies, we may be required to further restate our financial statements and our results of operations and financial condition could be negatively affected.

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

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

For those warrants traded on the Nasdaq under the ticker symbol (ICUCW) (herein the "Public Warrants"), we have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of our Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we gave proper notice of such redemption and provided certain other conditions are met. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force Public Warrant holders (i) to exercise the Public Warrants and pay the exercise price therefore at a time when it may be disadvantageous for Public Warrant holders to do so, (ii) to sell the Public Warrants at the then-current market price when the Public Warrant holders might otherwise wish to hold the Public Warrants or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of the Public Warrants. None of the private placement or PIPE warrants will be redeemable by us so long as they are held by the Sponsor, original PIPE warrant holders or its permitted transferees.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million, after deducting the Placement Agent's fees and estimated offering expenses payable by us, and assuming no sale of Pre-Funded Warrants in this offering and no exercise of the Warrants or Placement Agent Warrants being issued in this offering. However, because this is a reasonable best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the Placement Agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus. The table below depicts how we plan to utilize the proceeds in the event that 25%, 50%, 75% and 100% of the securities in this offering are sold, after deducting the Placement Agent's fees and estimated offering expenses payable by us:

	100%	**75%**	**50%**	**25%**
Gross Proceeds from Offering	**$**	**$**	**$**	$
Use of Proceeds				
Placement Agent Fees	$	$	$	$
Offering Expenses	$	$	$	$
General Corporate	$	$	$	$
Total Use of Proceeds	**$**	**$**	**$**	**$**

These estimates exclude the proceeds, if any, from the exercise of the Warrants issued in this offering. If all of the Warrants issued in this offering were to be exercised in cash at an exercise price of $ per share of Common Stock, we would receive additional proceeds of approximately $ million. We cannot predict when or if these Warrants will be exercised. It is possible that these Warrants may expire and may never be exercised. Additionally, the Warrants contain a cashless exercise provision that permit exercise of Warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act covering the issuance of the underlying shares.

These estimates also exclude the proceeds, if any, from the exercise of the Placement Agent Warrants issued in this offering. If all of the Placement Agent Warrants issued in this offering were to be exercised in cash at an exercise price of $ per share of Common Stock, we would receive additional proceeds of approximately $ million. We cannot predict when or if these Placement Agent Warrants will be exercised. It is possible that these Placement Agent Warrants may expire and may never be exercised. Additionally, the Placement Agent Warrants contain a cashless exercise provision that permit exercise of Placement Agent Warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act covering the issuance of the underlying shares.

We intend to use the net proceeds of this offering for general corporate purposes.

DILUTION

If you invest in our securities, your interest will be immediately diluted to the extent of the difference between the effective public offering price per share of Common Stock and the pro forma as adjusted net tangible book value per share of our Common Stock after this offering. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our Common Stock outstanding.

Our net tangible book value as of March 31, 2025 was approximately $565,000, or $0.06 per share of Common Stock. Net tangible book value per share is determined by dividing our total tangible assets, excluding goodwill and intangible assets, less total liabilities, by the number of shares of our Common Stock outstanding as of March 31, 2025.

After giving effect to the sale of shares of our Common Stock and accompanying Warrants to purchase up to shares of our Common Stock at an assumed combined public offering price per share of Common Stock and accompanying Warrant of $1.18, the last reported sale price of our Common Stock on The Nasdaq Capital Market on June 13, 2025, assuming no sale of any Pre-Funded Warrants in this offering, and after deducting the estimated Placement Agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Warrants and Placement Agent Warrants issued in this offering, our pro forma net tangible book value as of March 31, 2025 would have been approximately $5.37 million, or approximately $0.37 per share. This represents an immediate increase in the net tangible book value to existing stockholders of $0.31 per share and an immediate dilution in the pro forma net tangible book value of $0.81 per share of our Common Stock to the investors purchasing securities in this offering.

The following table illustrates this dilution to new investors purchasing shares of Common Stock in this offering:

Assumed combined public offering price per share of Common Stock and accompanying Warrant	$	1.18
Historical net tangible book value per share as of March 31, 2025	$	0.06
Increase in net tangible book value per share attributable to investors purchasing in this offering	$	0.31
Pro forma net tangible book value per share as of March 31, 2025 after giving effect to this offering	$	0.37
Dilution per share to investors purchasing in this offering	$	0.81

The number of shares of our Common Stock to be outstanding as shown above is based on 9,257,763 shares of our Common Stock outstanding as of March 31, 2025, and excludes (in each case as of March 31, 2025):

- 1,945,989 shares of Common Stock issued subsequent to March 31, 2025 through June 12, 2025;
- 21,931 shares of Common Stock issuable upon the exercise of stock options, with a weighted-average exercise price of $45.32 per share;
- 212,280 shares of Common Stock issuable upon the settlement of outstanding restricted stock units as of March 31, 2025;
- 6,882,300 shares of Common Stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of $30.89 per share as of March 31, 2025; and
- 261,751 additional shares of Common Stock reserved for future issuance under our 2022 Omnibus Equity Incentive Plan.

To the extent that outstanding options or warrants have been or may be exercised, new equity awards were or are issued, shares of our Common Stock are sold under our employee stock purchase plan, or we otherwise issued or issue additional shares of Common Stock, including in our “at the market” offering program, investors purchasing our Common Stock in this offering may experience further dilution.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- no exercise of the outstanding warrants described above;
- no exercise of the outstanding options described above; and
- no exercise of the Warrants or the Placement Agent Warrants issued to the Placement Agent or its designees as compensation in connection with this offering and no sale of the Pre-Funded Warrants.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, dated (the "Engagement Agreement"), we have engaged to act as our exclusive placement agent to solicit offers to purchase the securities offered pursuant to this prospectus on a "reasonable best efforts" basis. The Engagement Agreement does not give rise to any commitment by the Placement Agent to purchase any of our securities, and the Placement Agent will have no authority to bind us by virtue of the Engagement Agreement. The Placement Agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. This is a reasonable best efforts offering, and there is no minimum offering amount required as a condition to the closing of this offering. The Placement Agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. Therefore, we may not sell all of the shares of Common Stock, Pre-Funded Warrants and Warrants being offered. The terms of this offering are subject to market conditions and negotiations between us, the Placement Agent and prospective investors. The Placement Agent does not guarantee that it will be able to raise new capital in any prospective offering. The Placement Agent may engage sub-agents or selected dealers to assist with the offering.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of years following the closing of the offering, subject to certain exceptions; and (ii) a covenant to not enter into any equity financings for days from closing of the offering, subject to certain exceptions. The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and

- covenants regarding matters such as no integration with other offerings, filing of a Current Report on Form 8-K to disclose entering into these securities purchase agreements, no stockholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of shares of Common Stock and no subsequent equity sales for days.

Delivery of the shares of Common Stock, the Warrants and the Pre-Funded Warrants, if any, offered hereby is expected to occur on or about June , 2025, subject to the satisfaction of certain customary closing conditions.

Fees and Expenses

We have agreed to pay the Placement Agent a total cash fee equal to % of the aggregate gross proceeds raised in this offering and a management fee equal to % of the aggregate gross proceeds raised in this offering. We will also pay the Placement Agent a non-accountable expense allowance of $ and up to $ for the expenses of its clearing firm and will reimburse the Placement Agent's legal fees and expenses in an amount up to $. We estimate the total offering expenses of this offering that will be payable by us, excluding the Placement Agent's fees and expenses, will be approximately $. After deducting the Placement Agent's fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately $.

The following table shows the per share, per Pre-Funded Warrant and total cash fees we will pay to the Placement Agent in connection with the sale of the Common Stock, the Warrants and the Pre-Funded Warrants pursuant to this prospectus.

	Per Share and Accompanying Warrants	Per Pre-Funded Warrant and Accompanying Warrants	Total
Combined public offering price			
Placement Agent fees			
Proceeds to us, before expenses			

Placement Agent Warrants

We have agreed to grant Placement Agent Warrants to the Placement Agent or its designees to purchase a number of shares of our Common Stock equal to % of the aggregate number of shares of Common Stock and Pre-Funded Warrants sold to the investors in this offering. The Placement Agent Warrants will have an exercise price of $ per share (% of the combined public offering price per share of Common Stock and accompanying Warrant), will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, such Placement Agent Warrants will be exercisable upon issuance and will terminate on the anniversary of the commencement of sales in this offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrant will be included as an exhibit to this Registration Statement of which this prospectus forms a part. The Placement Agent Warrants provide for customary anti-dilution provisions (for stock dividends, splits and recapitalizations and the like) consistent with FINRA Rule 5110.

Right of First Refusal

We have granted the Placement Agent a right of first refusal for a period of months following the closing of this offering to act as sole book-running manager, sole underwriter or sole placement agent for each and every future public or private offering or other capital-raising financing of equity, equity-linked or debt securities by us or any of our successors or subsidiaries, subject to certain exceptions. Notwithstanding anything to the contrary contained in this paragraph, in accordance with FINRA Rule 5110(g)(6)(A)(i), any such right of first refusal described in this paragraph shall not have a duration of more than three years from the commencement of sales of the first offering or the termination date of the term of the Engagement Agreement.

Tail

We have also agreed to pay the Placement Agent a tail fee equal to (i) a cash fee of % raised in any financing subject to the tail provision, and (ii) warrant coverage equal to % of the aggregate number of shares of Common Stock (or Common Stock equivalent) placed in any offering financing subject to the tail provision, as applicable to such financing, provided that in each case (i) or (ii) such compensation shall not apply to the gross proceeds received by us upon exercise or conversion in the ordinary course of any warrants or other convertible securities issued as part of the offering (other than Pre-Funded Warrants), if any investor, who was contacted by the Placement Agent or introduced to us during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the -month period following expiration or termination of our engagement of the Placement Agent, subject to certain exceptions.

Other Relationships

From time to time, the Placement Agent or its affiliates has provided, or may provide in the future, various advisory, investment and commercial banking and other services to us or our affiliates in the ordinary course of business, for which it has or may receive customary fees and commissions. Except as disclosed in this prospectus, we have no present arrangements with the Placement Agent for any services.

In addition, in the ordinary course of their business activities, the Placement Agent and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The Placement Agent and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Determination of Offering Price

The combined public offering price per share of Common Stock and accompanying Warrant and the combined public offering price per Pre-Funded Warrant and accompanying Warrant we are offering, and the exercise prices and other terms of the Warrants were negotiated between us and the investors, in consultation with the Placement Agent based on the trading of our Common Stock prior to this offering, among other things. Other factors considered in determining the offering prices of the securities we are offering and the exercise prices and other terms of the Warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Lock-Up Agreements

We and each of our officers and directors have agreed with the Placement Agent to be subject to a lock-up period of sixty (60) days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of Common Stock or any securities convertible into, or exercisable or exchangeable for, shares of Common Stock, subject to customary exceptions. The Placement Agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our Common Stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of years following the closing date of this offering, subject to certain exceptions. The Placement Agent may waive this prohibition in its sole discretion and without notice.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Continental Stock Transfer and Trust Company. There is no established public trading market for the Warrants and the Pre-Funded Warrants, and we do not plan on making an application to list the Warrants or the Pre-Funded Warrants on Nasdaq, any national securities exchange or other nationally recognized trading system. We will act as the registrar and transfer agent for the Warrants and the Pre-Funded Warrants.

Indemnification

We have agreed to indemnify the Placement Agent against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the Placement Agent may be required to make with respect to any of these liabilities.

Regulation M

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent. Under these rules and regulations, the Placement Agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the Placement Agent, if any, participating in this offering and the Placement Agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the Placement Agent, and should not be relied upon by investors.

Our Common Stock and Listed Warrants are traded on the Nasdaq Capital Market under the symbols “ICU” and “ICUCW,” respectively.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to 4,237,288 shares of Common Stock, together with Warrants to purchase up to 4,237,288 shares of Common Stock. We are also offering Pre-Funded Warrants to purchase shares of Common Stock to those purchasers, whose purchase of shares of Common Stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering in lieu of the shares of our Common Stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Pre-Funded Warrant will be exercisable for one share of Common Stock. Each Pre-Funded Warrant is being issued together with the same Warrant described above being issued with each share of Common Stock. The shares of Common Stock or Pre-Funded Warrants, as the case may be, and the accompanying Warrants, can only be purchased together in this offering, but the shares of Common Stock and Pre-Funded Warrants and accompanying Warrants are immediately separable and will be issued separately in this offering. We are also registering the shares of Common Stock issuable from time to time upon exercise of the Pre-Funded Warrants and Warrants offered hereby.

Common Stock

The material terms and provisions of our Common Stock are described under the caption "*Description of Securities*."

Warrants

The following summary of certain terms and provisions of the Warrants included with the shares of Common Stock and the Pre-Funded Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the Warrants.

Duration, Exercise Price and Form

Each Warrant offered hereby will have an exercise price of $1.18 per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon the Initial Exercise Date. The Warrants will expire on the anniversary of the Initial Exercise Date. The exercise price and number of shares of Common Stock issuable upon exercise of the Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price. The Warrants will be issued separately from the Common Stock and Pre-Funded Warrants and may be transferred separately immediately thereafter.

If the Pricing Conditions are not met, we intend to promptly, and in no event later than 120 days after the consummation of this offering, seek stockholder approval for the issuance of shares of Common Stock issuable upon exercise of the Warrants but we cannot assure you that such stockholder approval will be obtained. We have agreed with the investors in this offering that, if we do not obtain stockholder approval for the issuance of the shares of Common Stock upon exercise of the Warrants at the first stockholder meeting for such purpose after this offering, we will call a stockholder meeting every 90 days thereafter until the earlier of the date we obtain such approval or the Warrants are no longer outstanding, provided, however, that, if and only if the Pricing Conditions are satisfied, then we will not seek Warrant Stockholder Approval.

Exercisability

The Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the Warrants, 9.99%) of the outstanding Common Stock immediately after exercise. Following the issuance of the Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding Common Stock after exercising the holder's Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants and in accordance with the rules and regulations of the SEC, provided that any increase in the beneficial ownership limitation shall not be effective until sixty-one (61) days following notice to us.

Cashless Exercise

If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable laws, a Warrant may be transferred at the option of the holder upon surrender of the Warrant to us together with the appropriate instruments of transfer.

Trading Market and Listing

There is no trading market available for the Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants will be extremely limited. The Common Stock issuable upon exercise of the Warrants is currently listed on The Nasdaq Capital Market.

Rights as a Stockholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding Common Stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction. In addition, in certain circumstances, upon a fundamental transaction, the holder of the Warrants will have the right to require us to repurchase its Warrants at the Black-Scholes value; provided, however, that, if the fundamental transaction is not within our control, including not approved by our Board, then the holder will only be entitled to receive the same type or form of consideration (and in the same proportion), at the Black-Scholes value of the unexercised portion of the Warrant that is being offered and paid to the holders of our Common Stock in connection with the fundamental transaction.

Waivers and Amendments

The Warrants may be modified or amended, or the provisions thereof waived, with the written consent of the holder of such Warrant and us.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

Duration, Exercise Price and Form

Each Pre-Funded Warrant offered hereby will have an initial exercise price per share equal to $0.0001. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price. The Pre-Funded Warrants will be issued separately from the accompanying Warrants.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the Pre-Funded Warrant, 9.99%) of the outstanding Common Stock immediately after exercise. Following the issuance of the Pre-Funded Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding Common Stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants and in accordance with the rules and regulations of the SEC. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding Common Stock, provided that any increase in the beneficial ownership limitation shall not be effective until sixty-one (61) days following notice to us.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrants.

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the Pre-Funded Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable law, the Pre-Funded Warrants may be transferred at the option of the holder upon surrender of the Pre-Funded Warrants to us together with the appropriate instruments of transfer.

Trading Market and Listing

There is no trading market available for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Pre-Funded Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Pre-Funded Warrants will be extremely limited. The Common Stock issuable upon exercise of the Pre-Funded Warrants is currently listed on The Nasdaq Capital Market.

Rights as a Stockholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their Pre-Funded Warrants. The Pre-Funded Warrants will provide that holders have the right to participate in distributions or dividends paid on our Common Stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding Common Stock, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Waivers and Amendments

The Pre-Funded Warrants may be modified or amended, or the provisions thereof waived, with the written consent of the holder of such Pre-Funded Warrant and us.

Placement Agent Warrants

We have also agreed to issue to the Placement Agent or its designees as compensation in connection with this offering, the Placement Agent Warrants to purchase up to 169,355 shares of Common Stock. The Placement Agent Warrants will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, such Placement Agent Warrants will be exercisable upon issuance and will have substantially the same terms as the Warrants described above, except that the Placement Agent Warrants will have an exercise price of $2.125 per share (representing 125% of the combined public offering price per share and accompanying Warrants) and a termination date that will be years from the commencement of the sales pursuant to this offering. See "Plan of Distribution" above.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of certain material U.S. federal income tax considerations relating to the acquisition, ownership, and disposition of shares of Common Stock, the acquisition, ownership, exercise and disposition of Pre-Funded Warrants, the exercise, disposition, or expiration of Warrants acquired together with the shares of Common Stock or Pre-Funded Warrants, the acquisition, ownership, and disposition of shares of Common Stock received upon exercise of the Pre-Funded Warrants, and the acquisition, ownership, and disposition of shares of Common Stock received upon exercise of the Warrants (referred to herein as "Warrant Shares"), all as acquired pursuant to this prospectus.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), U.S. Treasury Regulations (whether final, temporary or proposed) promulgated thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation that, if enacted, could be applied on a retroactive or prospective basis. We have not sought and will not seek any legal opinion of legal counsel or rulings from the Internal Revenue Service (the "IRS"), regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders who hold shares of Common Stock, Pre-Funded Warrants, Warrants, or Warrant Shares, as applicable, as a capital asset within the meaning of Section 1221 of the Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum tax and the additional tax on net investment income, nor does it address any aspect of U.S. state and local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate and gift taxes. Except as provided below, this summary does not address tax reporting requirements. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

- insurance companies;
- tax-exempt organizations and governmental organizations;
- banks or other financial institutions;
- brokers or dealers in securities or foreign currency;
- traders in securities who elect to apply a mark-to-market method of accounting;
- real estate investment trusts, regulated investment companies or mutual funds, and equity owners or other beneficial owners thereof;
- pension plans;
- controlled foreign corporations, passive foreign investment companies, and shareholders in such entities;
- corporations organized outside the U.S., any state thereof, or the District of Columbia that are nonetheless treated as U.S. persons for U.S. federal income tax purposes;
- persons that own (directly, indirectly or constructively) more than 5% of the total voting power or total value of our Common Stock;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons that have a "functional currency" other than the U.S. dollar;
- persons that acquire shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares in connection with the exercise of employee stock options (to the extent applicable) or otherwise as compensation for services;
- persons that hold shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- holders subject to special accounting rules;

- S corporations (and shareholders thereof);
- partnerships or other entities treated as partnerships for U.S. federal income tax purposes (and partners or other owners thereof); and
- U.S. holders that hold shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares in connection with a trade or business, permanent establishment or fixed base outside the United States.

If an entity or arrangement taxable as a partnership (or other "pass-through" entity) for U.S. federal income tax purposes holds shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares, the U.S. federal income tax treatment of such entity (or arrangement) and the partners (or other owners) of such entity generally will depend on the status of the partners, the activities of the entity and certain determinations made at the partner level. This summary does not address the tax consequences to any such owner. Partners (or other owners) of entities or arrangements that are classified as partnerships or as "pass-through" entities for U.S. federal income tax purposes should consult their own tax advisors regarding the U.S. federal, state and local, and non-U.S. tax consequences arising from and relating to the acquisition, ownership, and disposition of shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares.

For purposes of this discussion, the term "U.S. holder" means a beneficial owner of shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares acquired pursuant to this prospectus that is, for U.S. federal income tax purposes:

- an individual citizen or resident of the U.S.;
- a corporation created or organized in or under the laws of the U.S., any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A "non-U.S. holder" is a beneficial owner of shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares acquired pursuant to this prospectus that is neither a U.S. holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT, AND IS NOT INTENDED TO BE, LEGAL OR TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, LOCAL, AND NON-U.S. INCOME, ESTATE AND OTHER TAX CONSIDERATIONS OF ACQUIRING, HOLDING AND DISPOSING OF SHARES OF COMMON STOCK, PRE-FUNDED WARRANTS, WARRANTS OR WARRANT SHARES.

U.S. Federal Income Tax Consequences of the Acquisition of Shares of Common Stock and Warrants or Pre-Funded Warrants and Warrants

For U.S. federal income tax purposes, the acquisition by a U.S. holder or a non-U.S. holder of a share of Common Stock and the accompanying Warrant offered hereby will be treated as the acquisition of an investment unit composed of one share of Common Stock and one Warrant. The purchase price will be allocated among these two components in proportion to their relative fair market values at the time the securities are purchased by the U.S. holder or non-U.S. holder. This allocation of the purchase price will establish a U.S. holder's or non-U.S. holder's initial tax basis for U.S. federal income tax purposes in the one share of Common Stock and the one Warrant.

For this purpose, we will allocate $ of the purchase price to the one share of Common Stock and $ of the purchase price to the one Warrant composing each such investment unit. However, the IRS will not be bound by such allocation of the purchase price, and therefore, the IRS or a U.S. court may not respect the allocation set forth above. Each U.S. holder and non-U.S. holder should consult its own tax advisor regarding the allocation of the purchase price.

For U.S. federal income tax purposes, the acquisition by a U.S. holder or a non-U.S. holder of a Pre-Funded Warrant and accompanying Warrant will be treated as the acquisition of an investment unit composed of one Pre-Funded Warrant and one Warrant. The purchase will be allocated among these two components in proportion to their relative fair market values at the time the securities are purchased by the U.S. holder or non-U.S. holder. This allocation of the purchase price will establish a U.S. holder's or non-U.S. holder's initial tax basis for U.S. federal income tax purposes in the one Pre-Funded Warrant and one Warrant.

For this purpose, we will allocate $ of the purchase price to the one Pre-Funded Warrant and $ of the purchase price to the one Warrant composing each such investment unit. However, the IRS will not be bound by such allocation of the purchase price, and therefore, the IRS or a U.S. court may not respect the allocation set forth above. Each U.S. holder and non-U.S. holder should consult its own tax advisor regarding the allocation of the purchase price.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe that the Pre-Funded Warrants should be treated as a separate class of shares of our common stock for U.S. federal income tax purposes and a U.S. holder or non-U.S. holder of Pre-Funded Warrants should generally be taxed in the same manner as a holder of shares of Common Stock, except as described below. Accordingly, no gain or loss should be recognized upon the exercise of a Pre-Funded Warrant and, upon exercise, the holding period of a Pre-Funded Warrant should carry over to the Warrant Shares received upon exercise. Similarly, the tax basis of the Pre-Funded Warrant should carry over to the Warrant Shares received upon exercise, increased by the exercise price of $0.0001 per share. However, such characterization is not binding on the IRS, and the IRS may treat the Pre-Funded Warrants as warrants to acquire shares of Common Stock. If so, the amount and character of a U.S. holder's or non-U.S. holder's gain with respect to an investment in Pre-Funded Warrants could change. Accordingly, each U.S. holder and non-U.S. holder should consult its own tax advisors regarding the risks associated with the acquisition of a Pre-Funded Warrant pursuant to this prospectus including potential alternative characterizations. The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

U.S. Holders

Exercise, Disposition or Expiration of the Warrants and Certain Adjustments to the Warrants

Exercise of Warrants

A U.S. holder should not recognize gain or loss on the exercise of Warrants and related receipt of Warrant Shares (unless cash is received in lieu of the issuance of a fractional Warrant Share). A U.S. holder's initial tax basis in the Warrant Shares received on the exercise of Warrants should be equal to the sum of (a) such U.S. holder's tax basis in such Warrants plus (b) the exercise price paid by such U.S. holder on the exercise of such Warrants. It is unclear whether a U.S. holder's holding period for the Warrant Shares received on the exercise of Warrants would commence on the date of exercise of the Warrants or the day following the date of exercise of the Warrants.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of Warrants into Warrant Shares. The U.S. federal income tax treatment of a cashless exercise of Warrants into Warrant Shares is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of Warrants described in the preceding paragraph. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Warrants.

Disposition of Warrants

A U.S. holder will recognize gain or loss on the sale or other taxable disposition of a Warrant in an amount equal to the difference, if any, between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in the Warrant sold or otherwise disposed of. Any such gain or loss generally will be a capital gain or loss, which will be long-term capital gain or loss if the Warrant is held for longer than one year. Deductions for capital losses are subject to complex limitations under the Code.

Expiration of Warrants Without Exercise

Upon the lapse or expiration of a Warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the Warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the Warrant is held for longer than one year. Deductions for capital losses are subject to complex limitations under the Code.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of Warrant Shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a U.S. holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. holder's proportionate interest in the "earnings and profits" or our assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of Warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be

taxable whether or not there is an actual distribution of cash or other property. (See more detailed discussion of the rules applicable to distributions made by us at "*Distributions on Shares of Common Stock, Pre-Funded Warrants or Warrant Shares*" below).

Acquisition, Ownership, and Disposition of Shares of Common Stock, Pre-Funded Warrants and Warrant Shares

Distributions on Shares of Common Stock, Pre-Funded Warrants or Warrant Shares

A U.S. holder that receives a distribution, including a constructive distribution, with respect to a share of Common Stock, Pre-Funded Warrant or Warrant Share (as well as any constructive distribution on a Warrant, as described above) will be required to include the amount of such distribution in gross income as a dividend to the extent of our current and accumulated "earnings and profits", as computed under U.S. federal income tax principles. To the extent that a distribution exceeds our current and accumulated "earnings and profits", such distribution will be treated first as a tax-free return of capital to the extent of a U.S. holder's tax basis in the shares of Common Stock, Pre-Funded Warrants or Warrant Shares and thereafter as gain from the sale or exchange of such shares of Common Stock, Pre-Funded Warrants or Warrant Shares (see "*Sale or Other Taxable Disposition of Shares of Common Stock, Pre-Funded Warrants and/or Warrant Shares*" below). Dividends received on shares of Common Stock, Pre-Funded Warrants or Warrant Shares may be eligible for a dividends received deduction, subject to certain restrictions relating to, among others, the corporate U.S. holder's taxable income, holding period and debt financing. Dividends paid by us to non-corporate U.S. holders, including individuals, generally will be eligible for the preferential tax rates applicable to long-term capital gains for dividends, provided certain holding period and other conditions are satisfied. The dividend rules are complex, and each U.S. holder should consult its own tax advisor regarding the application of such rules.

Sale or Other Taxable Disposition of Shares of Common Stock, Pre-Funded Warrants and/or Warrant Shares

Upon the sale or other taxable disposition of shares of Common Stock, Pre-Funded Warrants or Warrant Shares, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such shares of Common Stock, Pre-Funded Warrants or Warrant Shares sold or otherwise disposed of. Gain or loss recognized on such sale or other taxable disposition generally will be long-term capital gain or loss if, at the time of the sale or other taxable disposition, the shares of Common Stock, Pre-Funded Warrants or Warrant Shares have been held for longer than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. There are no preferential tax rates for long-term capital gain of a U.S. holder that is a corporation. Deductions for capital losses are subject to significant limitations under the Code.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends including constructive distributions on our shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares and to the proceeds of a sale or other taxable disposition of shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares paid to a U.S. holder unless the U.S. holder is an exempt recipient (such as a corporation). Backup withholding, currently at the rate of 24%, will apply to those payments if the U.S. holder fails to provide its correct taxpayer identification number, or certification of exempt status, or if the U.S. holder is notified by the IRS that it has failed to report in full payments of interest and dividend income. Backup withholding is not an additional tax, and any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. holder's United States federal income tax liability, if any, provided the required information is furnished in a timely manner to the IRS.

Non-U.S. Holders

Exercise, Disposition or Expiration of the Warrants or Certain Adjustments to the Warrants

Exercise of Warrants

A non-U.S. holder generally will not recognize gain or loss on the exercise of Warrants and related receipt of Warrant Shares (unless cash is received in lieu of the issuance of a fractional Warrant Share, and certain other conditions are present, as discussed below under "*— Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares*"). A non-U.S. holder's initial tax basis in the Warrant Shares received on the exercise of Warrants should be equal to the sum of (i) the non-U.S. holder's tax basis in the Warrants, plus (ii) the exercise price paid by the non-U.S. holder on the exercise of the Warrants. It is unclear whether a non-U.S. holder's holding period for the Warrant Shares received on the exercise of Warrants would commence on the date of exercise of the Warrants or the day following the date of exercise of the Warrants.

In certain limited circumstances, a non-U.S. holder may be permitted to undertake a cashless exercise of Warrants into Warrant Shares. The U.S. federal income tax treatment of a cashless exercise of Warrants into Warrant Shares is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of Warrants described in the preceding paragraph. Non-U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Warrants.

Disposition of Warrants

A non-U.S. Holder will recognize gain or loss on the sale or other taxable disposition of a Warrant in an amount equal to the difference, if any, between (a) the amount of cash plus the fair market value of any property received and (b) such non-U.S. holder's tax basis in the Warrant sold or otherwise disposed of. Any such gain or loss generally will be a capital gain or loss, which will be long-term capital gain or loss if the Warrant is held for more than one year. Any such gain recognized by a non-U.S. holder will be taxable for U.S. federal income tax purposes according to rules discussed under the heading "*— Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares*" below.

Expiration of Warrants without Exercise

Upon the lapse or expiration of a Warrant, a non-U.S. holder will recognize loss in an amount equal to such non-U.S. holder's tax basis in the Warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the Warrants are held for longer than one year. Deductions for capital losses are subject to complex limitations under the Code.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of Warrant Shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a non-U.S. holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such non-U.S. holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of a Warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not result in a constructive distribution. See the more detailed discussion of the rules applicable to distributions made by us under the heading "*Distributions on Shares of Common Stock, Pre-Funded Warrants or Warrant Shares*" below.

Acquisition, Ownership, and Disposition of Shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares

Distributions on Shares of Common Stock, Pre-Funded Warrants or Warrant Shares

If we pay distributions of cash or property with respect to our shares of Common Stock, Pre-Funded Warrants or Warrant Shares (as well as any constructive distribution on a Warrant, as described above), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in its shares of Common Stock, Pre-Funded Warrants or Warrant Shares, as applicable. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "*— Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares*." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, shares of Common Stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations. If we are a USRPHC (as defined below) and we do not qualify for the Regularly Traded Exception (as defined below), distributions which constitute a return of capital will be subject to withholding tax unless an application for a withholding certificate is filed to reduce or eliminate such withholding.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States are generally not subject to the 30% (or lower rate as may be specified by an applicable tax treaty) withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business, the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Pre-Funded Warrants, Warrants and Warrant Shares

Subject to the discussions below in "*—Information Reporting and Backup Withholding*" and "*—Foreign Account Tax Compliance Act*", a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the U.S. and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the U.S.; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

- the non-U.S. holder is an individual present in the U.S. for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or

- we are or have been a "United States real property holding corporation" ("USRPHC") for U.S. federal income tax purposes at any time during the shorter of the non-U.S. holder's holding period or the five-year period ending on the date of disposition of our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares, as applicable. Even if we become a USRPHC, however, as long as our Common Stock is regularly traded on an established securities market as determined under applicable U.S. Treasury Regulations ("Regularly Traded" and the "Regularly Traded Exception"), our shares of Common Stock (including the Warrant Shares) will be treated as a U.S. real property interest only if a non-U.S. holder actually (directly or indirectly) or constructively (under certain attribution rules) holds or has held more than five percent of such Regularly Traded Common Stock (including the Warrant Shares) at any time during the shorter of the five-year period preceding such non-U.S. holder's disposition of, or holding period for, shares of our Common Stock (including the Warrant Shares) (a "5% Shareholder"). However, no assurance can be provided that our shares of Common Stock (including the Warrant Shares) will be considered to be Regularly Traded for purposes of the rules described above. Since the Warrants are not expected to be listed on a securities market, the Warrants are unlikely to qualify for the Regularly Traded Exception. Special rules may apply to non-U.S. holders of Pre-Funded Warrants and Warrants, who should consult their own tax advisors. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming in the future, a USRPHC (within the meaning of Section 897(c)(2) of the Code) for U.S. federal income tax purposes. No assurance can be provided that our shares of Common Stock will be Regularly Traded for purposes of the rule described above. Accordingly, we can provide no assurances that our shares of Common Stock, Pre-Funded Warrants or Warrant Shares will meet the Regularly Traded Exception at the time a non-U.S. holder purchases such securities or sells, exchanges or otherwise disposes of such securities. If we are determined to be a USRPHC and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the disposition of shares of Common Stock, Pre-Funded Warrants or Warrant Shares at the U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). The determination of whether a non-U.S. holder is a 5% Shareholder and the potential application of the Regularly Traded Exception is complex and subject to uncertainty. Non-U.S. holders should consult with their own tax advisors regarding such determinations and the consequences of these rules on their investment.

Information Reporting and Backup Withholding

Backup withholding, currently at a rate of 24%, generally will not apply to dividends including constructive distributions paid to a non-U.S. holder on our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares, or to the gross proceeds paid to a non-U.S. holder from a disposition of, our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares, provided that the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a United States person who is not an exempt recipient.

We are required to report annually to the IRS the amount of any dividends paid to a non-U.S. holder, regardless of whether we actually withheld any tax. Copies of the information returns reporting such dividends and the amount withheld may also be made available to the tax authorities in the country in which the non-U.S. holder resides under the provisions of an income tax treaty or other agreement between the United States and the tax authorities in such country. In addition, proceeds from the disposition by a non-U.S. holder of our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares that is transacted within the United States or conducted through certain United States-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. The U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If backup withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is timely furnished to the IRS.

Foreign Account Tax Compliance Act

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such sections commonly referred to as the Foreign Account Tax Compliance Act, or "FATCA") on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including constructive dividends) on, or, subject to the proposed U.S. Treasury Regulations discussed below, gross proceeds from the disposition of, our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares paid to or through a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the United States Department of Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Non-U.S. holders typically will be required to furnish certifications (generally on the applicable IRS Form W-8) or other documentation to provide the information required by FATCA or to establish compliance with or an exemption from withholding under FATCA. FATCA withholding may apply where payments are made through a non-U.S. intermediary that is not FATCA compliant, even where the non-U.S. holder satisfies the holder's own FATCA obligations.

Under the applicable U.S. Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends (including constructive dividends) on our shares of Common Stock, Pre-Funded Warrants. Warrants or Warrant Shares, and subject to proposed U.S. Treasury Regulations described below, to payments of gross proceeds from the sale or other disposition of our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares. The United States Department of Treasury has released proposed U.S. Treasury Regulations (the preamble to which specifies that taxpayers may rely on them pending finalization) which would eliminate FATCA withholding on payments of gross proceeds from the sale or other disposition of our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares. There can be no assurance that the proposed U.S. Treasury Regulations will be finalized in their present form.

The United States and a number of other jurisdictions have entered into intergovernmental agreements to facilitate the implementation of FATCA. Any applicable intergovernmental agreement may alter one or more of the FATCA information reporting and withholding requirements. Prospective investors should consult their own tax advisors regarding the potential application of withholding under FATCA to an investment in our shares of Common Stock, Pre-Funded Warrants, Warrants or Warrant Shares, including the applicability of any intergovernmental agreements.

THE ABOVE SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSIDERATIONS APPLICABLE TO PROSPECTIVE INVESTORS WITH RESPECT TO THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF SHARES OF COMMON STOCK, PRE-FUNDED WARRANTS, WARRANTS, OR WARRANT SHARES. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO

THE TAX CONSIDERATIONS APPLICABLE TO THEM IN LIGHT OF THEIR OWN PARTICULAR CIRCUMSTANCES.

DESCRIPTION OF SECURITIES

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities. The descriptions below are qualified by reference to the actual text of the Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation, as amended (the "Charter") and our Second Amended and Restated By-laws (the "Bylaws"). We urge you to read the Charter and the Bylaws in its entirety for a complete description of the rights and preferences of our securities.

Authorized and Outstanding Stock

The Charter authorizes the issuance of 460,000,000 shares, consisting of (a) 450,000,000 shares of Common Stock and (b) 10,000,000 shares of preferred stock (the "Preferred Stock").

The outstanding shares of Common Stock issued in the Business Combination are duly authorized, validly issued, fully paid and non-assessable. All outstanding shares of LMAO Class B Common Stock following the Business Combination were converted into shares of LMAO Class A Common Stock on a one-to-one basis. Immediately following the conversion of such Class B Common Stock into shares of Class A Common Stock, each share of Class A Common Stock issued and outstanding was reclassified, redesignated and changed into one validly issued, fully paid and non-assessable share of Common Stock.

Common Stock

The Charter provides the following with respect to the rights, powers, preferences and privileges of the Common Stock:

Holders

On May 14, 2025 there were approximately 84 holders of record of our Common Stock.

Voting Power

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of Common Stock possess all voting power for the election of our directors and all other matters requiring stockholder action. Holders of Common Stock are entitled to one vote 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 in its discretion out of funds legally available therefor.

Liquidation, Dissolution and Winding Up

In the event of our 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 our 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 our debts.

Preemptive or Other Rights

There are no preemptive rights or sinking fund provisions applicable to the shares of our Common Stock.

Preferred Stock

The Charter provides that shares of Preferred Stock may be issued from time to time in one or more series. Our Board 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. Our Board will be able to, without stockholder approval, issue Preferred Stock with voting and other rights that could adversely affect the voting power and other rights of the holders of the Common Stock and could have anti-takeover effects. The ability of our Board to issue Preferred Stock without stockholder approval could have the effect of delaying, deferring, or preventing a change of control of us or the removal of existing management. We have no Preferred Stock outstanding at the date hereof. Although we do not currently intend to issue any shares of Preferred Stock, we cannot assure you that we will not do so in the future.

While we have no current plans to issue Preferred Stock, circumstances in which we might issue Preferred Stock in the future could include, among others, offerings of Preferred Stock undertaken for capital raising purposes (whether before or in connection with our initial business combination or thereafter), issuances in connection with acquisitions we might make in the future, or issuances in connection with potential change of control or strategic transactions involving us. Any determination by us to issue shares of Preferred Stock in the future will be dependent on the facts and circumstances at the time.

Anti-Takeover Effects of Provisions of our Charter, our Bylaws and Delaware Law

Some provisions of Delaware law and our Charter and Bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with the Board. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, beneficially owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by Board, such as discouraging takeover attempts that might result in a premium over the market price of our Common Stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for the Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to institute a change of control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our Charter provides that a special meeting of stockholders may only be called by the Board.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the Board or a committee of the Board.

Elimination of Stockholder Action by Written Consent

Our Bylaws eliminate the right of stockholders to take action by written consent any action required to be taken at any annual or special meeting of our stockholders.

Classified Board; Election and Removal of Directors; Filling Vacancies

The Board is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of Common Stock outstanding will be able to elect all of our directors. Our Charter provides for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66-2/3% of the outstanding shares of our capital stock entitled to vote in the election of directors or class of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. Furthermore any new directorships or vacancies in the Board, including new directorships resulting from any increase in the number of directors to serve on the whole board and/or any unfilled vacancies by reason of death, resignation, disqualification, removal for cause, failure to elect or otherwise with respect to any director, may be filled by only the vote of a majority of the remaining directors then in office, although less than a quorum, or by the sole remaining director. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of our directors.

Choice of Forum

Our Charter provides that, unless a majority of the Board, acting on our behalf, consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware or, if no court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Charter, our Bylaws or as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our Charter also provides that the federal district courts of the United States of America are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors and officers. The exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Exchange Act.

Our exclusive forum provision does not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders are not deemed to have waived our compliance with these laws, rules and regulations.

Although our Charter contains the choice of forum provisions described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Amendment of Charter Provisions

Our Charter grants us the right to amend, alter, change or repeal any provision in our Charter in the manner prescribed by the DGCL (the "Delaware General Corporation Law"). Under Section 242 of the DGCL, our Charter requires a greater vote, a proposed amendment to our Charter must be approved by the affirmative vote of a majority of the voting power of the outstanding stock entitled to vote thereon and a majority of the outstanding stock of each class entitled to vote as a class.

Amendment of Bylaw Provisions

Our Bylaws grant the Board the authority to amend, alter, repeal, or adopt new Bylaws in accordance with the procedures outlined in the Bylaws themselves. The Board can make such changes by a majority vote of all Board members at any regular or special meeting. Additionally, stockholders have the right to amend, alter, repeal, or adopt new bylaws by an affirmative vote of at least 50% of the outstanding shares of capital stock entitled to vote in the election of directors.

The provisions of the Delaware General Corporation Law, our Charter and our Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Warrants

Listed Warrants

Exercising a total of 25 Listed Warrants entitles the holder thereof to purchase one share of Common Stock at an aggregate price of $287.50 per share, subject to adjustment as discussed below, at any time after November 27, 2022. The Listed Warrants will expire on October 28, 2027, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of Common Stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of Common Stock underlying the Listed Warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No warrant will be exercisable and we will not be obligated to issue shares of Common Stock upon exercise of a warrant unless Common Stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the Listed Warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any Listed Warrant. In the event that a registration statement is not effective for the exercised warrants, the purchaser of a unit containing such warrant will have paid the full purchase price for the unit solely for the share of Common Stock underlying such unit.

We will use our best efforts to maintain a current prospectus relating to those shares of Common Stock until the Listed Warrants expire, as specified in the warrant agreement. Notwithstanding the above, if our Common Stock is at the time of any exercise of a warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of Listed Warrants who exercise their Listed Warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event we so elect, we will not be required to file or maintain in effect a registration statement, but we will be required to use our reasonable best efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available.

Once the Listed Warrants become exercisable, we may call the Listed Warrants for redemption (other than the Private Placement Warrants, as described below):

- in whole and not in part;
- at a price of $0.01 per warrants;
- upon not less than 30 days' prior written notice of redemption (the "30-day redemption period") to each warrant holder; and
- if, and only if, the reported last sale price of the Common Stock equals or exceeds $450.00 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 3 business days before we send the notice of redemption to the warrant holders.

If and when the Listed 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.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the Listed Warrants, each warrant holder will be entitled to exercise its warrant prior to the scheduled redemption date. However, the price of the Common Stock may fall below the $450.00 redemption trigger price (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations, and the like) as well as the $287.50 warrant exercise price after the redemption notice is issued.

If we call the Listed Warrants for redemption as described above, our management will have the option to require any holder that wishes to exercise its warrant to do so on a "cashless basis." In determining whether to require all holders to exercise their Listed Warrants on a "cashless basis," our management will consider, among other factors, our cash position, the number of Listed Warrants that are outstanding and the dilutive effect on our stockholders of issuing the maximum number of shares of Common Stock issuable upon the exercise of our Listed Warrants. If our management takes advantage of this option, all holders of Listed Warrants would pay the exercise price by surrendering their Listed Warrants for that number of shares of Common Stock equal to the quotient obtained by dividing: (x) the product of the number of shares of Common Stock underlying the Listed Warrants, multiplied by the difference between the exercise price of the Listed Warrants and the "fair market value" (defined below); by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of the Common Stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of Listed Warrants. If our management takes advantage of this option, the notice of redemption will contain the information necessary to calculate the number of shares of Common Stock to be received upon exercise of the Listed Warrants, including the "fair market value" in such case. Requiring a cashless exercise in this manner will reduce the number of shares to be issued and thereby lessen the dilutive effect of a warrant redemption. We believe this feature is an attractive option to us if we do not need the cash from the exercise of the Listed Warrants after our initial business combination. If we call our Listed Warrants for redemption and our management does not take advantage of this option, our Sponsor and its permitted transferees would still be entitled to exercise their Private Placement Warrants (as described below) for cash or on a cashless basis using the same formula described above that other warrant holders would have been required to use had all warrant holders been required to exercise their Listed Warrants on a cashless basis, as described in more detail below.

A holder of a warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 4.9% or 9.8% (or such other amount as a holder may specify) of the shares of Common Stock outstanding immediately after giving effect to such exercise.

If the number of outstanding shares of Common Stock is increased by a stock dividend payable in shares of Common Stock, or by a split-up of shares of Common Stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of Common Stock issuable on exercise of each warrant will be increased in proportion to such increase in the outstanding shares of Common Stock. A rights offering to holders of Common Stock entitling holders to purchase shares of Common Stock at a price less than the fair market value will be deemed a stock dividend of a number of shares of Common Stock equal to the product of: (i) the number of shares of Common Stock actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Common Stock); and (ii) one (1) minus the quotient of: (x) the price per share of Common Stock paid in such rights offering, divided by (y) the fair market value. For these purposes: (i) if the rights offering is for securities convertible into or exercisable for Common Stock, in determining the price payable for Common Stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion; and (ii) fair market value means the volume weighted average price of Common Stock as reported during the ten (10) trading day period ending on the trading day prior to the first date on which the shares of Common Stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the Listed Warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to the holders of Common Stock on account of such shares of Common Stock (or other shares of our capital stock into which the Listed Warrants are convertible), other than: (a) as described above; or (b) certain ordinary cash dividends, then the warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of Common Stock in respect of such event.

If the number of outstanding shares of our Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of Common Stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of Common Stock issuable on exercise of each warrant will be decreased in proportion to such decrease in outstanding shares of Common Stock.

Whenever the number of shares of Common Stock purchasable upon the exercise of the Listed Warrants is adjusted, as described above, the warrant exercise price will be adjusted (to the nearest cent) by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of Common Stock purchasable upon the exercise of the Listed Warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of Common Stock so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding shares of Common Stock (other than those described above or that solely affects the par value of such shares of Common Stock), or in the case of any merger or consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our outstanding shares of Common Stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the Listed Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Listed Warrants and in lieu of the shares of our Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Listed Warrants would have received if such holder had exercised their Listed Warrants immediately prior to such event. If less than 70% of the consideration receivable by the holders of Common Stock in such a transaction is payable in the form of Common Stock in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the warrant properly exercises the warrant within thirty days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the warrant agreement based on the Black-Scholes value (as defined in the warrant agreement) of the warrant. The purpose of such exercise price reduction is to provide additional value to holders of the Listed Warrants when an extraordinary transaction occurs during the exercise period of the Listed Warrants pursuant to which the holders of the Listed Warrants otherwise do not receive the full potential value of the Listed Warrants.

The Listed Warrants were issued in registered form under a warrant agreement between Continental, as warrant agent, and us. The description of the Listed Warrants set forth herein is a summary and does not purport to be complete. The warrant agreement provides that the terms of the Listed Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then outstanding Listed Warrants to make any change that adversely affects the interests of the registered holders of Listed Warrants.

The Listed Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of Listed Warrants being exercised. The warrant holders do not have the rights or privileges of holders of Common Stock and any voting rights until they exercise their Listed Warrants and receive shares of Common Stock. After the issuance of shares of Common Stock upon exercise of the Listed Warrants, each holder will be entitled to one (1) vote for each share held of record on all matters to be voted on by stockholders.

We have agreed that, subject to applicable law, any action, proceeding or claim against us arising out of or relating in any way to the warrant agreement will be brought and enforced in the courts of the City of New York, County of New York, State of New York or the United States District Court for the Southern District of New York, and we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. This provision applies to claims under the Securities Act but does not apply to claims under the Exchange Act or any claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Listing

Our Common Stock and Listed Warrants are traded on the Nasdaq Capital Market under the symbols “ICU” and “ICUCW,” respectively.

BUSINESS

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

Overview

We are a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. Our SCD is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body. It has broad potential applications for patients suffering from both acute and chronic kidney disease as well as cardiovascular and other serious inflammatory diseases.

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

Our SCD therapy has been awarded BDD for six therapeutic indications by the FDA, including the use of the SCD therapy for adult patients with AKI, patients with cardiorenal syndrome LVAD implantation, patients with hepatorenal syndrome, and patients with ESRD. The BDD enables the potential for a speedier pathway to approval and the ability to have more frequent and flexible meetings with FDA.

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

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

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

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

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

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 150 patients reduced mortality rates by 50%, and, of those patients who survive 60 days, none have required dialysis.

SCD Therapy for Pediatric Patients

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

We commenced our first product shipment of QUELIMMUNE in July 2024 and are now targeting top-tier pediatric medical facilities for adoption of the QUELIMMUNE therapy. As a condition of the approval, the FDA stipulated that we would need to institute a post approval patient surveillance registry to track certain safety and performance metrics. This typically requires an Internal Review Board (“IRB”) review and approval to use QUELIMMUNE therapy at the medical facility, which can lengthen the QUELIMMUNE adoption process. To date, we have 5 active commercial sites that have completed the registry process and have purchased and used QUELIMMUNE therapy. Additional site activations are planned for 2025.

SCD Therapy for Adult Patients

We are currently conducting a pivotal trial, NEUTRALIZE-AKI, to evaluate the safety and efficacy of our SCD therapy in 200 adults with AKI in intensive care units receiving CRRT. The trial’s primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with SCD therapy in addition to CRRT as the standard of care, compared with the control group receiving only CRRT standard of care. The trial protocol includes an interim analysis by an independent Data Safety Monitoring Board (“DSMB”) at the trial’s 90-day primary endpoint with the first 100 subjects. As of June 12, 2025, we had enrolled 108 patients in the pivotal trial. We anticipate reporting topline clinical trial results and the submission of a Pre-market Approval (“PMA”) application in 2026.

We are also evaluating additional clinical development of the SCD therapy in adults based on unmet clinical needs and market opportunity. Our BDD awards by the FDA in four therapeutic areas are expected to expedite the clinical development and regulatory review of the SCD therapy for use in the designated patient populations and are the primary focus of our future clinical development decisions. We received our first BDD in 2022, two additional BDDs in 2023, and a fourth BDD in 2024.

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

- On September 28, 2023, we received BDD for our SCD for use in patients in the hospital ICU with acute or chronic systolic heart failure and worsening renal function due to cardiorenal syndrome or right ventricular dysfunction awaiting implantation of a left ventricular assist device.

- On October 18, 2023, we received BDD designation for our SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure.

- On November 6, 2024, we received BDD for our SCD to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic hemodialysis, also known as chronic dialysis. This is our first BDD in a chronic disease setting.

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

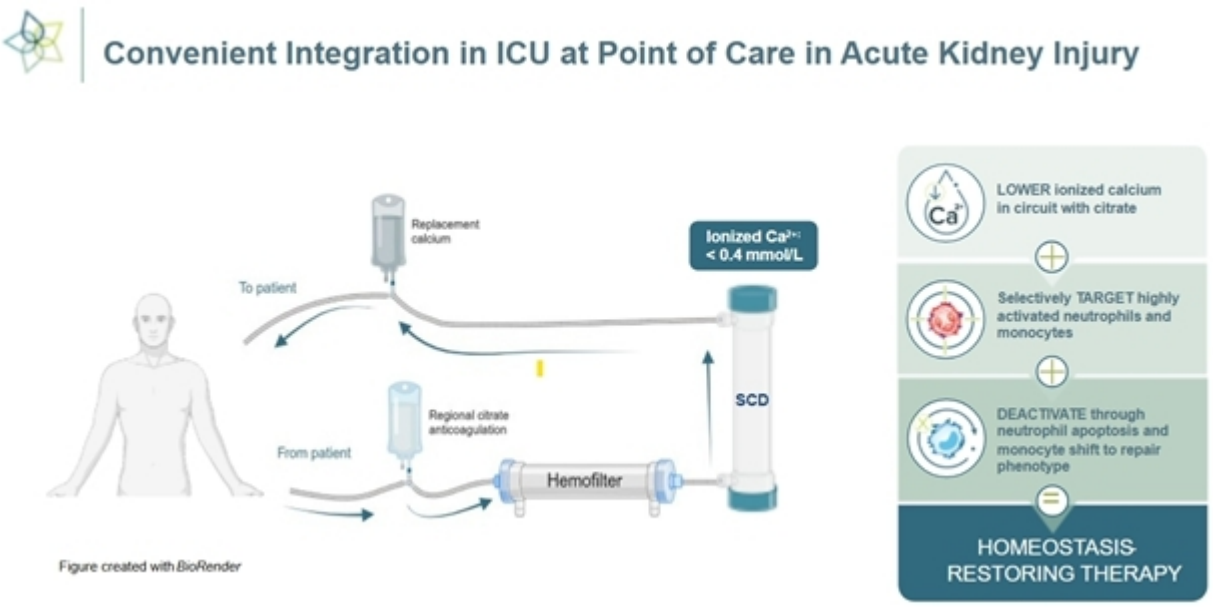
We have pursued patent protection for our SCD therapy as well as other technologies. Our patent portfolio consists of 34 patents and 7 pending patent applications in the U.S. and certain foreign jurisdictions. Of these patents and patent applications 20 patents and 4 patent applications are owned exclusively by us, and 14 patents and 3 patent applications are co-owned with the University of Michigan ("UOM"). The UOM has granted to us an exclusive worldwide, royalty bearing license to the UOM's interest in all of the co-owned patents and applications. This license permits us to commercialize our SCD therapy in all human therapeutic indications. For more information, see *"- Intellectual Property"* below.

Our Approach - The SCD Therapeutic Device

Our SCD therapy is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body. In many serious acute illnesses, a hyperinflammatory response occurs as a well-defined coordinated sequential response. Neutrophils are the first responders followed by monocytes. The monocytes, as they egress into tissue also follow another sequence of differentiation into tissue macrophages. The first are proinflammatory macrophages, followed by patrolling, reparative macrophages.

This complex highly coordinated process is critical for host defense and tissue repair but needs to be tightly regulated by the body's inflammatory signaling and cellular apoptosis. If it is not tightly regulated and begins to spiral out of control, further tissue destruction may occur when uncontrolled hyperinflammation leads to degradative 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 therapy is an extracorporeal synthetic membrane device designed to bind activated leukocytes (neutrophils and monocytes) when integrated into an existing CRRT circuit in conjunction with the use of regional citrate anticoagulation ("RCA"). The SCD is simply added to the standard CRRT circuit that uses regional citrate anticoagulation and is placed immediately following the standard hemofilter cartridge. Highly inflamed blood from the patient passes through the CRRT system and hemofilter and into the SCD. In the low calcium environment mediated by RCA, the inflamed cells in the blood are modulated towards a less inflammatory state. Upon exiting our SCD under a low calcium environment, the blood is returned to the patient's body.

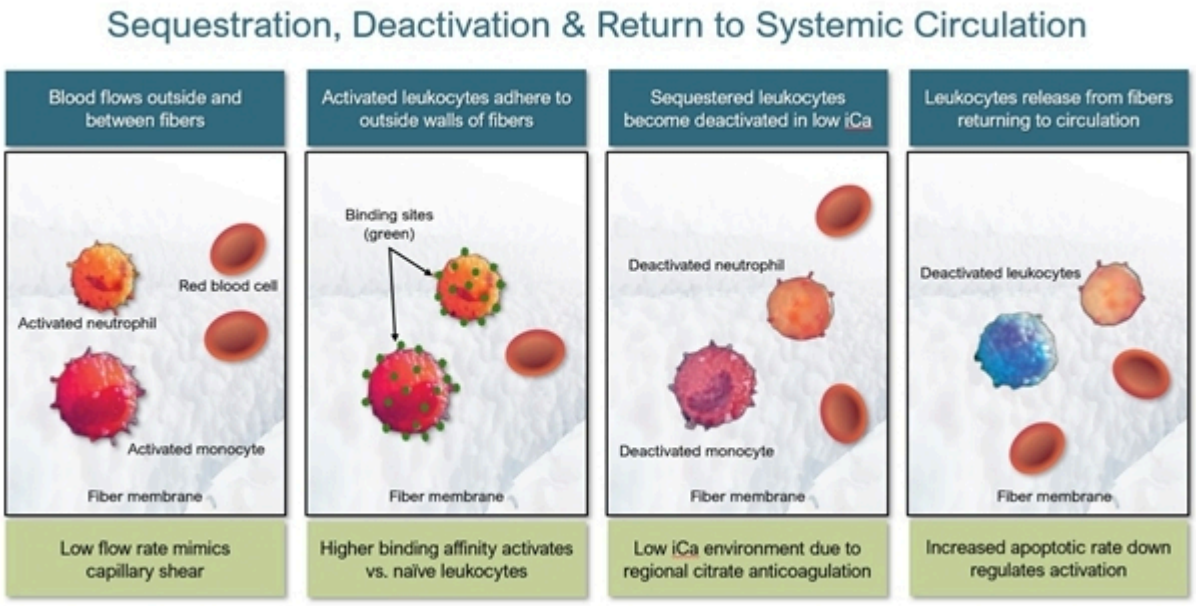


Our SCD therapy delivers its therapeutic benefit by attenuating the excessive inflammatory response of activated neutrophils and monocytes. Uninterrupted, the excessive inflammatory response progresses to multi-organ failure, with documented increases in both morbidity and mortality in critically ill patients. Our initial approved product, QUELIMMUNE, is focused on critically ill AKI pediatric patients on CRRT. Our SCD therapy leverages the existing footprint of CRRT pump systems in ICUs today, as well as the growing use and adoption of 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 has been shown to be more effective in preserving filter life and is used to create the low calcium environment for our SCD therapy, which impacts the white cells interaction with the SCD membrane leading to the reduction in inflammation.

Mechanism of Action

The mechanism of action of our SCD therapy consists of three elements: (i) selectively binding activated neutrophils and monocytes on our SCD biomimetic membrane (ii) deactivating the activated neutrophils by maintaining a specified ionized calcium level within our SCD, and (iii) shifting proinflammatory monocytes to a lower inflammatory profile. Our SCD utilizes clinically validated regional citrate anticoagulation protocols to lower the ionized calcium level, which not only prevents clotting within the circuit but also immuno-modulates the activated neutrophils and monocytes, which are then returned to the patient.

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



Our SCD and Neutrophils

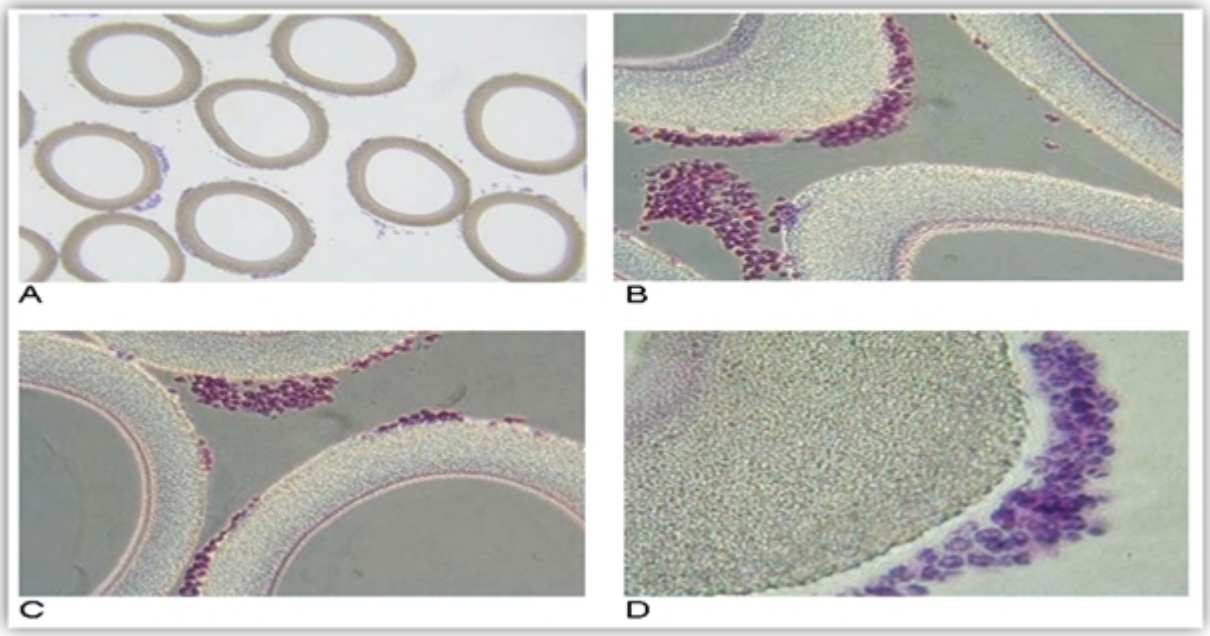
Calcium plays a critical role in many biological processes. In the case of neutrophils, calcium can have a profound effect on their activity. It has been shown that lowering calcium to critical levels in the regional circuit can lead to higher levels of neutrophil apoptosis (deactivation). Our SCD is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

Our SCD and Monocytes

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

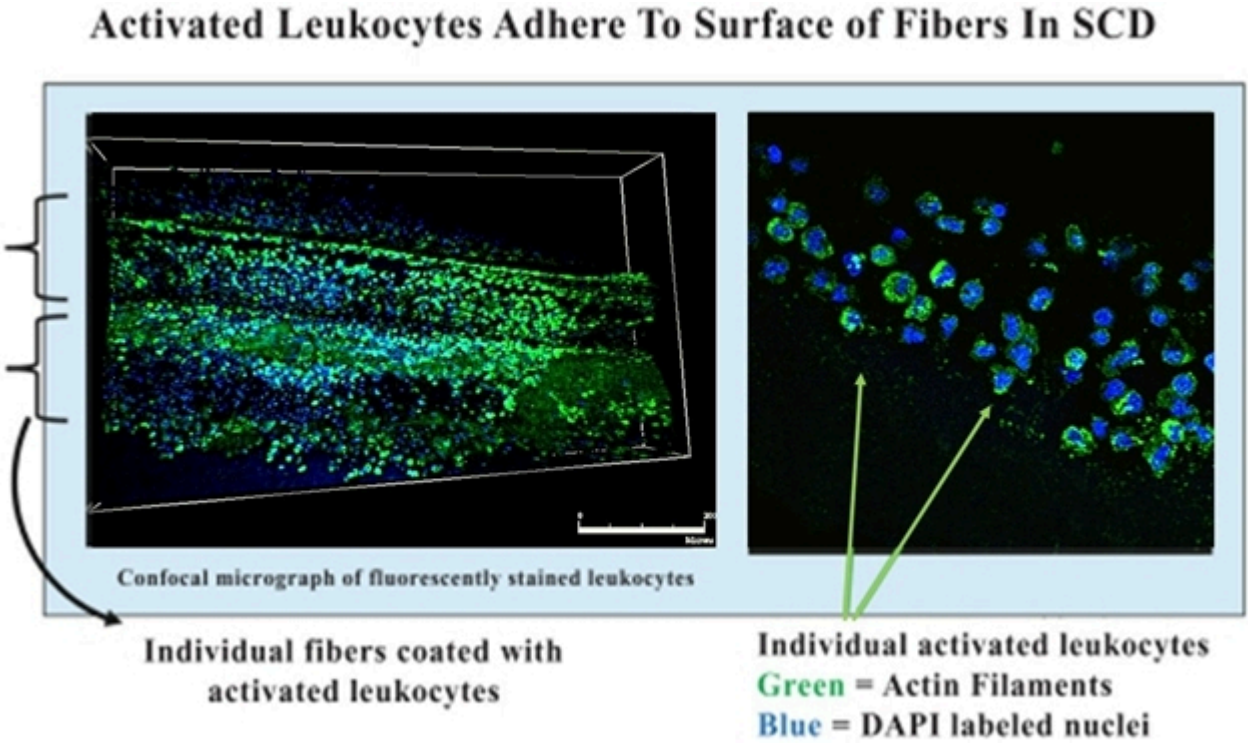
Histological evaluation of our SCD

Microscopy of our SCD after being used for patient treatment demonstrated the binding of leukocytes on the outer surface of the hollow fiber membranes of the cartridge along the blood flow path within the extracorporeal circuit. Flow cytometry confirmed that they were the most activated neutrophils and monocytes (see Figure 1 below).



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

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



Our Market Opportunity

We are a therapeutic medical device company pursuing multiple large market indications with our SCD. Our clinical data was initially used to support an HDE submission to the FDA to request approval to market our SCD to hospitals and clinicians with pediatric patients suffering from AKI. Our clinical data has also been used to support the initiation of a pivotal PMA study in adult AKI which has an estimated 210,000 patients annually in the United States. In the long term, based on preliminary clinical evidence, we intend to expand the application of our SCD technology to additional indications with large patient populations, including acute respiratory distress syndrome, chronic dialysis, cardiorenal syndrome and hepatorenal syndrome and others.

Our Initial Market Opportunity in Acute Kidney Injury

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, an international consensus classification for AKI staging and diagnosing guidelines introduced in 2004, the Acute Kidney Injury Network staging system in 2007, and finally the Kidney Disease: Improving Global Outcomes, AKI Staging and Diagnosing Guidelines published in 2012. These sources have helped clinicians to improve recognition, staging, diagnosing and subsequent documentation of less obvious cases of AKI secondary diagnoses. While our initial market is focused on AKI patients on CRRT, future indications will likely benefit from improved characterization and diagnosis of patients.

As a result, demand for ICU renal replacement therapy is growing. CRRT is the newest 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, complementary therapies, and pharmacoeconomics. 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 the UOM, which licenses to us certain key technology underpinning our novel immunomodulatory therapy, as well as other leading academic hospitals and institutions throughout the U.S. Such relationships enable us to expand and refine the design and execution of our clinical plans with a more targeted outcome and objectives. On February 21, 2024, we received the FDA HDE Approval Order, which allows sales to qualified healthcare facilities. In February 2023, we 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 a BDD for our patented and cell-directed SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure. On November 6, 2024, we received Breakthrough Device Designation for our patented and cell-directed SCD to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic hemodialysis, also known as chronic dialysis. We have been granted four 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 the commercial launch of our SCD in pediatrics (QUELIMMUNE) as well as additional adult 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 cartridges, tubing and other components, to establish redundancies and alternative sources to mitigate interruptions in the supply chain in the future. In addition, we may also explore strategic relationships with partners who can provide sources of raw materials while collaborating with us on the marketing and distribution of our product candidates.

Our Commercial Stage Product

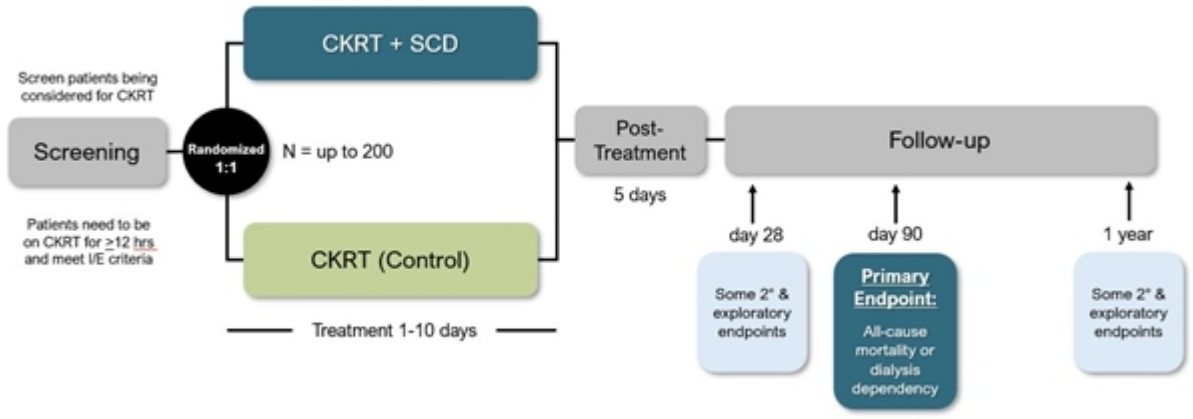
The following disclosure summarizes the key clinical studies in which our SCD product candidates (QUELIMMUNE for pediatrics) have been evaluated. All trials and studies below are conducted under IDEs approved by the FDA.

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, which allows us to commercialize QUELIMMUNE. As of the date of this report, we have five commercial customers and several potential customers evaluating QUELIMMUNE.

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 BDD (April 2022) by the FDA. This trial (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

As of June 12, 2025, we have enrolled 108 patients into our SCD-006 pivotal trial. 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 24 to 28 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 the middle of the 2025 calendar year and topline study results and submission of a PMA application in the middle of the 2026 calendar year. Additional clinical studies under IDEs include cardiorenal syndrome and hepatorenal syndrome. We are also conducting exploratory clinical research with the University of Michigan to define the patient population for potential treatment with SCD product candidates, and any future studies will be based upon initial clinical data collected in these studies.

Other Clinical Studies

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. *ASAIO J*. 2011;57(5):426-432).
ARF-002	AKI Safety, Mortality and Device Integrity Study	Safety and 60-day survival	AKI	N=35	None	Death from any cause at day 60 was 31.4% (11/35). Renal recovery, defined as dialysis independence, was observed in all of the surviving subjects at day 60. Standard of care therapy is associated with a >50% 60-day mortality (Tumlin JA, et al. *Semin Dial*. 2013;26(5):616-623).
SCD-003	To determine the difference between SCD therapy and CKRT alone in survival	Day 60 survival	AKI	N=134	None	This was a Phase 3A randomized controlled trial. Due to a nationwide calcium shortage during the study, most patients received ineffective therapy as regional ionized calcium (iCa) levels couldn't be maintained at the target range. This resulted in no differences in outcomes in the intent-to-treat patient population. However, the subset of patients who achieved the target iCa ranges showed a significant clinical benefit in a per-protocol (PP) analysis. In this group, the 60-day mortality rate was 16% in the SCD-treated group compared to 41% in the control group. Furthermore, the composite endpoint of mortality and/or dialysis dependency at day 60 was lower in the PP SCD-treated group compared to the control group (16% vs. 58%, respectively, p = 0.01) (Tumlin JA, et al. *PLoS One*. 2015;10(8):e0132482). See additional details below on the SCD-003 study
SCD-PED-01	To determine safety and efficacy of SCD therapy + CKRT in pediatric patients	Day 60 survival and 60-day dialysis dependency	AKI	N=16	None	75% of patients (12/16) survived to hospital discharge. 100% of surviving patients (12/12) were dialysis independent by day 60 (Goldstein SL, et al. *Kidney Int Rep*. 2020;6(3):775-784; Goldstein SL, et al. *Kidney Medicine.*2024, doi: https://doi.org/10.1016/j.xkme.2024.100). See additional details below on the SCD-PED studies.
SCD-PED-02	To assess the safety of SCD in children with AKI weighing ≥10 kg and ≤20 kg	Safety	AKI	N=6	None	5/6 (83%) patients survived to ICU discharge and all surviving patients were dialysis-independent by day 60 (Goldstein SL, et al. *Kidney Medicine*. 2024, doi: https://doi.org/10.1016/j.xkme.2024.100). See additional details below on the SCD-PED studies.
SCD-005	To assess the safety and efficacy of SCD in AKI or	Mortality at day 60; dialysis dependency	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

ARDS patients associated with COVID-19 infections	at day 60; ventilation at day 28	subjects who received >96 hours of SCD treatment, per protocol, had a further reduction in mortality to 31% (5/16) (P<0.012) (Yessayan LT, et al. *Crit Care Explor*. 2022;4(5):e0694).

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 intensive care units of each participating hospital were randomized to intensive care treatment for patients undergoing CRRT or CRRT + SCD. Each participating clinical site used their established RCA protocol for the CRRT + SCD circuits (treatment group) and for the CRRT only (control group). The recommended calcium (iCal) level (measured post SCD) in the CRRT and SCD blood circuit was specified to be between 0.25 and 0.40 mmol/L. Inclusion and exclusion criteria were similar to the previous IDE multicenter pilot clinical study except for an age range of 8-80 years and body weight of over 135 kilograms. Once the patient met all eligibility criteria, including being on CRRT for a minimum of four hours, but no longer than 24 hours, and had signed an informed consent, the subject was randomized in a 1:1 allocation utilizing a random permuted block design into either the control or treatment group, stratified by study center and the presence of severe sepsis. 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 groups were maintained in the recommended iCal range (0.23 - 0.40 mmol/L), as specified in the study protocol, was substantially lower than expected. Of the 134 patients enrolled in the SCD-003 protocol at the time of the interim analysis, 19 SCD patients (CRRT + SCD) and 31 control patients (CRRT alone) were maintained in the protocol’s recommended range for greater or equal to 90% of the therapy time. The study was subsequently terminated.

No statistically significant difference was found between the SAEs of the control and treatment groups. The study reported 71 SAEs in the control group (40 of the 63 patients) and 80 SAEs in the SCD treatment group (45 of the 69 patients). The most frequent categories of SAEs were infections and infestations as well as cardiac, respiratory, thoracic and mediastinal disorders. 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 UOM

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

Pilot Feasibility Trial of SCD Therapy in ESRD Patients

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

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 2023 (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 procure conventional components such as tubing sets, clamps, fittings, and labels from various suppliers. These components are then used in our assembly of SCD clinical kits. Critical components are procured from suppliers that have been approved and qualified through our supplier management program. Fresenius Medical Care North America ("FMCNA") is the current supplier of the cartridges used in our SCD.

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

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

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

Distribution

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

On December 27, 2022, we entered into a license and distribution agreement with Nuwellis. We appointed Nuwellis as our exclusive distributor for the sale and distribution of SCD product throughout the United States once we receive written authorization from the FDA to market our SCD for pediatric use pursuant to our HDE application. In May 2024, we provided notice to Nuwellis that Nuwellis had breached the Distribution Agreement and that the Distribution Agreement would terminate effective August 18, 2024. As of December 31, 2024, the license and distribution agreement with Nuwellis was terminated and we have hired sales and marketing employees focused on the commercialization of QUELIMMUNE into the U.S. market.

Third-Party Reimbursement

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

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

Intellectual Property

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

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

We currently have 16 issued U.S. patents and 4 pending U.S. patent applications. We also have 18 issued foreign patents and 3 pending foreign patent applications. We have issued patents that have terms expiring from 2025 through 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, 2024:

	U.S. Patents	Foreign Patents	U.S. Applications	Foreign Applications
SCD Technology (Patent Families 1-5)	14	18	2	3
Other Technology (Patent Families 6-9)	2	-	2	-
Total	16	18	4	3

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

Patent Family 1 contains nine U.S. patents 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 the UOM counterpart patents granted in Canada, Japan and New Zealand, and pending applications in Europe and Hong Kong. These counterpart patents, and pending applications, if granted, will expire in 2028, assuming that the required maintenance fees are paid. The patents and applications in Patent Family 1 are as follows:

Patent Family 1†

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2031	Methods for processing leukocytes and methods for treating subjects having inflammatory conditions using such methods
United States	Granted	2029	Methods for treating subjects undergoing a cardiopulmonary bypass
United States	Granted	2029	Methods for treating subjects with end-stage renal disease
United States	Granted	2029	Methods for treating subjects with acute renal failure
United States	Granted	2029	Methods for treating subjects with sepsis
United States	Granted	2031	A device that processes activated leukocytes and platelets
United States	Granted	2029	Methods for treating acute lung injury and acute respiratory distress syndrome
United States	Granted	2029	Systems for treating activated platelets
United States	Granted	2028	Systems for treating activated leukocytes
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
Europe	Pending	2028*	A device that processes platelets or leukocytes
Hong Kong	Pending	2028*	A device for treating an inflammatory condition

* 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 the UOM (as amended and restated, the "UOM License Agreement"), UOM has granted us a worldwide, royalty bearing, exclusive license to their interest in the co-owned patents and applications in Patent Family 1 in the field of medical devices for use in human therapeutics for certain technologies used in the SCD technology platform, including composition of matter and methods of use patents. In consideration for such exclusive license, during the term of the UOM License Agreement, we agreed to pay the UOM a royalty fee equal to 1% of net sales as well as a one-time milestone payment of $0.1 million upon FDA approval of the first licensed product under the license, and to reimburse patent costs. As of December 31, 2024, we have incurred less than $5 thousand in royalties owed from sales of the Pediatric SCD. Since January 2020, we have paid approximately $0.1 million to the UOM to reimburse patent costs under the license. 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, the UOM's liability is limited and we agreed to indemnify and hold the UOM harmless in connection with the use of the licensed technology and activities related to the products created using such licensed patents and/or technology. In October 2024, the parties amended the agreement to eliminate the 10% of any milestone payments, fees, etc. in exchange for extending the 1% royalty on net sales until the later of (a) expiration of the last to expire of the patent rights or (b) the ten (10) year anniversary of the first commercial sale, unless sooner terminated as provided in another specific article of this agreement.

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

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

Patent Family 2†

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2032	Cartridge for treating leukocytes or platelets
United States	Granted	2032	Methods for processing leukocytes or platelets and for treating a subject with an inflammatory condition
United States	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 and the United Kingdom	Granted	2031	Cartridge for sequestering leukocytes or platelets
Canada	Granted	2031*	Cartridge for processing leukocytes or platelets
Japan	Granted	2031	Cartridge for treating leukocytes or platelets
Japan	Granted	2031	Cartridge for treating leukocytes or platelets

* 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 Canada, and a patent application is pending in Europe. These patents, and patent application, if granted, will expire in 2032, assuming that the required maintenance fees are paid. The patents and applications in Patent Family 4 are as follows:

Patent Family 4†

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

* Expiration date if application is granted.

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

With respect to our other technologies, we solely own patents and patent applications in four additional patent families (Patent Families 5-8) which are summarized as follows:

Patent Family 5

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 6

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 7

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

Patent Family 8

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

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

Competition

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

In both the United States and international markets, the use of medical devices is related in part to the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Therapies that present a cost-neutral to cost-beneficial impact to the health economic system are generally viewed as more favorable from a reimbursement perspective. To this end, we conducted health economic outcomes research (HEOR) to estimate the economic impact of the SCD-PED (QUELIMMUNE) within the pediatric AKI-CKRT patient population. Our analysis revealed that pediatric AKI hospitalizations involving CKRT were estimated to cost over $450,000 per event, reflecting an enormous burden to healthcare institutions. The median length of stay (“LOS”) was 31 days per hospitalization. QUELIMMUNE therapy was projected to be cost-beneficial by lowering mortality as well as reducing hospital LOS by 3 days in pediatric AKI patients requiring CKRT, with estimated savings of ~$70,000 per hospitalization. These data were presented at the American Society of Nephrology Kidney Week 2024 and at the AKI-CRRT Annual meeting in March 2025, and have been submitted to a leading kidney disease journal for publication. The manuscript is currently in peer review. However, lack of third-party coverage and reimbursement for our devices could delay or limit their adoption, and as such harm our competitive advantage in the market.

Sales and Marketing

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

On December 27, 2022, we entered into a U.S. License and Distribution Agreement with Nuwellis (the "Distribution Agreement"), for the pediatric SCD. On December 29, 2023, we amended the Distribution Agreement with Nuwellis. In May 2024, we provided notice to Nuwellis that Nuwellis had breached the Distribution Agreement and that the Distribution Agreement would terminate effective August 18, 2024. As of December 31, 2024, the License and Distribution agreement with Nuwellis was terminated.

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

Government Regulation

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

FDA's Pre-market Clearance and Approval Requirements

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

Premarket Approval Pathway

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

After a premarket 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 premarket 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 gathers information to address FDA requests for additional information. The total review process is highly variable and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device.

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

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

Humanitarian Device Exemption Pathway

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

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

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

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

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

- occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

- occurs in adult patients and does not occur in pediatric patients or occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

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

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

HDE amendments, supplements, and reports are generally subject to similar requirements as those for PMAs, and in fact the requirements for each of these types of HDE submissions refers back to the regulatory requirements for its PMA counterpart.

FDA's decision to "file" or "not file" an HDE application will be made within 30 calendar days from the date the HDE application was received. Overall, an HDE must be reviewed and a final determination made by FDA within 75 days from the date of the application being filed; however, the review of the application may occur over a significantly longer period of time due to hold periods during which the submitting sponsor gathers information to address FDA requests for additional information.

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

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

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

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

The ADN is calculated by taking the number of devices reasonably necessary to treat or diagnose an individual per year and multiplying it by 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-PED (brand name QUELIMMUNE) is eligible to sell for profit as per the Final Approval Order issued to us on February 21, 2024.

Clinical Trials

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

Ongoing Regulation by the FDA

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

- Upkeep of establishment registration and device listing;
- Adherence to quality system regulations, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- Adherence to labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses and other requirements related to promotional activities;

- Adherence to medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; and

- Adherence to corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health.

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

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

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;

- customer notifications, voluntary or mandatory recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;

- delay in processing submissions or applications for new products or modifications to existing products;

- withdrawing approvals that have already been granted; and

- criminal prosecution.

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

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

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

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

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

Coverage and Reimbursement

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

Employees

As of May 13, 2025, we had 19 full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate History

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

On October 28, 2022, LMF Acquisition Opportunities, Inc. ("LMF"), a Delaware special purpose acquisition company, consummated a series of transactions that resulted in the combination Merger Sub and the Predecessor, a Delaware corporation, pursuant to 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. Following the consummation of the Business Combination, LMF was renamed "SeaStar Medical Holding Corporation".

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 prospectus.

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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Objective

The following discussion and analysis are intended to help you understand our business, financial condition, results of operations, liquidity, and capital resources. You should read this discussion in conjunction with our consolidated financial statements and related notes included elsewhere in this prospectus. 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 in this prospectus.

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 and the Predecessor (the transaction herein defined as the "Business Combination" or "Merger"). In connection with the Business Combination, the Predecessor was determined to be the accounting acquirer.

Overview

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

We are a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. Our Selective Cytopheretic Device ("SCD") is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body. It has broad potential applications for patients suffering from both acute and chronic kidney disease as well as cardiovascular and other serious inflammatory diseases.

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

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

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

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

Clinicians typically address hyperinflammation with therapies that are either immunosuppressive or that target one cytokine, both of which are generally suboptimal in the treatment of hyperinflammation. We believe our technology has the potential to overcome limitations in existing anti-inflammatory treatments and address the challenge of selectively targeting activated neutrophils and monocytes. Clinical and preclinical studies conducted over the last 15 years have demonstrated that our SCD therapy can modulate the degree of activity of proinflammatory cells to help reduce tissue damage and speed the repair and recovery of organ function. Data from our trials demonstrated that the use of our SCD therapy to reverse the cytokine storm in more than 150 pediatric and adult patients with acute kidney injury on CRRT reduced mortality rates by 50%, and of those patients who survived 60 days, none have required dialysis. We believe our SCD therapy has the potential to transform the treatment of acute organ failure in the intensive care unit ("ICU") and to improve organ function in patients with chronic kidney disease, certain cardiovascular diseases, and other serious inflammatory diseases.

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

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

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

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

We have incurred net losses in each year since our inception in 2007. As of March 31, 2025 and December 31, 2024, we had an accumulated deficit of $143.3 million and $139.6 million, respectively. Our net losses were $3.8 million and $12.7 million for the three months ended March 31, 2025, and 2024, respectively. For the three months ended March 31, 2025, substantially all 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. For the three months ended March 31, 2024, our net losses results from a combination of operating costs which comprised (i) research and development, and (ii) general and administrative, coupled with non-operating gains and losses due to changes in the fair value of certain liability classified financial instruments.

As of March 31, 2025, and December 31, 2024, we had cash of $5.3 million and $1.8 million, respectively.

Our accompanying unaudited condensed 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 unaudited condensed 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 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 unaudited condensed consolidated financial statements are made available. See Note 1 to our unaudited condensed consolidated financial statements for the three months ended March 31, 2025, included elsewhere in this prospectus 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 generated revenue of approximately $0.5 million from the sale of commercialized pediatric SCD products. Our ability to generate product revenue in the future will depend on the successful roll-out of our QUELIMMUNE pediatric SCD to hospitals and the development and eventual successful commercialization of our adult SCD. Until such time we are able to generate significant revenue from product sales, 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 and 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 information.

Key Components of Results of Operations

Revenue

Our QUELIMMUNE received HDE approval from the FDA in February 2024. Since that time, we have begun to build out our commercial operations, develop our customer base and initiate commercial sales of QUELIMMUNE. We shipped our first commercial QUELIMMUNE units in July 2024. Through March 31, 2025, we have recognized approximately $0.4 million of revenue from the sale of QUELIMMUNE. Historically, prior period revenue has been primarily derived from government and other grants. We will continue to focus our efforts on generating revenue in the future based on product sales of QUELIMMUNE, as well as potential future payments from license or collaboration agreements and government and other grants.

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

Research and Development Expenses

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

General and Administrative Expenses

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

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

Loss from Operations and Operating Margin

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

Other Income (Expense), Net

Total other income (expense), net primarily consists of interest expense relating to interest incurred on our notes, interest incurred on our convertible notes, change in the fair value of warrants liability, change in fair value of convertible notes, gain on issuance of convertible notes, change in fair value of forward-option forward contracts, and gain on sale of recycled shares.

Net Loss

Net loss consists of the loss from operations, less other expenses.

Factors Affecting Operating Results

We believe that our performance and future success depend on a number of factors that present significant opportunities for us but also pose risks and challenges. Please see the factors discussed elsewhere in this prospectus, including those discussed in the section titled "Risk Factors," for additional information.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 to the Three Months Ended March 31, 2024

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

	Three Months Ended March 31,		Change	
($ in thousands)	**2025**	**2024**	**$**	**%**
Revenue	$ 293	$ —	$ 293	*
Operating expenses				
Research and development	2,431	1,697	734	43%
General and administrative	1,684	2,253	(569)	(25)%
Total operating expenses	4,115	3,950	165	4%
Loss from operations	(3,822)	(3,950)	128	(3)%
Total other income (expense)	53	(8,747)	8,800	(101)%
Loss before income tax provision	(3,769)	(12,697)	8,928	(70)%
Income tax provision (benefit)	3	—	3	*
Net loss	$ (3,772)	$ (12,697)	$ 8,925	(70)%

(*) - there was no activity for the three months ended March 31, 2024.

Revenue

Revenue increased $0.3 million for the three months ended March 31, 2025 compared to the three months ended March 31, 2024, as we commenced commercial sales in July 2024. This was made possible because we obtained an HDE for QUELIMMUNE in February 2024, and final regulatory clearance to sell commercially from the FDA under this HDE in July 2024. The Company has five customer sites for QUELIMMUNE as of March 31, 2025.

Research and Development Expenses

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

($ in thousands)	Three Months Ended March 31, 2025	2024	Change $	Change %
Clinical trials	$ 1,268	$ 613	$ 655	107%
External services	102	345	(243)	(70)%
Payroll and personnel expenses	925	690	235	34%
Other research and development expenses	136	49	87	178%
	$ 2,431	$ 1,697	$ 734	43%

Research and development expenses for the three months ended March 31, 2025 and 2024 were $2.4 million and $1.7 million, respectively. The increase in research and development expenses of approximately $0.7 million, or 43%, was primarily driven by (i) a $0.7 million increase in clinical trial costs due the Company's NEUTRALIZE-AKI pivotal trial, which increased from five (5) clinical trial sites as of March 31, 2024, to sixteen (16) clinical trial sites as of March 31, 2025, (ii) a $0.2 million increase in personnel costs related to increased headcount during the three months ended March 31, 2025 compared to this same period ended March 31, 2024, (iii) $0.1 million increase in other costs, mostly due to an increase in medical affairs activities.

This was offset by a $0.2 million decline in external services, due to (i) pre-clinical activities declined during the three months ended March 31, 2025 compared to the same period ended March 31, 2024, as the NEUTRALIZE-AKI pivotal trial was in its formative stage during the three months ended March 31, 2024, while, as of March 31, 2025, the Company had already enrolled 94 patients, and (ii) a $0.1 million decline in device component expenses, as the Company did not commence commercial operations until July 2024, and the cost of components used to manufacture the Company's SCDs were expensed to research and development expense in Q1 2024, while components purchased in Q1 2025 are recognized as inventory.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2025 and 2024 were approximately $1.7 million and $2.3 million, respectively. The $0.6 million decrease in general and administrative expenses of approximately was the result of (i) $0.2 million decline in accounting related costs, as the Company during the three months ended March 31, 2024, incurred additional costs due to certain financial statement restatements that were not incurred during the three months ended March 31, 2025, (ii) $0.2 million decline in legal related expenses, (iii) $0.2 million decline in consulting expenses. This was offset by a $0.1 million increase in SEC-related expenses due to the Company's need for a special meeting of the shareholders during the three months ended March 31, 2025, and other non-routine filing demands.

Other Income (Expense)

Other expenses (net) decreased approximately $8.8 million, or near a decline of 100% for the three months ended March 31, 2025, compared to the three months ended March 31, 2024. The key drivers for this decrease were as follows: (i) the Company recognized a loss of $5.8 million for changes in the fair value of convertible notes during the three months ended March 31, 2024, however, the Company did not have any convertible notes outstanding during the three months ended March 31, 2025, (ii) the Company recognized a gain of $16 thousand for its liability classified warrants for the three months ended March 31, 2024, while incurring a loss of approximately $2.8 million for the three months ended March 31, 2023, largely driven by the value of the Company's stock, (iii) the Company recognized interest income, net of expenses of $37 thousand, compared to interest expense of $143 thousand during the three months ended March 31, 2024. This was because the Company reduced its outstanding debt obligations from approximately $4.2 million at March 31, 2024, to $0.4 million as of March 31, 2025, and implemented an overnight sweep program with its main commercial banking financial institution beginning in the second quarter of 2024.

Income Tax Provision (Benefit)

We recorded a provision for income taxes of $3 thousand for the three months ended March 31, 2025, and no provision for income taxes for the three months ended March 31, 2024.

Net Loss

During the three months ended March 31, 2025, we had a net loss of approximately $3.8 million compared to a net loss of approximately $12.7 million for the three months ended March 31, 2024. The decreased net loss of approximately $8.9 million has been disclosed in the above discussion.

Comparison of Year Ended December 31, 2024 to Year Ended December 31, 2023

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 prospectus.

	Year Ended December 31,		Change	
($ in thousands)	**2024**	**2023**	**$**	**%**
Net Revenue	$ 135	$ -	$ 135	(*)
Operating expenses				
Research and development	9,105	5,973	3,132	52.4%
General and administrative	8,872	8,237	635	7.7%
Total operating expenses	17,977	14,210	3,767	26.5%
Loss from operations	(17,842)	(14,210)	(3,632)	25.6%
Total other income (expense)	(6,985)	(12,022)	5,037	-41.9%
Loss before income tax provision	(24,827)	(26,232)	1,405	-5.4%
Income tax provision (benefit)	3	-	3	(*)
Net loss	$ (24,830)	$ (26,232)	$ 1,402	-5.3%

(*) - revenue or expenses which were new to the year ended December 31, 2024 compared to the year ended December 31, 2023.

Revenue

Net revenue increased $0.1 million to $0.1 million for the year-ended December 31, 2024, compared to no net revenue for the year-ended December 31, 2023. The increase is attributable to the commencement of sales after receiving approval from the FDA to commercially sell our pediatric selective cytopheretic device, QUELIMMUNE, on February 21, 2024. Sales did not occur until after July 1, 2024.

Research and Development Expenses

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

	Year Ended December 31,		Change	
($ in thousands)	**2024**	**2023**	**$**	**%**
Clinical trials	$ 4,391	$ 2,546	$ 1,845	72.5%
External services	1,254	1,111	143	12.9%
Payroll and personnel expenses	3,184	2,164	1,020	47.1%
Other research and development expenses	276	152	124	81.6%
	$ 9,105	$ 5,973	$ 3,132	52.4%

Research and development expenses for the years ended December 31, 2024 and 2023 were approximately $9.1 million and $6.0 million, respectively. The increase in research and development expenses of $3.1 million, or 52.4%, was primarily driven by increases in clinical trial expenses of $1.8 million and external services of $0.1 million due to the Neutralize-AKI Adult SCD study, in which we ended the year 2024 with 14 clinical trial sites enrolled, an increase in payroll and personnel expenses of $1.0 million due to increased head count and equity grants, and an increase in other costs of approximately $0.1 million, due to increased travel and other costs relating to increasing clinical trial site enrollees.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2024 and 2023 were $8.9 million and $8.2 million, respectively. The increase in general and administrative expenses 7.7% is due primarily to (i) an increase in payroll and related expenses of $0.6 million, due to increased head count as we invested in our finance and commercial functions, (ii) a $0.6 million increase in accounting related costs due to the restatement of certain financial statements for the 2023 and 2022 Forms 10-K and for interim period financial statements on Forms 10-Q, (iii) a $0.1 million increase in legal expense, and (iv) a $0.2 million increase in consulting expenses for various strategic and commercial endeavors, offset by (i) a $0.6 million reduction in SEC related expenses as we transitioned from outside parties to internal resources for SEC related filings and compliance activities, and (ii) a $0.3 million decline in other activities such as public relations, investor relations and certain marketing activities.

Other Income (Expense)

Other income (expense) for the years ended December 31, 2024 and 2023 was expense of $7.0 million and $12.0 million, respectively. The decrease of approximately $5.0 million primarily resulted from (i) $4.2 million decline in the loss from the change in fair value on extinguishments of convertible notes, (ii) a decrease in interest expense of $0.8 million due to the reduction in our outstanding notes and convertible notes, (iii) interest income of $0.1 million during 2024 compared to $0.0 million for 2023, and (iv) we did not recognize a loss from the change in the fair value of forward purchase agreement derivative liabilities for 2024 as the instrument did not exist during 2024, while incurring a loss on the change in fair value of forward purchase agreement derivative liabilities of $1.3 million in 2023.

This was primarily offset by an approximately $1.2 million unfavorable impact due to the change in the fair value of liability classified warrants in 2024 compared to 2023.

Income Tax Provision (Benefit)

We recorded a provision for income taxes of $3 thousand for the year ended December 31, 2024, and did not record a provision for income taxes for the year ended December 31, 2023.

Under Accounting Standards Codification (“ASC”) 740-10-30-5, Income Taxes, deferred tax assets should be reduced by a valuation allowance if, based on the weight of available evidence, it is more-likely-than-not (i.e., a likelihood of more than 50%) that some portion or all of the deferred tax assets will not be realized. We consider all positive and negative evidence available in determining the potential realization of deferred tax assets including, primarily, the recent history of taxable earnings or losses. Based on operating losses reported during 2024 and 2023, we concluded there was not sufficient positive evidence to overcome this recent operating history. As a result, we believe that a valuation allowance continues to be necessary based on the more-likely-than-not threshold noted above. A valuation allowance of $28.5 million and $25.6 million was recorded as of and for the years ended December 31, 2024 and 2023, respectively.

Net Loss

During the year ended December 31, 2024, we had a net loss of $24.8 million compared to a net loss of $26.2 million for the year ended December 31, 2023. The decline in net loss of $1.4 million primarily resulted from a decline in other expense of $5.0 million (as discussed above in “Other Income (Expense)”) offset by increases in general and administrative expenses of $0.6 million, and increases in research and development expenses of $3.1 million.

Liquidity and Capital Resources

Sources of Liquidity

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 March 31, 2025 and December 31, 2024, we had an accumulated deficit of approximately $143.3 million and $139.6 million, respectively.

As of March 31, 2025 and December 31, 2024, we had cash of $5.3 million and $1.8 million, respectively. Based on our results of operations and liquidity as of March 31, 2025, we believe our cash and cash equivalents, including the cash we obtained from the registered direct financing in the first quarter of 2025 and the registered direct offering in July 2024, are not sufficient to meet our working capital and capital expenditure requirements for a period of at least twelve months from the date of our unaudited condensed consolidated financial statements for the three months ended March 31, 2025, are made available. We believe that this raises substantial doubt about our ability to continue as a going concern.

To finance our operations, we will need to raise additional capital. As described below, we do not expect to receive any 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 such 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. We do not currently have any committed external source of funds. 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 prospectus. See Note 1 to our unaudited condensed consolidated financial statements for the period ended March 31, 2025.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing 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.

We would receive the proceeds from any exercise of warrants that are exercised for cash pursuant to their terms. To the extent any warrants are exercised 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. The likelihood that warrant holders will exercise the warrants, and therefore the amount of cash proceeds that we would receive from such exercise, is dependent upon the trading price of our common stock. If the trading price for our common stock remains less than the respective exercise price of our outstanding warrants, 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.

As of the date of this registration statement, 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 merit of including potential cash proceeds from the exercise in our liquidity projections.

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 adult SCD for approval by the FDA, invest in our commercialization of our pediatric SCD, and (ii) if regulatory approval is obtained, to launch and commercialize our adult SCD in the U.S. market, including potential 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 new and existing funding sources;
- 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 personnel expense 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.

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. Until such time, if ever, as we are able to generate significant revenue from the commercialization of 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.

Contractual Obligations and Commitments

Insurance Financing

In October 2024, the Company entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of $0.7 million. The Company will pay the remaining five monthly installments of principal and interest totaling approximately $0.4 million with the last payment being made in August 2025.

Cash Flows

Comparison of the Three Months Ended March 31, 2025 to the Three Months Ended March 31, 2024

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

	Three Months Ended March 31,	
($ in thousands)	**2025**	**2024**
Statement of cash flow data:		
Total cash (used in)/provided by:		
Operating activities	$ (2,654)	$ (3,488)
Investing activities	—	—
Financing activities	6,131	8,331
Net increase in cash	$ 3,477	$ 4,843

Cash Flow from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2025 was $2.7 million compared to $3.5 million for the three months ended March 31, 2024. The decrease in cash used for operating activities of $0.8 million is primarily due to the $0.8 million due to the timing of certain (i) payments from customers or to vendors to reduce our cash outflows for operating activities.

Cash Flow from Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2025 was $6.1 million, was primarily related to (i) $1.6 million received from the issuance of new shares of common stock, and (ii) $4.8 million in proceeds from issuance of pre-funded warrants. This was offset by (i) $0.2 million paid to settle outstanding notes payable.

Comparison of Year Ended December 31, 2024 to Year Ended December 31, 2023

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

	Year Ended December 31,	
($ in thousands)	**2024**	**2023**
Statement of cash flow data:		
Total cash (used in)/provided by:		
Operating activities	$ (16,007)	$ (10,285)
Investing activities	-	-
Financing activities	17,650	10,414
	$ 1,643	$ 129

Cash Flow from Operating Activities

Net cash used in operating activities for the fiscal year ended December 31, 2024 was $16.0 million compared to $10.3 million for the fiscal year ended December 31, 2023. The increase in cash used for operating activities of $5.7 million is primarily due to the increased activity related to clinical trial activities for the Neutralize-AKI clinical trial, and certain general and administrative costs.

Cash Flow from Financing Activities

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

Cash provided by financing activity for the fiscal 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

Capital Resources

Sources of Liquidity

Shelf Registrations

Shelf Registration 333-275968 - On December 8, 2023, we filed a shelf registration on Form S-3. which was declared effective by the SEC on December 22, 2023. This shelf registration statement covered the offering, issuance and sale by us of up to an aggregate of $100.0 million of our Common Stock, preferred stock, debt securities, warrants, rights and units (the "2023 Shelf"). Since the date of effectiveness, we have raised approximately $23.5 million as of December 31, 2024, through the combination of registered direct offerings and "*At-the-Market*" offerings. As of December 31, 2024, we have approximately $76.5 million remaining for future offerings, of which, $20.5 million is currently restricted to capital raised from the "*At-the-Market*" offering.

We have raised $1.9 million from our "At-the-Market" program since January 1, 2025. On February 3, 2025, we raised approximately $6.0 million through an offering of our Common Stock.

Future Funding Requirements

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

- conditions in the capital markets;
- our ability to receive cash proceeds from our existing funding instruments, including a potential 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, issuance of debt, borrowings under credit facilities or through potential collaborations with other companies, other strategic transactions or government or other grants. Adequate capital may not be available when needed or on acceptable terms.

Based on our results of operations and liquidity as of March 31, 2025, we believe our cash and cash equivalents 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 fiscal year ended December 31, 2024. 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.

Critical Accounting Policies and Estimates

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

Significant estimates include the valuation of the (i) incurred-but-not-billed clinical trial costs, (ii) prepaid forward purchase agreement derivative liability, (iii) convertible notes (iv) liability classified warrants, (v) 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 consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our annual consolidated financial statements.

Incurred-But-Not-Billed Clinical Trial Site Costs. Our Neutralize-AKI clinical trial study is conducted at 14 qualified healthcare facilities as of December 31, 2024. We are responsible to cover the costs of these clinical trial efforts, including the cost of patient care relating to the adult SCD. It is common practice that the costs incurred by the clinical trial sites are incurred-but-not-billed until months after the event giving rise to the unbilled activity. Accordingly, we estimate the value of these "*incurred-but-not-billed*" activities at the end of each reporting period. Any impact to the Statement of Operations is recognized as a component of research and development expense and included as a component of accrued expenses on the Balance Sheet.

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. 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. This instrument no longer existed as of December 31, 2024.

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. These notes no longer existed at December 31, 2024.

Liability Classified Warrants. We have entered into or assumed various financial instruments in the form of warrant agreements that require classification as liabilities. This classification requires us to measure the warrants at fair value at inception, and the remeasure the warrants. The liability classified warrants consist of the following: (see Note 10 for more information):

- *Private Placement Warrants.* We assumed 229,520 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 years ended December 31, 2024 and 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"). These warrants no longer exist as of December 31, 2024.

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

Share Based Compensation Expense. We estimate the grant date fair value of all grants of equity-based awards (which has historically consisted of either stock options or restricted stock units).

Emerging Growth Company Status

We are an emerging growth company ("EGC"), as defined in the JOBS Act. The JOBS Act permits companies with EGC status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an 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 $1.235 billion, (iii) the date on which we are deemed to be a "large-accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding securities held by non-affiliates, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three-years.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2024:

($ in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual Obligations:					
Note Payable (Insurance Financing)	$ 574	$ 574	$ -	$ -	$ -
Total contractual obligations	$ 574	$ 574	$ -	$ -	$ -

Insurance Financing

In October 2024, we entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of $0.7 million. It is to be paid down in 10 monthly installments through August 2025.

Properties.

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

Legal Proceedings.

Shareholder Derivative Claims

On July 5, 2024, Forrest A K Wells, a purported stockholder of ours, filed a putative class action complaint in the United States District Court for the State of Colorado, captioned Wells v. SeaStar Medical Holding Corporation et al, Case No. 1:24-cv-0187 (D. Colorado). The Class Action alleges that we, our Chief Executive Officer and former Chief Financial Officer made or caused to be made material misstatements or omissions regarding our business and operations, allegedly culminating in our restatement of our consolidated financial statements, disclosed in a Form 8-K and filed on March 27, 2024. The Class Action asserts claims pursuant to the Securities Exchange Act of 1934, including Section 10(b), Rule 10b-5 promulgated thereunder and Section 20(a). The Class Action seeks to recover, among other remedies, compensatory damages. On March 4, 2025, the Plaintiff filed an amended complaint. We intend to vigorously defend the action.

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

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

DIRECTORS AND EXECUTIVE OFFICERS

The following table identifies our current directors and executive officers:

Name	Age	Position
Eric Schlorff	52	Chief Executive Officer and Class III Director
David Green	62	Chief Financial Officer
Kevin Chung, MD	52	Chief Medical Officer
Rick Barnett	65	Class I Director and Chairman of the Board
Jennifer A. Baird	57	Class II Director
Bernadette N. Vincent	66	Class II Director
Kenneth Van Heel	61	Class III Director
John Neuman	59	Class I Director

Directors

Eric Schlorff has served as one of our Directors and our Chief Executive Officer since July 2019 and as Chief Operating Officer from March 2019 to July 2019. Mr. Schlorff also previously served as one of our Directors from June 2016 to May 2019. From 1999 to 2019, Mr. Schlorff served in multiple roles at The Dow Chemical Company in Midland, Michigan and Indianapolis, Indiana. From June 2016 to February 2019, Mr. Schlorff served as Global Director of Alternative Investments for The Dow Chemical Pension Plan, and Global Finance Leader for Crop Protection & Seeds at Dow AgroSciences from June 2013 to June 2016. Additional leadership positions held by Mr. Schlorff include the Global Market Intelligence Leader at Dow AgroSciences, Global Financial Manager of Royalties at Dow AgroSciences, Senior Investment Manager of Alternative Investments at The Dow Chemical Company, New Business Development of Pharmaceuticals at The Dow Chemical Company, Global Financial Analyst within the New Businesses division at The Dow Chemical Company, and Global Financial Analyst within Dow AgroSciences at The Dow Chemical Company. We believe that Mr. Schlorff is well-qualified to serve on the Board due to his intimate knowledge of our business operation, including the scientific basis, regulatory requirements and sales and marketing channels of the SCD products, as well as his extensive experience in financial planning and managing large and complex organizations.

Rick Barnett has served as one of our Directors since January 2021. Mr. Barnett served as President, Chief Executive Officer and Board Member of Satellite Healthcare, Inc. from 2014 to February 2021. Mr. Barnett has served as the Chairman of the Strategic Planning Committee, as well as a member of the Finance, Quality, Risk/Compliance, and Governance/Compensation committees for Satellite Healthcare, Inc. Mr. Barnett has served on the CutisCare, Inc. Board of Directors since 2021 and is a member of the Strategy and Audit Committee. CutisCare Inc. focuses on innovative approaches to wound care. Mr. Barnett also joined the Boards of Nephrosant and Laugh M.D. in the last year. Mr. Barnett has served a term as Chair of the Board of Directors of the National Kidney Foundation-Northern California, Pacific Northwest & NV Region, and as a Board Member since 2018, where he served as a member of the Nominating, Strategic Partnerships, and Membership committees. He also served as Chair of the Board of Directors for the West Coast Sourcing Solutions, a product procurement company, from 2011 to 2014. From 2009 to 2014, Mr. Barnett served as a Senior Vice President of VHA, Inc., a purchasing cooperative for community-owned, nonprofit healthcare institutions. From 2006 to 2008, Mr. Barnett served as General Partner & Board Member of North State Surgery Centers, LLC, an ambulatory surgical clinic center. From 2005 to 2009, Mr. Barnett served as Chair of the Board of Directors of the Hospital Council of Northern California-Northern Sierra Section, a non-profit hospital and health systems trade association. Mr. Barnett received the Corporate Director certification from NACD in 2021. We believe that Mr. Barnett is well-qualified to serve on the Board due to his extensive expertise and skills in hospital operations, risk and compliance management, which will enhance and expand the Board’s oversight capabilities over our strategic directions in a complex healthcare market.

Jennifer Baird has served as one of our Directors since June 2024. Since 2023, Ms. Baird has served as the Executive Chair of the Board of Directors for Culturewell, Co., an organization that delivers actionable insights for healthcare infection prevention through environmental sampling testing and germ risk assessments. From 2017 to 2022, Ms. Baird founded and served as the Chief Executive Officer of Fifth Eye Inc., an FDA-regulated software medical device company developing and commercializing healthcare-related clinical algorithms and predictive analytics using steaming physiologic parameter inputs (acquired by Airstrip Technologies, Inc.). From 2010 to 2017, Ms. Baird was the Chief Executive Officer of Accio Energy, Inc., an organization that focused on developing transformational renewable energy technology. In addition, Ms. Baird has co-founded other healthcare-based companies, including Accuri Cytometers, Inc. (acquired by Becton Dickinson) and Sonetics Ultrasound, Inc. Ms. Baird served in Chief Executive Officer-Director roles for each of Fifth Eye, Inc., Accio Energy, Inc., Accuri Cytometers Inc., and Sonetics Ultrasound, Inc. Ms. Baird has served as a director for Hope Clinic, a nonprofit, since 2009. Ms. Baird has a Bachelor of Arts in Organizational Psychology/Leadership from the University of Michigan and a Master of Business Administration from Kellogg Graduate School of Management Northwestern University. Ms. Baird became NACD Directorship Certified® in 2025. We believe that Ms. Baird is well-qualified to serve on the Board due to her leadership, management, and executive experience and that her service will enhance the ability of the Board to provide effective support and oversight of our operations.

Bernadette Vincent has served as one of our Directors since June 2024. Ms. Vincent is currently CEO of WC Operations, LLC, (d.b.a., Winners Circle Group), a start-up behavioral health organization that serves foster children and adolescents. She has also serviced on the Board of WC Operations, LLC since 2024. Ms. Vincent served in various roles at Satellite Healthcare Inc., a national non-profit kidney care company offering treatment options education, applied pragmatic research and clinical trials, and chronic, home and acute dialysis therapies, including as President & Chief Operating Officer from 2021 to 2023, as Chief Operating Officer from 2020 to 2021, and as Chief Field Operations Officer from 2018 to 2020. Prior to that from 2015 to 2017, Ms. Vincent served in various divisions as Chief Operating Officer for Mednax, Inc., a national medical group providing multi-specialty physician and health system services company. Prior to that, Ms. Vincent served in various leadership roles with Fresenius Medical Care North America. She was Group Vice President from 2008-2014, overseeing Acute, Chronic and Home Dialysis operations over the southeastern part of the United States. She served as Vice President of Operations from 2006-2008 and was a selected to participate in several advanced leadership development programs at Harvard Business School and INSEAD. She also oversaw clinical trials throughout her regions for End Stage Kidney Disease Care Populations, working with the Research Division of Fresenius Medical Care. Ms. Vincent's Board of Directors experience spanned from 2014-2023, where she served from 2018 to 2023, as a director for Satellite Healthcare Inc., serving on the Quality, Safety & Patient Experience; Government & Compensation, Executive & Strategy committees. Ms. Vincent served as a director for the National Kidney Foundation, California & Pacific Northwest chapter since 2021, and was Founder Board member for the Laureate Academy Charter School from 2014 to 2015, serving on the Finance Committee. Ms. Vincent holds a Bachelor of Science in Nursing from Dillard University and Master of Business Administration from Pepperdine University. We believe that Ms. Vincent is well-qualified to serve on the Board due to her industry expertise and experience, and that she will provide valuable insight and knowledge to our operations.

Kenneth Van Heel has served as one of our Directors since 2021 and previously served as a Director from 2011 to 2015. Mr. Van Heel has also served as Chief Executive Officer at Motorcity Systems, a software provider in the trucking and transportation industry, since November 2021. Since June 2012, Mr. Van Heel has also served as a Director and Advisor at Gantec, Inc., a biotechnology company for agricultural products through April 2025. Prior to joining Motorcity Systems, Mr. Van Heel served in various roles at The Dow Chemical Company. At The Dow Chemical Company, from 2016 to 2021, Mr. Van Heel served as the Global Director of Strategic Planning; from 2012 to 2016, Mr. Van Heel served as the Director of Alternative Investments and CIO Canadian Pension Plan; from 2006 to 2016, Mr. Van Heel served as Director of Alternative Investments; from 2003 to 2006, Mr. Van Heel served as the Senior Manager of Private Equity; from 2000 to 2003, Mr. Van Heel served as the Manager of Dow Corporate Venture Capital; and from 1986 to 2000, Mr. Van Heel held various positions within the Ventures and Business Development division. We believe that Mr. Van Heel is well-qualified to serve on the Board due to his extensive and deep experience in venture capital investment, financial analysis and reporting, risk management, strategic planning, and public company operations, as well as his expertise and skills in working with companies in the medical device and healthcare industries, which will provide valuable oversight and guidance to our governance.

John Neuman has served as one of our Directors since June 2024. Mr. Neuman, retired from Dow Chemical Company ("Dow") in 2023 following 30 years of service. He retired as Vice President of Global Financial Accounting at Dow, directing a global team of more than 350 team members. His organization was responsible for ensuring efficient and accurate financial accounting and reporting for a network of more than 400 legal entities across the globe including preparing the financial filings with the U.S. Securities and Exchange Commission. Additionally, Mr. Neuman provided oversight and direction for Corporate Controllers and for Mumbai Global Accounting. He joined Dow in 1993, and held various positions in Finance, including roles in corporate auditing, corporate controllers, business finance and controllers. His business finance role included a five-year international assignment in Switzerland. His tenure at Dow included finance integration and reporting responsibilities for several M&A transactions, including the Rohm & Haas and Dow Corning acquisitions and the DowDuPont merger. Prior to joining Dow, Mr. Neuman worked as an audit manager for Deloitte & Touche LLP. He holds a degree in accounting from Michigan State University, is a CPA, and has served as a member of the MSU External Advisory Board for the Department of Accounting and Information Systems. We believe that Mr. Neuman is well-qualified to serve on the Board due to his extensive expertise in financial accounting, corporate governance, financial risk management, and strategic opportunities, as well as his proven track record of executing investment and business strategies for public companies, which will contribute to the Board's ability to effectively manage our growth and commercial plans.

Executive Officers

Eric Schlorff See *"- Directors"* for the biography of Eric Schlorff who serves as the Chief Executive Officer and as a Class III Director.

David Green has served as our Chief Financial Officer since January 2024. Prior to joining us, Mr. Green served as Chief Financial Officer of BlackSwan Vascular, Inc. and LamaMed Solutions, Inc., related medical device development companies, from May 2021 to January 2024. Mr. Green served as Interim Chief Financial Officer of Prolacta Biosciences, Inc., a private company providing specialized nutrition products to critically ill premature infants, from September 2021 to October 2022. From December 2017 to March 2021, Mr. Green was Chief Financial Officer at Aytu BioSciences, Inc., a Nasdaq listed pharmaceutical and medical device manufacturer and marketer. Mr. Green served as Chief Accounting Officer at Intarcia Therapeutics, Inc., a venture backed biopharmaceutical company engaged in late stage clinical development, from May 2016 to February 2017. Prior to Intarcia Therapeutics, Mr. Green held various CFO and consulting roles for SEC reporting and privately held life science companies. Mr. Green was a founding member of Ernst & Young's Palo Alto Center for Strategic Transactions, where he advised the firm's clients on using strategic transactions to accelerate growth. Mr. Green earned a Bachelor of Science from the State University of New York, and a Master of Business Administration from the University of Rochester. Mr. Green is a Certified Public Accountant.

Kevin Chung, MD has served as our Chief Medical Officer since July 1, 2022. Dr. Chung served as a professor in the Department of Medicine at the Uniformed Services University of the Health Sciences from 2016 to 2022, and as Chair of the Department of Medicine since 2018. From 2014 to 2020, Dr. Chung served as Critical Care Consultant to the U.S. Surgeon General. From 2016 to 2018, Dr. Chung served as Department of Medicine Chief at the Brooke Army Medical Center. From 2015 to 2016, Dr. Chung served as Director of Research at the US Army Institute of Surgical Research, and as Task Area Manager, Clinical Trial from 2012 to 2015. From 2006 to 2013, Dr. Chung served as Medical Director, Burn Intensive Care Unit at the US Army Burn Center. Dr. Chung is a retired army colonel and holds medical licenses in Texas and Maryland.

CORPORATE GOVERNANCE

General

Our Board has adopted a Code of Business Conduct and Ethics, and charters for our Nominating and Corporate Governance Committee, Audit Committee and Compensation Committee to assist the Board in the exercise of its responsibilities and to serve as a framework for our effective governance. You can access our current committee charters and our Code of Business Conduct and Ethics in the "Governance" section under "Governance Documents" of our investor relations page of our website located at *investors.seastarmedical.com.*

Board Composition

Our Board currently consists of six members: Rick Barnett; John Neuman; Jennifer Baird; Bernadette Vincent; Eric Schlorff; and Kenneth Van Heel. As set forth in our Charter, the Board is currently divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our Charter provides that the authorized number of directors may be fixed from time to time by the Board, except as otherwise provided for or fixed relating to the rights of the holders of any series of Preferred Stock to elect additional directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our Company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the total voting power of the outstanding shares of our capital stock entitled to vote in the election of directors.

Independence of the Board

As required under Nasdaq listing standards, a majority of the members of a listed company's Board must qualify as "independent," as affirmatively determined by the Board. The Board consults with our counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independence," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and us, our senior management and our independent auditors, the Board has affirmatively determined that the following five directors, representing a majority of the members of the Board, are independent directors within the meaning of the applicable Nasdaq listing standards: Mr. Barnett, Mr. Neuman, Ms. Baird, Ms. Vincent, and Mr. Van Heel. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with us. As Mr. Schlorff serves as our Chief Executive Officer, he is not independent. Additionally, in accordance with our Corporate Governance Guidelines, the Board determined that all members of the audit, compensation, and nominating and corporate governance committees of the Board are independent.

Director Candidates

The Nominating and Corporate Governance Committee is primarily responsible for searching for qualified director candidates for election to the Board and filling vacancies on the Board. To facilitate the search process, the Nominating and Corporate Governance Committee may solicit our current directors and executives for the names of potentially qualified candidates or ask directors and executives to pursue their own business contacts for the names of potentially qualified candidates. The Nominating and Corporate Governance Committee may also consult with outside advisors or retain search firms to assist in the search for qualified candidates or consider director candidates recommended by our stockholders. Once potential candidates are identified, the Nominating and Corporate Governance Committee reviews the backgrounds of those candidates, evaluates candidates' independence from us and potential conflicts of interest and determines if candidates meet the qualifications desired by the Nominating and Corporate Governance Committee for candidates for election as a director.

In evaluating the suitability of individual candidates (both new candidates and current Board members), the Nominating and Corporate Governance Committee, in recommending candidates to the Board, and the Board, in approving and recommending for election (and, in the case of vacancies, appointing) such candidates, will consider candidates who have a high level of personal and professional integrity, strong ethics and values and the ability to make mature business judgments. In evaluating director candidates, the Nominating and Corporate Governance Committee and the Board may also consider the following criteria as well as any other factor that they may deem to be relevant: the candidate's experience in corporate management, such as serving as an officer or former officer of a publicly held company; the candidate's experience as a board member of another publicly held company; the candidate's professional and academic experience relevant to our industry; the strength of the candidate's leadership skills; the candidate's experience in finance and accounting and/or executive compensation practices; and whether the candidate has the time required for preparation, participation and attendance at Board meetings and committee meetings, if applicable. In addition, the Board will consider whether there are potential conflicts of interest with the candidate's other personal and professional pursuits. In addition, the Board monitors the mix of specific experience, qualifications and skills of its directors in order to assure that the Board, as a whole, has the necessary tools to perform its oversight function effectively in light of our business and structure. Although the Board does not have a formal written diversity policy with respect to the evaluation of director candidates, in its evaluation of director candidates, the Nominating and Corporate Governance Committee will consider factors including, without limitation, issues of judgment, diversity, age, skills, background and experience, and with respect to diversity, such factors as gender, race, ethnicity, experience, and area of expertise, as well as other individual qualities and attributes that contribute to the total diversity of viewpoints and experience represented on the Board.

Stockholders may recommend individuals to the Nominating and Corporate Governance Committee for consideration as potential director candidates by submitting the names of the recommended individuals, together with appropriate biographical information and background materials as set forth in our Bylaws, to the Nominating and Corporate Governance Committee, c/o Corporate Secretary, SeaStar Medical Holding Corporation, 3513 Brighton Blvd, Suite 410, Denver, CO 80216. In the event there is a vacancy, and assuming that appropriate biographical and background material has been provided on a timely basis, the Nominating and Corporate Governance Committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates recommended by other sources.

Communications from Interested Parties

Anyone who would like to communicate with, or otherwise make his or her concerns known directly to the chairperson of any of the Audit, Nominating and Corporate Governance, and Compensation Committees, or to the non-management or independent directors as a group, may do so by addressing such communications or concerns to c/o Corporate Secretary, SeaStar Medical Holding Corporation, 3513 Brighton Blvd, Suite 410, Denver, CO 80216, which will forward such communications to the appropriate party. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we tend to receive repetitive or duplicative communications.

Board Leadership Structure

The Board has not implemented a policy requiring the positions of the Chairman of the Board and Chief Executive Officer to be separate or held by the same individual. Any further determination to create such a policy is expected to be based on circumstances existing from time to time, based on criteria that are in our best interests and the best interests of its stockholders, including the composition, skills and experience of the Board and its members, specific challenges faced by us or the industry in which we operate, and governance efficiency. Mr. Barnett serves as the Chairman of the Board. The Board believes that having an independent director serving as the Chairman provides better and effective oversight and management of us as a publicly traded company, which also improves management efficiency as the Chief Executive Officer can focus on our day-to-day operations. If the Board convenes for a meeting, the non-management directors will meet in one or more executive sessions, if the circumstances warrant it. The Board may also consider appointing a lead independent director, if the circumstances warrant it.

Risk Oversight

The Board will administer the risk oversight function directly through the Board as a whole, as well as through its committees, where applicable, monitoring and assessing strategic risk exposure, enterprise risk, and governance risks. The audit committee will be responsible for considering and discussing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The compensation committee is responsible for reviewing and assessing the risks associated with the compensation arrangements of executive management, including the lack of alignment between the incentives of management and the interests of stockholders. The allocation of risk oversight responsibility may change, from time to time, based on our evolving needs.

Executive Sessions of Non-Management Directors

As provided in the Corporate Governance Guidelines, the non-management directors meet, without management directors or management present on a regularly scheduled basis. If the non-management directors include directors who are not considered independent, the independent directors must also meet in executive session the conclusion of each board meeting. Our Chairman of the Board, Rick Barnett currently presides over executive sessions.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics applicable to our directors, executive officers and employees. The Code of Business Conduct and Ethics is available on our website at *https://investors.seastarmedical.com/governance/governance-documents/*. We will disclose any amendments to, or waivers of, provisions of our Code of Business Conduct and Ethics on our website.

Insider Trading Policy

We are committed to promoting high standards of ethical business conduct and compliance with applicable laws, rules, and regulations. As part of this commitment, we have adopted an Insider Trading Policy governing transactions in our securities by our directors, employees, contractors, consultants, and other personnel providing services to us, that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and Nasdaq listing standards. While we have not adopted a formal policy governing insider trading restrictions on ourself, as a matter of practice we generally observe the same procedures and restrictions, including the potential existence of material non-public information, with respect to transactions by us in our securities, including repurchases of common stock.

Anti-Hedging Policy

Our Board has adopted an Insider Trading Policy, which applies to all of our directors, officers and employees. The policy prohibits our employees and directors from engaging in any hedging transactions (including transactions involving options, puts, calls, prepaid variable forward contracts, equity swaps, collars and exchange funds or other derivatives) that are designed to hedge or speculate on any change in the market value of our equity securities.

Attendance by Members of the Board at Meetings

As of December 31, 2024, the Board held 13 meetings of the Board. During the fiscal year ended December 31, 2024, except for Rick Russell and Bruce Rodgers, whose terms as directors expired on June 4, 2024, each director attended at least 75% of the aggregate of (i) all meetings of the Board and (ii) all meetings of the committees on which the director served during the period in which he or she served as a director.

Each director is expected to spend the time and effort necessary to properly discharge his or her responsibilities. Accordingly, a director is expected to attend all meetings of the Board and meetings of the committees on which the director sits (including separate meetings of the independent directors), with the understanding that, on occasion, a director may be unable to attend a meeting. We do not maintain a formal policy regarding director attendance at the Annual Meeting; however, we encourage our directors to attend the Annual Meeting.

COMMITTEES OF THE BOARD

Our Board has established three standing committees — Audit, Compensation, and Nominating and Corporate Governance — each of which operates under a written charter that has been approved by our Board.

The members of each of the Board committees and committee Chairpersons are set forth in the following chart.

Name	Audit	Compensation	Nominating and Corporate Governance
Rick Barnett		X	Chair
John Neuman	Chair		X
Jennifer Baird	X	Chair	
Bernadette Vincent		X	
Kenneth Van Heel	X		X

Audit Committee

Our Audit Committee will be responsible for, among other things:

- retaining, overseeing and evaluating the independence and performance of our independent auditor;
- reviewing and discussing with our independent auditor their annual audit, including the timing and scope of audit activities;
- pre-approving audit services;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the quarterly and annual financial statements that we file with the SEC;
- reviewing the adequacy and effectiveness of our accounting and internal controls over financial reporting, disclosure controls and policies and procedures;
- reviewing and discussing guidelines and policies governing the process by which our senior management assesses and manages our exposure to risk;
- reviewing, and if appropriate, approving or ratifying any related party transactions and other significant conflicts of interest;
- establishing procedures for the receipt, retention and treatment of complaints received by us and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing our program to monitor compliance with our code of ethics; and
- overseeing significant deficiencies and material weaknesses in the design or operation of our internal controls over financial reporting.

Our Audit Committee currently consists of John Neuman, Jennifer Baird and Kenneth Van Heel, with Mr. Neuman serving as chair of the Audit Committee. Rule 10A-3 of the Exchange Act, and Nasdaq rules require that our audit committee must be composed entirely of independent members. Each of John Neuman, Jennifer Baird and Kenneth Van Heel meet the definition of "independent director" for purposes of serving on the audit committee under Rule 10A-3 of the Exchange Act and Nasdaq rules. Each member of our audit committee also meets the financial literacy requirements of the Nasdaq listing standards. In addition, the Board determined that John Neuman qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Following the completion of the Annual Meeting, we expect John Neuman, Jennifer Baird, and Kenneth Van Heel to continue to serve as members of the Audit Committee, with Mr. Neuman serving as the chair of the Audit Committee.

Compensation Committee

Our Compensation Committee is responsible for, among other things:

- reviewing and approving the compensation of our executive officers;
- reviewing and recommending to our Board the compensation of our directors;
- overseeing the development and implementation of compensation plan programs;
- establishing and administering our incentive compensation and equity-based plans and approving or to our Board for approval amendments to these plans if deemed appropriate;
- reviewing and approving any severance or termination arrangements to be made with any of our executive officers; and
- reviewing and approving at least annually the corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers.

Our Compensation Committee currently consists of Jennifer Baird, Rick Barnett and Bernadette Vincent, with Ms. Baird serving as the chair of the Compensation Committee. Each member of the committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. Following the completion of the Annual Meeting, we expect Jennifer Baird, Rick Barnett, and Bernadette Vincent to continue to serve as members of the Compensation Committee, with Ms. Baird serving as the chair of the Compensation Committee.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee will be responsible for, among other things:

- identifying, screening and recommending to our Board director candidates for election (or re-election);
- overseeing the policies and procedures with respect to the consideration of director candidates recommended by stockholders;
- reviewing and recommending to our Board for approval, as appropriate, disclosures concerning our policies and procedures for identifying and screening Board nominee candidates, the criteria used to evaluate Board membership and director independence as well as any policies regarding Board diversity;
- reviewing independence qualifications of directors under the applicable Nasdaq rules;
- developing and coordinating with management on appropriate director orientation programs; and
- our stockholder engagement plan, if any, and overseeing relations with stockholders.

Our Nominating and Corporate Governance Committee currently consists of Rick Barnett, John Neuman and Kenneth Van Heel, with Mr. Barnett serving as the chair of the Nominating and Corporate Governance Committee. Following the completion of the Annual Meeting, we expect Rick Barnett, John Neuman and Kenneth Van Heel to continue to serve as members of the Nominating and Corporate Governance Committee, with Mr. Barnett serving as the chair of the Nominating and Corporate Governance Committee.

EXECUTIVE COMPENSATION

Overview

This section discusses the material components of the executive compensation program for our executive officers who are named below. As a smaller reporting company, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies" as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for our principal executive officer and our two other most highly compensated executive officers.

In 2024, our chief executive officer and two other executive officers, referred to collectively as our "named executive officers," were as follows:

- Eric Schlorff, Chief Executive Officer
- David Green, Chief Financial Officer
- Kevin Chung, MD, Chief Medical Officer

2024 Compensation of Named Executive Officers

Base Salary

Base salaries are intended to provide a level of compensation sufficient to attract and retain an effective management team, when considered in combination with the other components of the executive compensation program. In general, we seek to provide a base salary level designed to reflect each executive officer's scope of responsibility and accountability. As a result of the financial constraints on our cash during 2023, a portion of the base salaries for our executive officers and other employees was paid in shares of our Common Stock. Please see the "Salary" column in the "Summary Compensation Table for Fiscal Years 2024 and 2023" below for the base salary amounts received by the named executive officers in fiscal 2024 and 2023.

Long-Term Equity Incentive Awards

To further focus our named executive officers on our long-term performance, we may grant equity compensation in the form of stock options and restricted stock units. Restricted stock units and options were granted to Mr. Schlorff and Mr. Chung during the year ended December 31, 2023, and restricted stock units were granted to Mr. Schlorff, Mr. Green, and Mr. Chung during the year-ended December 31, 2024. For more information, see "Summary Compensation Table for Fiscal Years 2024 and 2023," "Outstanding Equity Awards at December 31, 2024," and "Employee Benefit and Equity Compensation Plans" below.

Incentive Compensation

We periodically use bonuses to incentivize and retain our employees, including our named executive officers. Please see the "Bonus" column in the "Summary Compensation Table for Fiscal Years 2024 and 2023" below for the bonus amounts received by the named executive officers in fiscal 2024.

We periodically enter into agreements to grant short- and long-term cash or stock incentive awards to our employees including our named executive officers to encourage achievement of certain performance goals. This includes incentive awards based on the achievement of certain business development, financing milestone, and exit event goals. In addition, we periodically award our named executive officers annual bonuses from a discretionary bonus pool.

Timing of Certain Equity Awards

Equity awards are discretionary and are generally granted to our named executive officers upon approval at the March meeting of the Compensation Committee and Board of Directors each year. Awards to non-employee directors, if any, are generally granted following approval at the May meeting of the Compensation Committee and Board of Directors each year. However, depending on the availability of shares authorized under the 2022 Omnibus Incentive Plan, the approval, if any, or timing of the approval of grants could deviate from above. We did not grant any stock options, stock appreciation rights or similar awards under the 2022 Omnibus Incentive Plan in the period beginning four business days before the filing of a periodic report on Form 10-Q, Form 10-K, or Form 8-K that disclosed material nonpublic information, and ending one business day after the filing or furnishing of such information. Our Compensation Committee did not take material nonpublic information into account when determining the timing and terms of equity awards in 2024, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Summary Compensation Table for Fiscal Years 2024 and 2023

The following table sets forth information for the years ended December 31, 2024 and 2023, regarding compensation awarded to or earned by our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus[1] ($)	Stock Awards ($)[2]	Option Awards[3] ($)	Non-Equity Incentive Plan Compensation	Total ($)
Eric Schlorff	2024	$ 420,000	$ —	$ 142,350[4]	—	$ —	$ 562,350
Chief Executive Officer	2023	$ 420,000	$ —	$ 97,863[8]	$ 120,097[7]	$ —	$ 637,960
David Green							
Chief Financial Officer	2024	$ 363,702[6]	2,800	395,650[5]	—	—	762,152
Kevin Chung[6]	2024	$ 350,000	$ 2,800	$ 32,850[4]	$ —	$ —	$ 385,650
Chief Medical Officer	2023	$ 350,000	$ —	$ 65,242[8]	$ 80,065[7]	$ —	$ 495,307

(1) Amounts reflect a one-time holiday bonus of approximately $2,800 provided to all employees except for the Chief Executive Officer.

(2) Amounts reflect the grant date fair value of restricted stock units granted in each reported fiscal year calculated in accordance with FASB ASC Topic 718, without taking into account any estimated forfeitures related to service-vesting conditions. The grant date fair value was determined using the closing share price of the Corporation's Common Stock on the date of grant. For information regarding assumptions underlying the valuation of equity awards, see Notes 2 and 12. to our audited financial statements appearing in the 2024 Annual Report.

(3) Amounts reflect the grant date fair value of options granted in 2023 calculated in accordance with FASB ASC Topic 718, without taking into account any estimated forfeitures related to service-vesting conditions. our named executive officers will only have a benefit to the extent the fair market value of our Common Stock is greater than the exercise price of such stock options. For information regarding assumptions underlying the valuation of equity awards, see Notes 2 and 12 to our audited financial statements appearing in the 2023 Annual Report. These options have a one-year vesting period and became fully vested on April 6, 2024.

(4) The restricted stock units granted in November 2024 vest in three equal annual installments of 33.33%, beginning on July 1, 2025, with the final installment vesting on July 1, 2027.

(5) These restricted stock units granted in April 2024 vest with respect to (i) twenty-five percent (25%) upon the completion of one (1) year of service from date of hire (January 10, 2024), and (ii) the balance of the units vest in a series of thirty-six successive equal monthly installments upon completion of each additional month of service over a thirty-six (36)-month period from the one-year anniversary of the hire date (January 10, 2024), subject to the terms of the award agreement.

(6) Mr. Green commenced his employment with us on January 10, 2024.

(7) The options granted on April 6, 2023, vested 100% upon the one (1) year anniversary date of the grant date, subject to the terms of the award agreement. The options expire on the ten-year (10) anniversary date from the grant date.

(8) The restricted stock units granted on April 6, 2023, vested 100% upon the one (1) year anniversary date of the grant date, subject to the terms of the award agreement.

Narrative to Summary Compensation Table

Employment Agreements

The terms of the employment arrangements with each named executive officer are as follows:

Eric Schlorff

Mr. Schlorff's employment agreement, dated April 21, 2022, governs the terms and conditions of his employment as our Chief Executive Officer. Mr. Schlorff's employment agreement entitles him to an annual base salary and the opportunity to participate in the executive bonus plan approved by the Compensation Committee. In addition, Mr. Schlorff is eligible to receive an annual discretionary bonus of up to a maximum amount of 53% of his base salary, with the actual amount (if any) to be determined in the sole discretion of the Board based on a combination of factors, including the performance of us and Mr. Schlorff individually. Mr. Schlorff also is eligible to participate in the benefit plans that are generally available to all Company employees.

Under the employment agreement, if Mr. Schlorff is terminated by us without cause, he is entitled to receive continued base salary and health benefits continuation for up to twelve (12) months, offset by any compensation and benefits received from any subsequent employer during such period, subject to Mr. Schlorff executing a general release. For purposes of Mr. Schlorff's employment agreement, "cause" means (i) executive's commission of any act of fraud, embezzlement, dishonesty, or sexual harassment, (ii) executive's refusal or failure to comply in any material respect with our written policies and procedures, (iii) executive's unauthorized use or disclosure of our confidential information or trade secrets, or (iv) executive's gross negligence or misconduct adversely affecting our business or affairs in a material manner.

The employment agreement provides that upon a "Change in Control" (as defined in the agreement), all outstanding stock options will vest. All vested and outstanding stock options will remain exercisable for up to twelve months following a termination of Mr. Schlorff's employment, other than for cause.

David Green

Mr. Green's employment agreement governs the terms and conditions of his employment as our Chief Financial Officer. Mr. Green's employment agreement entitles him to an annual base salary and the opportunity to participate in the executive bonus plan approved by the Compensation Committee. In addition, Mr. Green is eligible to receive an annual discretionary bonus of up to a maximum amount of 40% of his base salary, with the actual amount (if any) to be determined in the sole discretion of the Board based on a combination of factors, including the performance of us and Mr. Green individually. Mr. Green also is eligible to participate in the benefit plans that are generally available to all Company employees.

Under the employment agreement, if Mr. Green is terminated by us without cause, he is entitled to receive continued base salary and health benefits continuation for up to twelve (12) months, offset by any compensation and benefits received from any subsequent employer during such period, subject to Mr. Green executing a general release. For purposes of Mr. Green's employment agreement, "cause" means (i) executive's commission of any act of fraud, embezzlement, dishonesty, or sexual harassment, (ii) executive's refusal or failure to comply in any material respect with our written policies and procedures, (iii) executive's unauthorized use or disclosure of our confidential information or trade secrets, or (iv) executive's engagement in dishonesty, illegal conduct or misconduct, which is, in each case, materially injurious to us.

The employment agreement provides that upon a "Change in Control" (as defined in the agreement), all outstanding RSU awards will vest.

Kevin Chung, MD

On May 18, 2022, we entered into an employment agreement with Dr. Chung to serve as our Chief Medical Officer, commencing on July 1, 2022. Dr. Chung is entitled to receive an annual base salary. In addition, Dr. Chung is eligible to receive an annual discretionary bonus of up to a maximum amount of 40% of his base salary, with the actual amount (if any) to be determined in the sole discretion of the Board based on a combination of factors, including the performance of us and Dr. Chung individually.

Cash Incentive Compensation

In December 2021, SeaStar Medical, Inc. entered into transaction bonus agreements with certain of its named executive officers and directors, which provided for two long-term incentive bonuses: a business development bonus and an exit bonus.

Outstanding Equity Awards at December 31, 2024

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2024.

	Option Awards[1]				Stock Awards[2]	
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration**	**Number of Shares or Units of Stock that have not Vested (#)**	**Market Value of Shares or Units of Stock that have not Vested ($)**
Eric Schlorff	720[3]	—	$ 250.00	3/1/2029	671[6]	
Chief Executive Officer	3,360[4]	—	$ 13.25	2/20/2030	65,000[7]	
	3,989[5]	—	$ 46.00	4/6/2033		$ 127,402
David Green	—				18,000[8]	
Chief Financial Officer	—					
	—					$ 34,920
Kevin Chung	2,660[5]	—	$ 46.00	4/6/2033	15,000[7]	
Chief Medical Officer	—	—	$ —	—		$ 29,100

(1) This column provides information pertaining to all outstanding stock options held by our named executive officers as of December 31, 2024. Stock options granted prior to 2021 were exercisable upon completion of six (6) months of service following the date of grant, subject to a repurchase right in favor of us which lapsed as the option vested. Stock options granted in 2021 were exercisable immediately, subject to a repurchase right in favor of us which lapsed as the option vested. Accordingly, the columns and footnotes below reflect the extent to which stock options held by our named executive officers were vested (as opposed to exercisable) as of December 31, 2024.

(2) This column provides information pertaining to unvested restricted stock units held by our named executive officers as of December 31, 2024.

(3) The option was granted on October 28, 2022, and vested with respect to (i) twenty-five percent (25%) of the shares upon completion of one (1) year of service measured from March 1, 2019 and (ii) the balance of the shares subject to the option in a series of thirty-six (36) successive equal monthly installments upon completion of each additional month of service over the thirty-six (36)-month period measured from March 1, 2019. As of December 31, 2024, the option was fully vested and exercisable.

(4) The option was granted on October 28, 2022, and vested with respect to (i) twenty-five percent (25%) of the shares upon completion of one (1) year of service measured from February 20, 2020, and (ii) the balance of the shares subject to the option in a series of thirty-six (36) successive equal monthly installments upon completion of each additional month of service over the thirty-six (36) month period measured from February 20, 2021. As of December 31, 2024, the option was fully vested and exercisable.

(5) The option was granted on April 6, 2023, and became fully vested on April 6, 2024, the first anniversary of the date of grant.

(6) The restricted stock units were granted on April 4, 2022, and vested with respect to (i) fifty percent (50%) of the units upon completion of one (1) year of service measured from April 21, 2022, and (ii) the balance of the units vest in a series of twenty-four (24) successive equal monthly installments upon completion of each additional month of service over the twenty-four (24) month period measured from April 21, 2022, subject to the terms of the award agreement.

(7) The restricted stock units granted in November 2024 vest in three equal annual installments of 33.33%, beginning on July 1, 2025, with the final installment vesting on July 1, 2027.

(8) These restricted stock units granted in April 2024 vest with respect to (i) twenty-five percent (25%) upon the completion of one (1) year of service from date of hire (January 10, 2024), and (ii) the balance of the units vest in a series of thirty-six successive equal monthly installments upon completion of each additional month of service over a thirty-six (36)-month period from the one-year anniversary of the hire date (January 10, 2024), subject to the terms of the award agreement.

Compensation Recovery Policy

On December, 1, 2023, the Compensation Committee adopted a compensation clawback policy (the "Clawback Policy") in compliance with the final rules promulgated by the SEC under Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Rule 10D-1 and Nasdaq (together, the "Clawback Rules") that provides for the recovery of certain incentive-based compensation in the event we are required to restate our financial statements. The Clawback Policy provides that, in the event of the restatement of any financial reporting required under the securities laws or other similar laws or regulations, our board of directors (or applicable committee thereof) will take such actions as necessary to recover the portion of any incentive-based compensation that was granted, earned or vested based wholly or in part on the attainment of a financial reporting measure which was received by the executive officer that was in excess of the amount that he or she would have received had our financial results been calculated under the restated financial statements; provided that such compensation was paid to or awarded to the executive officer, or which vested (or became eligible to vest) during the Clawback Period. "Clawback Period" under the Clawback Policy is defined as the three completed fiscal years immediately prior to the date on which our board of directors or management determine we are required to (or we are otherwise legally directed to) prepare an accounting restatement and any transition period between the last day of our previous fiscal year end and the first day of our new fiscal year (that results from a change in our fiscal year) within or immediately following such three-year period; provided that any transition period between the last day of our previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months will be deemed a completed fiscal year.

As disclosed in the 2023 Annual Report, certain of our previously filed interim unaudited and annual audited consolidated financial statements should no longer be relied upon and we therefore restated in the 2023 Annual Report (i) our consolidated financial statements as of and for the year ended December 31, 2022 and (ii) our unaudited quarterly financial data for the first three quarters of the year ended December 31, 2023. However, because we did not award to any of our executive officers any incentive-based compensation during the fiscal years ended December 31, 2023, 2022 and 2021 that was granted, earned, vested or eligible to vest based wholly or in part on the attainment of a financial reporting measure, we concluded that no recovery of erroneously awarded compensation was required pursuant to our Clawback Policy and the Clawback Rules.

Employee Benefit and Equity Compensation Plans

The principal features of our existing employee benefit and equity incentive plans are summarized below.

Equity Incentive Plans

2022 Omnibus Incentive Plan

The 2022 Omnibus Incentive Plan was originally adopted by our Board on August 22, 2022, was approved by our stockholders as of October 18, 2022, and was subsequently amended and approved by our stockholders effective September 6, 2023, and replaced the existing 2019 Stock Incentive Plan. The 2022 Omnibus Incentive Plan was later further amended and approved by our stockholders effective June 4, 2024.

Employee Stock Purchase Plan (ESPP)

The LMF Acquisition Opportunities, Inc. 2022 Employee Stock Purchase Plan (the "ESPP") was originally adopted by our Board on August 22, 2022, was approved by our stockholders as of October 18, 2022, and became effective on October 28, 2022. The ESPP is broad-based and allows us to provide an incentive to attract, retain and reward our eligible employees and those of any participating subsidiary companies (whether now existing or subsequently established) with the opportunity to periodically purchase shares of our Common Stock at a discount through their accumulated periodic payroll deductions. The ESPP is intended to qualify as an employee stock purchase plan under Section 423 ("Section 423") of the Code. Favorable tax treatment is available for United States tax residents participating in a Section 423 plan. The ESPP also authorizes the grant of rights to purchase shares that do not qualify under Section 423 pursuant to rules, procedures or sub-plans adopted by the plan administrator to achieve tax, securities law, or other compliance objectives in particular locations outside of the United States. Up to 380,000 shares of Common Stock will be available for issuance under the ESPP (subject to adjustments).

Subject to the terms of the ESPP, a committee of two or more Board members appointed by the Board, in its role as plan administrator, has the authority to interpret and construe any provision of the ESPP, establish rules and regulations relating to administering the ESPP, and make all other determinations necessary or advisable for the administration of the ESPP. To the extent applicable law permits, the plan administrator may, to the extent it deems appropriate, delegate, administrative duties.

Change in Control. In the event of a change in control (as defined in the ESPP), the plan administrator may take such action as deemed appropriate including (i) having the successor entity (or its parent or subsidiary corporation) assume our obligations under the ESPP and the outstanding purchase rights, (ii) accelerating the next purchase date in the then current offering period to a date immediately before the closing date of the change in control, and applying the accumulated payroll deductions to the purchase of shares of our Common Stock at the purchase price in effect for that offering period or (iii) terminating all outstanding purchase rights and refunding all accumulated payroll deductions.

Health and Welfare Plans

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical, dental, vision, voluntary life insurance, voluntary short-term and long-term disability insurance, and employee assistance program benefits made available to our employees.

Non-Employee Director Compensation

For 2024, members of our board of directors earned cash director fees and were granted options and restricted stock unit awards as set forth below.

Name	Fees Earned or Paid in Cash[1] ($)	Stock Awards[2] ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Rick Barnett	$ 103,000	$ 13,040[3]	$ —	$ —	$ 116,040
Allan Collins	$ 50,000	$ 13,040[3]	$ —	$ —	$ 63,040
Kenneth J. Van Heel	$ 62,000	$ 13,040[3]	$ —	$ —	$ 75,040
Andres Lobo[5]	$ 23,000	$ —	$ —	$ —	$ 23,000
Jennifer A. Baird[6]	$ 27,000	$ 26,080[4]	$ —	$ —	$ 53,080
Bernadette N. Vincent[7]	$ 23,000	$ 26,080[4]	$ —	$ —	$ 49,080
John Neuman[8]	$ 30,000	$ 26,080[4]	$ —	$ —	$ 56,080
Richard Russell[9]	$ 23,000	$ —	$ —	$ —	$ 23,000
Bruce Rodgers[10]	$ 26,000	$ —	$ —	$ —	$ 26,000

(1) Amounts reflect the director fees earned during fiscal year 2024. As a result of the financial constraints on our cash during 2024, none of the fees were paid during the fiscal year ended December 31, 2024.
(2) Amounts reflect the grant date fair value of restricted stock granted to our non-employee directors calculated in accordance with FASB ASC Topic 718 and accordingly determined on the basis of the closing selling price per share of our Common Stock on the award date and does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Notes 2 and 12 to our audited financial statements in the 2024 Annual Report.
(3) Restricted stock units vest 100% on June 30, 2025.
(4) Restricted stock units vest in three equal annual installments of 33.33%, beginning on June 30, 2025, with the final installment vesting on June 30, 2027.
(5) Mr. Lobo resigned from the Board effective June 5, 2024.
(6) Ms. Baird was elected to the Board effective June 4, 2024.
(7) Ms. Vincent was elected to the Board effective June 4, 2024.
(8) Mr. Neuman was appointed to the Board effective June 5, 2024.
(9) Mr. Russell's term on the Board ended on June 4, 2024, as he was not nominated for reelection at the 2024 Annual Meeting.
(10) Mr. Rodgers's term on the Board ended on June 4, 2024, as he was not nominated for reelection at the 2024 Annual Meeting.

Equity Compensation Plan Information

The following table sets forth additional information as of December 31, 2024, about shares of our Common Stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options and other rights and the number of shares remaining available for future grants excluding the shares to be issued upon exercise of outstanding options, warrants, and other rights.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights and RSUs	Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights and RSUs (*)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders	242,183	$ 45.78	82,434
Equity compensation plans not approved by security holders	—	$ —	—
Total	242,183	$ 45.78	82,434

* Reflects the weighted-average exercise prices of options outstanding. Restricted stock and restricted stock units do not have exercise prices (see Note 12 — Stock Based Compensation Awards of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024).

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of Common Stock on June 12, 2025, by:

- each person known by us to be the beneficial owner of more than 5% of outstanding Common Stock;
- each of our current named executive officers and directors; and
- all of our current executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security or the right to acquire such power within 60 days. Except as indicated by the footnotes below, we believe, based on the information furnished to it, that the persons and entities named in the table below will have sole voting and investment power with respect to all stock that they beneficially own, subject to applicable community property laws.

Common stock issuable upon exercise of warrants or options currently exercisable within 60 days are deemed outstanding solely for purposes of calculating the percentage of total voting power of the beneficial owner thereof.

Subject to the paragraph above, the percentage ownership of Common Stock is based on 11,203,752 shares of Common Stock outstanding as of June 12, 2025.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	% of Class
Five Percent Holders		
Armistice Capital, LLC[1]	1,019,958	[1]
Directors and Executive Officers[2]		
Eric Schlorff[3]	63,253	*
David Green[4]	17,073	*
Kevin Chung[5]	25,844	*
Rick Barnett[6]	8,927	*
John Neuman[7]	42,667	*
Kenneth Van Heel[8]	11,764	*
Jennifer A. Baird[9]	12,667	*
Bernadette N. Vincent[10]	2,667	*
All directors and executive officers as a group (8 persons)	184,881[11]	1.7%

* Less than 1%.

(1) The information regarding the number of shares beneficially owned or deemed to be beneficially owned by Armistice Capital, LLC (“Armistice”), is based on the Schedule 13G filed by Armistice on May 15, 2025. According to the Schedule 13G, Armistice and related entities beneficially own shares of common stock as follows:

Entity	Shared Voting Power	Shared Dispositive Power	Aggregate Amount Beneficially Owned
Armistice Capital, LLC	1,019,958	1,019,958	1,019,958
Steven Boyd	1,019,958	1,019,958	1,019,958

According to the Company's records, 4,464,220 warrants to purchase common stock (collectively, the "Armistice Warrants"). The Armistice Warrants are subject to a beneficial ownership limitation of 9.99%, which such limitation restricts Armistice from exercising that portion of the Armistice Warrants that would result in Armistice and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation.

(2) Unless otherwise noted, the business address of each of the following entities or individuals is c/o SeaStar Medical Holding Corporation, 3513 Brighton Blvd Ste 410, Denver, CO 80216.

(3) Includes 21,667 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12, 2025, and 8,069 vested options to purchase the Company's Common Stock with a weighted-average exercise price of $50.57

(4) Includes 750 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12. 2025.

(5) Includes 5,000 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12, 2025, and 2,660 vested options to purchase the Company's Common Stock with a weighted-average exercise price of $46.00

(6) Includes 4,000 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12, 2025, and 1,459 vested options to purchase the Company's Common Stock with a weighted-average exercise price of $24.34

(7) Includes 2,667 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12, 2025.

(8) Includes 4,000 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12, 2025, and 1,384 options to purchase the Company's Common Stock with a weighted-average exercise price of $24.91, of which 40 options are expected to vest within 60 days of June 12, 2025.

(9) Includes 2,667 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12. 2025.

(10) Includes 2,667 shares of Common Stock issuable upon the vesting of restricted stock units within 60 days of June 12, 2025.

(11) Includes 43,417 shares of Common Stock Issuable upon the vesting of restricted stock units within 60 days of June 12, 2025, and 13,572 options to purchase the Company's Common Stock with a weighted-average exercise price of $44.24, of which 40 options are expected to vest within 60 days of June 12, 2025.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Certain Relationships and Related Person Transactions

Other than as described in "— *Executive Compensation*" the following is a summary of transactions since January 1, 2023 to which we were or will be a party in which the amount involved exceeds $120,000 and in which any director, nominee for director, executive officer, beneficial holder of more than 5% of our capital stock or any member of their immediate family or any entity affiliated with any of the foregoing persons had or will have a direct or indirect material interest.

Unless the context indicated otherwise, "SeaStar Medical" referenced herein refers to SeaStar Medical, Inc., our predecessor company prior to the consummation of the closing of the transactions contemplated by the Merger Agreement, dated April 21, 2022, pursuant to which SeaStar Medical, Inc. became a subsidiary of LMF Acquisition Opportunities, Inc. (the "Business Combination").

Business Combination Transactions and Related Agreements

In connection with the closing of the Business Combination, SeaStar Medical entered into various transactions with certain related parties as set forth below:

Amended and Restated Registration Rights Agreement

On April 21, 2022 and in connection with the execution of the Merger Agreement, certain stockholders of SeaStar Medical and LMAO entered into the Amended and Restated Registration Rights Agreement, pursuant to which we were required to file, not later than 30 days after the closing date of the Business Combination, a registration statement covering the shares of Common Stock issued or issuable to the Registration Rights Stockholders. In addition, the Amended and Restated Registration Rights Agreement imposed certain lock-up restrictions on shares of Common Stock held by Registration Rights Stockholders following the consummation of the Business Combination.

On October 25, 2022, LMAO and SeaStar Medical agreed to waive the lock-up restrictions with respect to shares of Common Stock held by two Registration Rights Stockholders, Mr. David Humes and Mr. Michael Humes ("Humes Lock-up Release"). Also on October 25, 2022, LMAO and Registration Rights Stockholders entered into an Amendment No. 1 to Amended and Restated Registration Rights Agreement and Waiver of Lock-Up Period (the "Lock-Up Waiver"), pursuant to which, among other things, LMAO and certain Registration Rights Stockholders agreed to waive their right to require us to the release of their lock-up restrictions as a result of the Humes Lock-up Release.

Amendment to Credit Agreement with LM Funding America, Inc. ("LMFA")and Amended Promissory Note

On October 28, 2022, SeaStar Medical and LMFA entered into the First Amendment to the Credit Agreement originally executed on September 9, 2022, pursuant to which the parties amended the Credit Agreement and entered into the LMFA Note to (i) extend the maturity date of the loan under the Credit Agreement to October 30, 2023; (ii) permit the LMFA Note be prepaid without premium or penalty; (iii) require us 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 is not required for the first $500,000 of cash proceeds; (iv) reduce the interest rate of the LMFA Note from 15% to 7% per annum; and (iv) reduce the default interest rate 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 the LMFA Security Agreement, pursuant to which we and SeaStar Medical granted LMFA a security interest in substantially all of the assets and property of us and SeaStar Medical, subject to certain exceptions, as collateral to secure our obligations under the amended Credit Agreement. In addition, SeaStar Medical entered into the LMFA Guaranty, pursuant to which SeaStar Medical unconditionally guarantees and promises to pay to Sponsor the outstanding principal amount under the LMFA Note.

On March 15, 2023, we and LMFA entered into the First Amendment, Consent and Waiver Agreement, to extend the maturity date of the loan under the Credit Agreement to June 15, 2024, and the Third Amendment, Consent and Waiver Agreement, dated August 7, 2023, pursuant to which the Lender agreed to (i) waive its right to receive any mandatory prepayment for any proceeds received by us in the Convertible Note Financing and (ii) agreed to extend the maturity date under the applicable promissory note to 91 days after the last maturity date applicable to any of the LMFA Note issued pursuant to the Credit Agreement, as amended.

Sponsor Promissory Note

On October 28, 2022, we entered into the Sponsor Note with Sponsor as the lender, for an aggregate principal amount of $2,785,000 to amend and restate in their entirety the Original Notes. The Sponsor Note amended and consolidated the Original Notes to: (i) extend maturity dates of the Original Notes to October 30, 2023; (ii) permit outstanding amounts due under the Sponsor Note to be prepaid without premium or penalty; and (iii) require us to use 5.0% of the gross cash proceeds received from any future debt and equity financing to pay outstanding balance of Sponsor Note, provided that such repayment is not required for the first $500,000 of cash proceeds. The Sponsor Note carries an interest rate of 7% per annum and contains customary representations and warranties and affirmative and negative covenants. The Sponsor Note is also subject to customary events of default, the occurrence of which may result in the Sponsor Promissory Note then outstanding becoming immediately due and payable, with interest being increased to 15.0% per annum. In addition, on October 28, 2022, the parties entered into the Sponsor Security Agreement, pursuant to which we and SeaStar Medical granted Sponsor a security interest in substantially all of the assets and property of us and SeaStar Medical, subject to certain exceptions, as collateral to secure our obligations under the Sponsor Note. In addition, SeaStar Medical entered into the Sponsor Guaranty, pursuant to which SeaStar Medical unconditionally guarantees and promises to pay to Sponsor the outstanding principal amount under the LMFA Note.

On March 15, 2023, we and Sponsor entered into the Amendment, Consent and Waiver Agreement to extend the maturity date of the Original Notes to June 15, 2024. On January 31, 2024, we paid off all outstanding balances under the Sponsor Note.

Related Person Transaction Policy

We adopted a related person transaction policy that sets forth its procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities and any of their respective immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of the Board, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests (direct and indirect) of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from (as the case may be) an unrelated third party or to or from employees generally. Under the policy, we will collect information that it deems reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy. In addition, under the Code of Conduct, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of the Board, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

- the availability of other sources for comparable services or products; and

- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of the Board, must consider, in light of known circumstances, whether or not the transaction is consistent with our best interests and those of our stockholders, as our audit committee, or other independent body of the Board, determines in the good faith exercise of its discretion.

Limitation on Liability and Indemnification of Directors and Officers

Our Charter limits the liability for directors to the fullest extent permitted under the Delaware General Corporation Law ("DGCL"). The DGCL provides that directors of a corporation will not be personally liable for monetary damages for a breach of their fiduciary duties as directors, except for liability:

- for any transaction from which the director derives an improper personal benefit;

- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

- for any unlawful payment of dividends or redemption of shares; or

- for any breach of a director's duty of loyalty to the corporation or its stockholders.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the directors will be further eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Delaware law and the Bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment, or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe these provisions in the Charter and Bylaws are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

LEGAL MATTERS

The validity of the securities offered by this prospectus has been passed upon for us by Dorsey & Whitney LLP, Salt Lake City, Utah.

EXPERTS

The consolidated financial statements as of December 31, 2024 and 2023 and for the years then ended included in this prospectus have been so included in reliance on the report of WithumSmith+Brown, PC, an independent registered public accounting firm, which report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which forms a part of such registration statement, does not contain all of the information included in the registration statement. For further information pertaining to us and our securities, you should refer to the registration statement and to its exhibits. The registration statement has been filed electronically and may be obtained in any manner listed below. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement or a report we file under the Exchange Act, you should refer to the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit to a registration statement or report is qualified in all respects by the filed exhibit.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the internet at the SEC's website at www.sec.gov and on our website, free of charge, at https://seastarmedical.com/. The information found on, or that can be accessed from or that is hyperlinked to, our website is not part of this prospectus. You may inspect a copy of the registration statement through the SEC's website, as provided herein.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements (audited) for the Years Ended December 31, 2024 and December 2023

Consolidated Financial Statements (unaudited) for the three months ended and year-to-date ended March 31, 2025 and March 31, 2024

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 sheets of SeaStar Medical Holding Corporation (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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

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

Basis for Opinion

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

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

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

/s/ WithumSmith+Brown, PC

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

East Brunswick, New Jersey
March 27, 2025

PCAOB ID No. 100

SeaStar Medical Holding Corporation
Consolidated Balance Sheets
As of December 31, 2024 and 2023
(in thousands, except for share and per-share amounts)

	2024	2023
ASSETS		
Current assets		
Cash	$ 1,819	$ 176
Accounts receivable	112	—
Prepaid expenses	1,835	2,132
Total current assets	3,766	2,308
Other assets	892	1,205
Total assets	$ 4,658	$ 3,513
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 3,046	$ 4,372
Accrued expenses	3,188	1,523
Contract liabilities	—	100
Notes payable, net of deferred financing costs	574	565
Convertible notes, current portion	—	4,179
Liability classified warrants	33	2,307
Total current liabilities	6,841	13,046
Notes payable, net of deferred financing costs	—	4,143
Convertible notes, net of current portion	—	194
Total liabilities	6,841	17,383
Commitments and contingencies (Note 13)		
Stockholders' deficit		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023.	—	—
Common stock - $0.0001 par value per share; 500,000,000 shares authorized at December 31, 2024 and 2023; 5,977,246 and 2,016,045 shares issued and outstanding at December 31, 2024 and 2023, respectively	2	1
Additional paid-in capital	137,379	100,863
Accumulated deficit	(139,564)	(114,734)
Total stockholders' deficit	(2,183)	(13,870)
Total liabilities and stockholders' deficit	$ 4,658	$ 3,513

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, 2024 and 2023
(in thousands, except for share and per-share amounts)

	2024	2023
Net Revenue	$ 135	$ —
Cost of goods sold	—	—
Gross profit	135	—
Operating expenses		
Research and development	9,105	5,973
General and administrative	8,872	8,237
Total operating expenses	17,977	14,210
Loss from operations	(17,842)	(14,210)
Other income (expense)		
Interest income	101	—
Interest expense	(244)	(1,081)
Change in fair value of convertible notes	(6,145)	(5,380)
Change in fair value of warrants liability	(697)	545
Change in the fair value of the forward purchase agreement derivative liability	—	(1,308)
Loss on extinguishment of convertible notes	—	(4,949)
Other income	—	151
Total other income (expense), net	(6,985)	(12,022)
Loss before provision for income taxes	(24,827)	(26,232)
Provision for income taxes	3	—
Net loss	$ (24,830)	$ (26,232)
Net loss per share of common stock, basic and diluted	$ (6.63)	$ (30.26)
Weighted-average shares outstanding, basic and diluted	3,743,554	866,813

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, 2024 and 2023
(in thousands, except for share and per-share amounts)

	Stockholders' Deficit				
	Common Shares		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance, December 31, 2022	**618,452**	**$ 1**	**$ 67,739**	**$ (88,502)**	**$ (20,762)**
Issuance of shares - equity line of credit	261,000	—	4,742	—	4,742
Issuance of shares - commitment fee for equity line of credit	8,754	—	1,000	—	1,000
Issuance of shares - conversion of convertible notes	913,910	—	10,410	—	10,410
Issuance of shares - exercise of warrants	118,207	—	1,651	—	1,651
Issuance of shares - vesting of RSUs	8,238	—	—	—	—
Issuance of shares - prepaid forward contracts	43,879	—	1,870	—	1,870
Forward purchase agreement derivative liability	—	—	11,521	—	11,521
Stock-based compensation	43,638	—	1,930	—	1,930
Net loss	—	—	—	(26,232)	(26,232)
Balance, December 31, 2023	**2,016,078**	**$ 1**	**$ 100,863**	**$ (114,734)**	**$ (13,870)**
Issuance of shares - conversion of convertible notes	600,770	—	10,215	—	10,215
Issuance of shares - exercise of warrants	352,074	—	3,960	—	3,960
Issuance of shares - equity offerings, net of issuance costs	2,974,745	1	21,244	—	21,245
Issuance of shares - stock issued for Board compensation in-lieu of cash	10,120	—	210	—	210
Issuance of shares - vesting of RSUs	13,136	—	—	—	—
Issuance of shares - stock issued for employee bonuses	10,323	—	73	—	73
Stock-based compensation	—	—	814	—	814
Net loss	—	—	—	(24,830)	(24,830)
Balance, December 31, 2024	**5,977,246**	**$ 2**	**$ 137,379**	**$ (139,564)**	**$ (2,183)**

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, 2024 and 2023
(in thousands, except for shares and per-share amounts)

	2024	2023
Cash flows from operating activities		
Net loss	$ (24,830)	$ (26,232)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	102	48
Change in fair value of convertible notes	6,145	5,380
Change in fair value of forward purchase agreement derivative liability	—	1,308
Change in fair value of liability classified warrants (exercised and outstanding)	697	(545)
Stock-based compensation	887	1,930
Loss on extinguishment of convertible notes	—	4,949
Change in operating assets and liabilities		
Account receivable	(112)	—
Other receivables	—	12
Prepaid expenses	297	(97)
Other assets	313	—
Accounts payable	(1,281)	2,445
Accrued expenses	1,875	517
Other liabilities	(100)	—
Net cash used in operating activities	(16,007)	(10,285)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	979	8,000
Payment of convertible notes	(700)	(400)
Proceeds from issuance of notes payable	713	800
Payment of notes payable	(5,402)	(4,870)
Proceeds from issuance of shares, net of offering costs	17,441	4,742
Proceeds from exercise of convertible note warrants	853	592
Proceeds from issuance of pre-funded warrants	3,766	—
Proceeds from exercise of additional warrants	—	180
Payment of commitment fee - equity line of credit	—	(500)
Proceeds from sale of recycled shares	—	1,870
Net cash provided by financing activities	17,650	10,414
Net increase in cash	1,643	129
Cash, beginning of period	176	47
Cash, end of period	$ 1,819	$ 176

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, 2024 and 2023
(in thousands, except for shares and per-share amounts)

	2024	2023
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 3	$ —
Cash paid for interest	$ 553	$ 1,126
Supplemental disclosure of noncash financing activities		
Exercise of liability classified warrants	$ 3,106	$ —
Shares issued as payment of convertible notes	$ 10,210	$ 10,411
Shares issued to settle forward option-prepaid forward contracts	$ —	$ 1,870
Board compensation settled in shares of common stock in-lieu-of-cash	210	$ —
Offering costs incurred but not paid	$ 45	$ —
Issuance of convertible note warrants	$ 586	$ 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, 2024 and 2023

Note 1. Description of Business

Organization and description of business

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

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

Basis of Presentation

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

On June 7, 2024, the Company effected a 1-for-25 reverse-stock split (the "Reverse Stock-Split") of its issued and outstanding shares of common stock, par value $0.0001 (the "common stock"). Following the effect of the Reverse Stock Split, each 25 shares of the Company's common stock that were issued and outstanding automatically converted into one outstanding share of common stock. All stock options and warrants of the Company outstanding immediately prior to the Reverse Stock-Split were proportionally adjusted except for the Listed Warrants and the private placement warrants that were issued as part of the SPAC transaction that closed on October 28, 2022, which total 16,788,000 outstanding warrants in the aggregate (the "Unadjusted Warrants"). The Unadjusted Warrants each retained an $11.50 exercise price and require the exercise of 25 warrants to purchase one share of common stock. Unless otherwise indicated, all other share and per share amounts in this prospectus reflect the effect of the Reverse-Stock Split. The par value of the Company's common stock remained unchanged at $0.0001 per share and the number of authorized shares of common stock remained the same after the Reverse-Stock Split.

Liquidity and going concern

As of December 31, 2024, the Company has an accumulated deficit of approximately $139.6 million and cash of approximately $1.8 million. The Company does not believe that its cash on hand will be sufficient to enable it to fund its operations, including clinical trial expenses and capital expenditure requirements for at least 12 months from the issuance of these consolidated financial statements. The Company believes that these conditions raise substantial doubt about its ability to continue as a going concern.

The Company's need for additional capital will depend in part on the scope and costs of its development activities. To date, the Company has generated very little revenue from the sales of it's commercialized product, QUELIMMUNE. Its ability to generate meaningful product revenue will depend on the successful launch of QUELIMMUNE and development and eventual commercialization of the adult SCD. Until such time, if ever, it expects to finance its operations through the sale of equity or debt, 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

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 (i) valuation of the liability classified warrants, (ii) prepaid forward purchase agreement derivative liability, (iii) provision for income taxes, (iv) convertible debt measured at fair value, (v) unbilled clinical trial costs, (vi) and stock-based compensation expense. Although actual results could differ from those estimates, such estimates are developed based on the best information available to management and management's best judgments at the time.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The company did not have any cash equivalents as of December 31, 2024 and 2023.

Concentrations of credit risk

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

Accounts Receivable

The need for a credit loss allowance is evaluated each reporting period based on the Company's assessment of the credit worthiness of its customers or any other potential circumstances that could result in a credit loss. The Company initially estimates credit losses based on a portfolio-wide method using an aging schedule at the end of each reporting period. Any customer specific collections subsequent to the reporting period are then adjusted accordingly.

All outstanding accounts receivable customer balances at December 31, 2024 were fully paid subsequent to December 31, 2024. Accordingly, there is no reserve for a credit loss allowance provided as of December 31, 2024.

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.

Use of Derivative Instruments

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

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

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

Fair value option of accounting

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

Based on the eligibility assessment discussed above, the Company concluded that its convertible notes (see Note 8) were eligible for the FVO and accordingly elected the FVO for those debt instruments. This election was made because of operational efficiencies in valuing and reporting for these debt instruments at fair value in their entirety at each reporting date. The convertible notes contained certain embedded derivatives that otherwise would require bifurcation and separate accounting at fair value.

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

Fair value of financial instruments

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

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.

Investor D Convertible Notes. The convertible notes were recorded as liabilities and were recorded at fair value based on Level 3 measurements until they were fully settled in 2024. The estimated fair values of the convertible notes were 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 was then discounted back to each reporting period in which the convertible notes were 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 was appropriate for those probability-adjusted cash flows. The change in fair value of the Investor D Convertible Notes each reporting period was recorded to the change in fair value of convertible notes in the consolidated statement of operations.

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

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

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

Classification of Derivative Gains and Losses on the Statement of Cash Flows. Changes in fair value related to the Company's derivative financial instruments consisting of (i) liability classified warrants, (ii) convertible notes, and (iii) forward purchase agreements are classified in operating cash flows as adjustments to net income.

Revenue Recognition

Overall

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

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

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

Product Sales Revenue

The Company has sold and intends to continue to sell its products either through a combination of distributor(s) and/or directly to end-user qualified customers through the Company's own internal commercial/sales resources. The acting distributor during the year ended December 31, 2024 subsequently resold and was to continue to resell the products to present and future customers, until such time the Company terminated its agreement with the distributor (see Notes 3 and 13).

- Timing of Revenue Recognition – During the brief history (commenced July 2024) of selling pediatric SCDs, revenue has been recognized based on a *freight-on-board destination* ("FOB Destination") requirement.

- Chargebacks, Government Rebates and Discounts – During the brief history of selling pediatric SCDs commercially, the Company has not agreed to chargebacks, government rebates or discounts.

- Returns – Returns are specific to each order, but generally the Company allows for returns of any damaged or non-conforming product within 30 days of receipt of product. Given the (i) overall rate of product shipped that is defective/damaged, (ii) overall volume of sales to individual end-user customers, (iii) expected supply in the customer channel, and (iv) expected usage by customers, the Company does not anticipate that there will be significant risk of product returns overall.

- Variable Consideration – based on the above and given the materiality of current sales (less than $0.1 million sold through the year ended December 31, 2024), the Company does not currently estimate a constraint on revenue recognized on product sales.

- Transaction Price – based on the above, as currently constructed, the Company's transaction price is fixed, based on the agreed-upon price per each purchase order submitted by each customer. Milestone or up-front payments unique to the distributor were disclosed in Note 3 (also see Note 13), and are not expected to be recognized as revenue, but were returned as a result of a settlement to cease the relationship with the distributor.

- Allocation of Consideration – each sale of a pediatric SCD is independent of any and all other sales. The entire transaction price for each pediatric SCD is allocated to the sale of that pediatric SCD.

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

Cost of Goods Sold

Prior to July 2024, the Company only manufactured/assembled pediatric or adult SCDs for research oriented and/or clinical trial related activities. Accordingly, as of and during the year ended December 31, 2024, all inventory on-hand or utilized had $0 carrying value, as it was expensed to research and development expense at the time of purchase. Accordingly, for pediatric SCDs sold during the year ended December 31, 2024, the Company recognized no cost of goods sold, as there was no carrying value attributed to those units sold. As the Company procures inventory in the future, the Company will place value on raw materials and component parts, as there is the potential that the raw materials could be used either for (i) commercial purposes (*QUELIMMUNE sales*) or (ii) research and development purposes (*adult SCDs used in ongoing clinical trials*).

Stock-based compensation

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

Research and development expenses

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

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

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 16 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 adopted accounting standards

Accounting Standards Update 2023-07 - In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07 – Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. See Note 17 - *Segment Reporting.* The Company adopted this as of December 31, 2024, resulting in a dedicated segment reporting footnote with the requisite disclosures (see Note 17 - *Segment Reporting*).

Recently issued accounting standards not yet adopted

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

Accounting Standards Update 2023-09 — In December 2023, the FASB issued ASU 2023-09 *Income Taxes (Topic 740) Improvements to Income Tax Disclosures*. ASU 2023-09 enhances the transparency and decision usefulness of income tax disclosures. The amendments in this update are effective for public business entities for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently assessing the impact of this guidance on its consolidated financial statements and disclosures.

Note 3. Revenues and Contract Obligations

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

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

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

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

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

Since the termination of the Distribution Agreement, the Company developed its own commercial operations and sold approximately $0.1 million of pediatric SCDs to an end-user customer during the year ended December 31, 2024.

The following table summarizes the changes in the Company's contract liability balance for the years ended December 31, 2024 and 2023:

	Year Ended	
($ in thousands)	**2024**	**2023**
Contract liabilities, beginning of period	$ 100	$ —
Consideration received	450	100
Consideration refunded	(550)	—
Revenue	—	—
Contract liabilities, end of period	$ —	$ 100

The Company had no contract assets at the beginning or end of the fiscal years ended December 31, 2024 and 2023. The accounting policies used to measure the profit and loss of the segment are the same as those described in the summary of significant accounting policies.

Note 4. Trade Accounts Receivable

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

($ in thousands)	Accounts Receivable, Gross	Expected Credit Losses	Accounts Receivable, Net
December 31, 2023	$ —	$ —	$ —
Increase in trade account receivable, gross	112	—	—
December 31, 2024	$ 112	$ —	$ —

Note 5. Accrued Expenses

Accrued expenses consisted of the following amounts as of December 31, 2024 and 2023:

($ in thousands)	December 31, 2024	December 31, 2023
Accrued bonus	$ 1,391	$ 501
Accrued director compensation	391	427
Accrued research and development	1,023	507
Other	383	88
Total accrued expenses	$ 3,188	$ 1,523

Note 6. Forward Purchase Agreements

In October 2022, LMF, entered into Forward Purchase Agreements ("FPAs") with (i) Vellar Opportunity Fund SPV LLC – Series 4 and (ii) HB Strategies LLC (collectively the "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 FPAs, 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") 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, an additional 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 statements of operations for the year ended December 31, 2023.

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 liability was remeasured at each reporting date until the liability was extinguished in 2023. The Company recognized a loss of $2.3 million during the year ended December 31, 2023, from the remeasurement of the liability.

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 and (ii) all remaining 773,400 unsold Recycled Shares to the FPA Sellers. Upon the final settlement of the FPA, the Company recognized a gain of approximately $1.0 million as the ultimate amount to settle the repurchase of the Company's shares of common stock underlying the FPAs was reduced by the counterparties to the agreements. Approximately $11.5 million was reclassed to equity as a result of the settlement of the forward purchase agreements during the year ended December 31, 2023.

Note 7. Notes Payable

Notes payable consisted of the following:

($ in thousands)	**December 31, 2024**	**December 31, 2023**
LMFA notes payable	$ —	$ 296
LMFAO note payable	—	1,128
Maxim note payable	—	2,771
Insurance financing	574	565
Unamortized deferred financing costs	—	(52)
Total	574	4,708
Less current portion	(574)	(565)
	$ —	$ 4,143

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 8, 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 10). The $0.1 million consideration for the modification was capitalized as a deferred financing cost. The Company amortized $52 thousand and $48 thousand of the deferred financing cost during the years ended December 31, 2024 and 2023, respectively.

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. 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. As of December 31, 2024, the Company had fully extinguished all notes payable to LMFA, LMFAO and Maxim for $5.4 million of cash.

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 originally 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 was 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 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 contained 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 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 originally due on demand at any time on or after March 31, 2023.

The Company paid the LMFA notes in full during the year ended December 31, 2024.

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 carried an interest rate of 7% per annum and contained customary representations and warranties and affirmative and negative covenants.

The LMFAO Note was subject to events of default, which could have resulted 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 Company paid this note in full during the year ended December 31, 2024.

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 received any cash proceeds from a debt or equity financing transaction prior to the maturity date, then the Company was 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 was due at 7.0% per annum.

The Maxim Note contained customary representations and warranties, and affirmative and negative covenants. The Maxim Note was subject to events of default, which could have resulted in the Maxim Note becoming immediately due and payable, with interest of 15.0% per annum.

As a result of the Reverse Stock-Split, the Maxim Note balance became due within 90 days of the June 2024 Reverse Stock-Split event. The Maxim Note was paid in full during the year ended December 31, 2024.

Insurance Financing

In October 2024, the Company entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of $0.7 million. Interest on the financing agreement was 8.440% per annum. The October 2024 financing agreement is to be paid in 10 monthly installments, with an outstanding balance of approximately $0.6 million at December 31, 2024.

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 was 9.55% per annum. The October 2023 financing agreement had an outstanding balance of approximately $0.6 million as of December 31, 2023, and was paid in full during the year ended December 31, 2024.

Related Party Notes

The Company from time to time has entered into short-term financings with LMFA to provide short-term liquidity needs. A total of three notes were entered into during the 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, 2024 and 2023.

Investor D Note

On June 28, 2024, the Company and Investor D agreed to exchange all of the remaining outstanding warrants held by Investor D, which were issued in connection with Investor D's convertible debt issued between March 2023 and January 2024, into a short-term note of approximately $0.5 million. The interest rate on the loan was 7.0% per annum and the note was paid in full during the year ending December 31, 2024.

Note 8. Convertible Notes

Convertible notes payable activity for the year ended December 31, 2024, consisted of the following:

($ in thousands)	3rd Investor D Note 3-1	3rd Investor D Note 3-2	3rd Investor D Note 3-3	3rd Investor D Note 3-4	4th Investor D Note	5th Investor D Note	6th Investor D Note	Total
Balance as of December 31, 2023	$ 1,012	$ 999	$ 972	$ 568	$ 822	$ —	$ —	$ 4,373
Issuance (Face Value)	—	—	—	—	—	272	815	1,087
Fair value of detachable warrants at issuance	—	—	—	—	—	(147)	(439)	(586)
(Gain)/loss on conversion	1,201	636	615	381	77	482	2,005	5,397
Conversion to common stock	(2,213)	(1,635)	(1,587)	(949)	(947)	(607)	(2,381)	(10,319)
(Gain)/loss on reporting period remeasurement	—	—	—	—	748	—	—	748
Redemption	—	—	—	—	(700)	—	—	(700)
Balance as of December 31, 2024	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —

Investor D Unsecured Convertible Notes

On March 15, 2023, the Company entered into a Securities Purchase Agreement (the "Investor D SPA") with an institutional investor ("Investor D"), whereby the Company agreed to issue a series of four senior unsecured convertible notes (collectively, the "Investor D Convertible Notes") during the year ended December 31, 2023 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 48,309 shares of common stock at an initial conversion price of $67.50. The First Investor D Note was issued at an 8.0% discount, bore interest at 7.0% per annum, matured on June 15, 2024, and required monthly installments of principal and interest. In addition, the Company issued warrants to purchase 13,134 shares of common stock (the "First Investor D Warrants"). The First Investor D Warrants have an initial exercise price of $74.25 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 32,206 shares of common stock at an initial conversion price of $67.50. The Second Investor D Note was issued at an 8.0% discount, bore interest at 7.0% per annum, matured on August 12, 2024, and required monthly installments of principal and interest. In addition, the Company issued warrants to purchase 8,756 shares of common stock (the "Second Investor D Warrants"). The Second Investor D Warrants have an initial exercise price of $74.25 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, bore interest at 7.0% per annum and required monthly installments of principal and interest. Each tranche of the Third Investor D Note was convertible into 108,686 shares of common stock at an initial conversion price of $5.00, in a principal amount of $0.5 million, and includes a warrant to purchase up to 29,552 shares of common stock with an exercise price of $5.00 per share. The Third Investor D Notes had maturity dates of November 6, 2024, November 29, 2024, December 25, 2024, and February 26, 2025.

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) $5.00, (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 190,625 shares of common stock with an exercise price of $5.00 per share of common stock.

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 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 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 $14.00 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 21,108 shares of common stock with an exercise price of $14.00 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 496,831 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 417,078 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 not 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".

Investor D Unsecured Convertible Notes Issued in 2024

The Company completed additional closings related to the Second Amendment to the Investor D Securities Purchase Agreement on January 12, 2024, and January 24, 2024, issuing notes in principal amounts of $0.3 million and $0.8 million, respectively, each at 7.00% per annum (collectively the "2024 Investor D Notes"). The 2024 Investor D Notes were to mature on April 12, 2025 and April 24, 2025, respectively. The 2024 Investor D Notes had an initial conversion price of $350.00 per share and were convertible into shares of the Company's 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. The Company also issued warrants to purchase up to 5,278 and 15,382 shares of common stock, respectively, with an exercise price of $14.00 per share, and additional warrants to purchase up to 5,278 and 15,382 shares of common stock, respectively, with an exercise price of $350.00 per share.

On January 30, 2024, 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 within three (3) trading days after the Suspension Period at an amount equal to 200% of the Conversion Amount.

During the quarter-ended March 31, 2024, the institutional investor converted approximately $3.3 million (face value) of the outstanding convertible notes into approximately $9.5 million of the Company's common stock. As of March 31, 2024, the Company still owed the institutional investor approximately $1.0 million (face value) in convertible notes, with a fair value of approximately $1.1 million, which as disclosed below, was ultimately either converted or redeemed by June 30, 2024.

The Company incurred a loss of approximately $5.8 million as a result of the following: (i) $4.7 million loss on conversion into equity as a result of the difference between the fair value of the convertible notes being converted and the equity being delivered, (ii) $0.7 million loss on issuance of the Investor D convertible notes issued during the quarter ended March 31, 2024, as a result of the combination of the fair value of detachable warrants issued in conjunction to the Investor D Notes issues during the quarter ended March 31, 2024, and the excess fair value over the proceeds received for the Investor D convertible notes issues during the quarter ended March 31, 2024, and (iii) $0.4 million loss on the change in fair value of those Investor D convertible notes that were still outstanding as of March 31, 2024.

Investor D April 2024 Side Letter

On April 1, 2024, the Company and Investor D entered into a side letter agreement (the "April 2024 Side Letter") whereby each party agreed to suspend certain rights of Investor D for a 60-day period, extending those rights from March 30, 2024, to May 30, 2024. Those rights included a 10-day notice period for any subsequent financing and rights to review terms of such financing arrangements. Finally, Investor D waived its rights and notice of default in the event of such financings. In addition, if at the end of the suspension period of May 30, 2024 the convertible notes were still outstanding, Investor D had the right to require the Company to redeem all or a portion of any outstanding Investor D convertible notes at 200% of the conversion amount (the "Make-Whole Amount").

On June 5, 2024, Investor D and the Company completed the following two transactions, eliminating the remaining outstanding convertible debt:

- Investor D converted approximately $0.6 million of outstanding principal and $0.7 million of accrued interest and Make-Whole Amount, into 92,858 shares of the Company's common stock, resulting in a loss of approximately $0.4 million, and

- The Company paid the remaining $0.7 million of outstanding convertible debt and Make-Whole Amount.

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 10). 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. The Investor D Convertible Notes were measured at fair value each reporting date until they were satisfied with changes in fair value recognized in the consolidated statements of operations, unless the change was concluded to be related to the changes in the Company's credit rating, in which case the change would have been recognized as a component of accumulated other comprehensive income in the consolidated balance sheets. As the fair value option under ASC 825 was elected, the Company does not recognize interest expense, but instead the change in fair value at each reporting period is impacted by either the accrual or payment of interest.

Note 9. Equity Transactions

January 2024 Offering

On January 26, 2024, the Company entered into a Securities Purchase Agreement with a single institutional investor, pursuant to which the Company issued to the investor (the "Q1 2024 SPA"), (i) in a registered direct offering, 252,182 shares of the Company's common stock, par value $0.0001 per share, and pre-funded warrants to purchase 181,449 shares of Common Stock

(the “Pre-Funded Warrants”) with an exercise price of $0.0001 per share, and (ii) in a concurrent private placement, series A warrants to purchase 433,631 shares of common stock (the “Series A Common Warrants”) and series B warrants to purchase 216,816 shares of common stock each with an exercise price of $20.76 (the “Series B Common Warrants” and together with the Series A Common Warrants, the “Investor E Warrants”). Such registered direct offering and concurrent private placement are referred to herein as the “January 2024 Offering”. The January 2024 Offering was priced at-the-market consistent with the rules of the Nasdaq Stock Market.

The Company received aggregate gross proceeds from the January 2024 Offering of approximately $9.0 million, before deducting fees to the Maxim Group LLC and other offering expenses payable by the Company. The Investor E Warrants became exercisable on June 4, 2024, the effective date of stockholder approval for the issuance of the shares of common stock issuable upon exercise of the Investor E Warrants (the "Stockholder Approval Date"). The Series A Common Warrants will expire on the fifth anniversary of the Stockholder Approval Date and the Series B Common Warrants will expire on the twelve-month anniversary of the Stockholder Approval Date. The Pre-Funded Warrants will not expire and were exercisable commencing on January 26, 2024. All Pre-Funded Warrants were exercised during the quarter ended March 31, 2024.

The Company paid approximately $0.7 million in fees to Maxim Group LLC and issued 21,682 warrants (the "PA Warrants") to purchase shares of the Company's common stock, with a fair value of approximately $0.3 million at issuance. The exercise price of these warrants is $22.83 per share and the warrants become exercisable on July 30, 2024, expiring five years after the closing date.

July 2024 Offering

On July 10, 2024, the Company entered into a securities purchase agreement (the "Q3 2024 SPA") with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market: (i) 947,868 shares of the Company's common stock, $0.0001 par value per share and (ii) Common Stock purchase warrants to purchase up to 947,868 shares of Common Stock (the "July 2024 Investor Warrants") in a concurrent private placement (together the "July 2024 Offering"). The July 2024 Investor Warrants were immediately exercisable, expire five years following the issuance date and have an exercise price of $10.55 per share. The Company agreed to register the shares of Common Stock underlying the Common Warrants within 30 days of the date of the Purchase Agreement. The combined purchase price of each share of Common Stock and July 2024 Investor Warrant is $10.55. The gross proceeds to the Company from the Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by the Company.

On May 17, 2024, the Company entered into an engagement letter with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which Wainwright agreed to serve as the exclusive placement agent for the Company, on a reasonable best-efforts basis, in connection with the offering. The Company paid Wainwright an aggregate cash fee equal to (i) 6.4% and 1% management fee of the gross proceeds of the July 2024 Offering and (ii) for certain expenses incurred by Wainwright totaling approximately $0.8 million. Additionally, the Company agreed to issue to Wainwright or its designees as compensation, warrants to purchase up to 66,351 shares of Common Stock, equal to 7.0% of the aggregate number of Shares placed in the Offering (the "July 2024 PA Warrants", which combined with the July 2024 Investor Warrants are herein referred to as the "July 2024 Warrants"). The July 2024 PA Warrants have a term of five years from the commencement of sales under the Offering and an exercise price of $13.1875 per share of Common Stock (equal to 125% of the offering price).

August 2024 At-The-Market Offering

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

Through December 31, 2024, the Company raised approximately $0.1 million utilizing the ATM, issuing 12,218 shares of the Company's Common Stock.

Tumim 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, of which $1.5 million was paid in cash in 2022 and 2023 and $1.0 million was paid by issuing 8,730 shares of common stock to Tumim in 2023.

During the year ended December 31, 2023, the Company sold 260,000 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 million was available to be drawn. In February 2024, the Company and Tumim agreed to terminate the Purchase Agreement.

Note 10. Warrants

The Company has the following warrants outstanding at December 31, 2024 and 2023:

	2024	2023
Liability Classified Warrants		
Investor D Warrants	—	254,732
Private Placement Warrants	229,520	229,520
PIPE Investor Warrants	20,000	20,000
Subtotal	249,520	504,252
Equity Classified Warrants		
Investor E Warrants	650,446	—
July 2024 Warrants	1,014,219	—
Placement Agent Warrants	21,682	—
Public Stockholders' Warrants	422,000	422,000
Legacy Warrants	1,957	1,957
Subtotal	2,110,304	423,957
Grand Total	2,359,824	928,209

The following tables provides the weighted-average strike price and time to maturity for each warrant tranche as of December 31, 2024 and 2023:

December 31, 2024	**Warrant Share Equivalents**	**Weighted-Average Strike Price**	**Weighted-Average Time to Maturity**
Liability Classified Warrants			
Private Placement Warrants	229,520	$ 287.50	2.82
PIPE Investor Warrants	20,000	$ 287.50	2.82
Equity Classified Warrants			
Investor E Warrants	650,446	$ 20.76	4.03
July 2024 Warrants	1,014,219	$ 10.72	4.53
Placement Agent Warrants	21,682	$ 22.75	4.08
Public Stockholders' Warrants	422,000	$ 287.50	2.82
Legacy SeaStar Inc. Warrants	1,957	$ 250.00	1.38

December 31, 2023	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Maturity
Liability Classified Warrants			
Investor D Warrants	254,732	$ 12.50	4.65
Private Placement Warrants	229,520	$ 287.50	3.82
PIPE Investor Warrants	20,000	$ 287.50	3.82
Equity Classified Warrants			
Public Stockholders' Warrants	422,000	$ 287.50	3.82
Legacy SeaStar Inc. Warrants	1,957	$ 250.00	2.38

July 2024 Warrants

As discussed in Note 8, as part of the Q3 2024 SPA, the Company issued the following warrants to purchase the Company's common stock to certain institutional investors and the placement agent in July 2024:

- *July 2024 Investor Warrants* - warrants to purchase 947,868 shares of the Company's common stock with an exercise price of $10.55, expiring July 10, 2029.

- *July 2024 PA Warrants* - warrants to purchase 66,351 shares of the Company's common stock, with an exercise price of $13.1875, expiring July 10, 2029.

Investor E Warrants

As discussed in Note 8 as part of the Q1 2024 SPA, the Company issued the following warrants to purchase the Company's common stock to Investor E in January 2024:

- *Pre-Funded Warrants* - warrants to purchase 181,449 shares of common stock with an exercise price of $0.0001. The Pre-Funded Warrants had no expiration date and were exercisable commencing on the date of issuance and at any time until all of the Pre-Funded Warrants are exercised in full. The Pre-Funded Warrants were exercised in full during the quarter ended March 31, 2024.

- *Series A and Series B Common Warrants* - in a concurrent private placement, Series A Common Warrants to purchase 433,631 shares of Common Stock and Series B Common Warrants to purchase 216,816 shares of common stock each with an exercise price of $20.76.

- *PA Warrants* – in a concurrent private placement, PA Warrants to purchase 21,682 shares of common stock with an exercise price of $22.83 per share.

Investor E Warrants became exercisable on June 4, 2024, the effective date of stockholder approval for the issuance of the shares of common stock issuable upon exercise of the Investor E Warrants. The Series A Common Warrants will expire on June 4, 2029, and the Series B Common Warrants will expire on June 4, 2025.

Maxim Group LLC ("Maxim") acted as the placement agent in connection with the transactions pursuant to the Placement Agency Agreement, dated January 26, 2024, by and between the Company and Maxim. On January 30, 2024, Maxim received warrants to purchase 21,682 shares of common stock covering a number of shares equal to 5% of the total number of shares of common stock sold in the Transactions. The PA Warrants became exercisable six months after the closing and will expire on January 30, 2029. The PA Warrants are exercisable at $22.83 per share.

In accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity's own Equity*, the Company determined the Investor E and July 2024 Warrants meet the conditions for equity classification and are included on the consolidated balance sheets as a component of stockholders' equity (deficit).

Investor D Warrants

As disclosed in Note 8, the following summarizes warrants issued in connection with the Original and Amended Investor D SPA during the year ended December 31, 2023:

- On March 15, 2023, as part of the issuance of the First Investor D Note, 13,134 warrants were issued with an exercise price of $74.25 per share.

- On May 12, 2023, as part of the issuance of the Second Investor D Note, 8,756 warrants were issued with an exercise price of $74.25 per share.

- On August 7, 2023, as part of the Letter Agreement, 19,061 warrants were issued with an exercise price of $5.00 per share. Also on August 7, 2023, as part of the issuance of the first tranche of the Third Investor D Note, 29,552 Convertible Note Warrants were issued with an exercise price of $5.00 per share.

- On August 30, 2023, as part of the issuance of the second tranche of the Third Investor D Note, 29,552 warrants were issued with an exercise price of $5.00 per share.

- On September 26, 2023, as part of the issuance of the third tranche of the Third Investor D Note, 29,552 warrants were issued with an exercise price of $5.00 per share.

- On November 27, 2023, as part of the issuance of the fourth tranche of the Third Investor D Note, 29,552 warrants were issued with an exercise price of $5.00 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 21,108 shares of common stock with an exercise price of $350.00 per share.

- The Company, in conjunction with additional borrowing of convertible debt related to the Second Amendment to the Investor D SPA on January 12, 2024 and January 24, 2024, issued warrants to purchase up to 5,277 and 15,831 shares of common stock, respectively, with an exercise price of $350.00 per share, and additional warrants to purchase up to 5,277 and 15,831 shares of common stock, respectively, with an exercise price of $350.00 per share.

- The Company, in conjunction with additional borrowing of convertible debt related to the Second Amendment to the Investor D SPA on January 12, 2024 and January 24, 2024, issued warrants to purchase up to 5,277 and 15,831 shares of common stock, respectively, with an exercise price of $350.00 per share, and additional warrants to purchase up to 5,277 and 15,831 shares of common stock, respectively, with an exercise price of $350.00 per share.

The Investor D Warrants expired five years from their issuance date and contained cashless exercise provisions. The Company did not have the ability to redeem the warrants.

In 2024, 17,025 of the Investor D Warrants were converted into shares at an exercise price of $5.00. All remaining Investor D Warrants issued in connection with the Investor D SPA were exchanged for a short-term note payable of approximately $0.5 million on June 28, 2024, eliminating all Investor D Warrants, and recognizing a gain of approximately $1.3 million.

The Investor D Warrants were determined to be liability classified. The initial 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 was five years. Subsequent changes in fair value were recognized through earnings at each reporting period end-date or settlement date.

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, 2,318 outstanding warrants were converted into 2,789 warrants to purchase common stock of SeaStar Medical Holding Corporation ("Legacy SeaStar Inc. Warrants") at their previous exercise prices.

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 414,000 warrants each of which entitled the holder to purchase one share of common stock at an exercise price of $287.50 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 the ability to redeem outstanding Public Stockholders' Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.25 per warrant, provided that the last reported sales price of our common stock equals or exceeds $450.00 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 229,520 million warrants each of which entitled the holder to purchase one share of common stock at an exercise price of $287.50 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.

The Company does not have the ability to redeem the Private Placement Warrants.

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 28,000 shares of common stock at $250.00 per share and received 28,000 PIPE Investor Warrants ("PIPE Investor Warrants"), which entitled the holder to purchase one share of common stock of SeaStar Medical Holding Corporation for $287.50 per share, for an aggregate purchase price of approximately $7.0 million.

Below is the warrant activity for the year ended December 31, 2024:

	Investor D Warrants	Investor E (January 2024) Warrants	July 2024 Warrants	Placement Agent Warrants	Private Placement Warrants	PIPE Investor Warrants	Public Stockholders' Warrants	Legacy Warrants
Outstanding as of December 31, 2023	254,732	—	—	—	229,520	20,000	422,000	1,957
Issuance	42,217	831,895	1,014,219	21,682	—	—	—	—
Exercised	(170,625)	(181,449)	—	—	—	—	—	—
Forfeited / cancelled	—	—	—	—	—	—	—	—
Exchanged for Investor D Note	(126,324)	—	—	—	—	—	—	—
Outstanding as of December 31, 2024	—	650,446	1,014,219	21,682	229,520	20,000	422,000	1,957

Note 11. Common Stock and Preferred Stock

As of December 31, 2024, the Company is authorized to issue 510,000,000 shares, consisting of (a) 500,000,000 shares of common stock and (b) 10,000,000 shares of preferred stock (the "Preferred Stock"). On November 26, 2024, the Company's shareholders voted at a Special Meeting to reduce the authorized shares of common stock to 450,000,000. The change became effective on January 27, 2025.

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 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, 2024 or 2023.

Note 12. Stock-Based Compensation Awards

The following table sets forth the total stock-based compensation cost included in the Company's consolidated statements of operations for the years ended December 31, 2024 and 2023:

($ in thousands)	**2024**	**2023**
Research and development	$ 157	$ 160
General and administrative (*)	730	292
Total	$ 887	$ 452

(*) - Includes approximately $72,000 in stock bonuses pursuant to the 2022 Omnibus Incentive Plan.

Equity incentive plan - summary

2022 Omnibus Incentive Plan

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

2019 Stock Incentive Plan

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

Stock Options

Option activity for the year ended December 31, 2024, 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, 2023	14,045	$ 46.00	$ —	9.3
Exercised	—			
Issued	—			
Forfeited / cancelled	(931)			
Outstanding as of December 31, 2024	13,114	$ 46.00	$ —	8.5
Vested and exercisable as of December 31, 2024	13,114	$ —	$ —	8.5

2019 Stock Incentive Plan - Options

($ in thousands)	Options	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
Outstanding as of December 31, 2023	9,797	$ 46.00	$ —	6.7
Exercised	—			
Issued	—			
Forfeited / cancelled	(980)			
Outstanding as of December 31, 2024	8,817	$ 46.00	$ —	5.9
Vested and exercisable as of December 31, 2024	8,503	$ 46.00	$ —	5.9

Restricted Stock Units

A summary of the Company's restricted stock unit ("RSU") activity for the year ended December 31, 2024, is as follows:

2022 Omnibus Incentive Plan - RSUs

	Restricted Stock Units	Weighted Average Grant Date Fair Value (per share)
Outstanding as of December 31, 2023	9,361	$ 36.75
Granted	219,500	
Vested	(9,183)	
Forfeited / cancelled	(178)	
Outstanding as of December 31, 2024	219,500	$ 5.09

2019 Stock Incentive Plan - RSUs

	Restricted Stock Units	Weighted Average Grant Date Fair Value (per share)
Outstanding as of December 31, 2023	3,698	$ 200.00
Granted	—	
Vested	(2,529)	
Forfeited / cancelled	(422)	
Outstanding as of December 31, 2024	747	$ 200.00

Note 13. Commitments and Contingencies

License and distribution agreement

On December 27, 2022, the Company entered into a license and distribution agreement ("the Distribution Agreement") with Nuwellis, Inc., appointing Nuwellis as the exclusive distributor to promote, advertise, market, distribute and sell the SCD in the United States. The Company received a potentially refundable upfront payment of $0.1 million on January 3, 2023. The Company also received milestone payments in the amount of approximately $0.5 million for obtaining FDA approval . The term of the Distribution Agreement was for three years. The Distribution 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.

In May 2024, the Company provided notice to Nuwellis that Nuwellis had breached the Distribution Agreement and that the Distribution Agreement would terminate effective August 18, 2024. Nuwellis disputed the validity of the termination and on October 20, 2024, the Company entered into a confidential settlement agreement and release with Nuwellis, pursuant to which the Company agreed to pay Nuwellis an aggregate of $900 thousand, payable in three installments through December 31, 2024. The Company paid the first installment of $500 thousand on October 22, 2024, with the final payment of $0.2 million on December 31, 2024. As of December 31, 2024, the Company had fulfilled all of its obligations to Nuwellis.

Lease agreements

The Company is part of a membership agreement for shared office space and can cancel at any time, consisting of office space and new to 2024, dedicated space for warehousing and assembly of SCDs. Rent expense was approximately $43 thousand and $32 thousand for the years ended December 31, 2024 and 2023.

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.

On July 5, 2024, Forrest A K Wells (the "Plaintiff"), a purported stockholder of the Company, filed a putative class action complaint in the United States District Court for the State of Colorado, captioned Wells v. SeaStar Medical Holding Corporation et al, Case No. 1:24-cv-0187 (D. Colorado) (the "Class Action"). The Class Action alleges that the Company, its Chief Executive Officer and former Chief Financial Officer made or caused to be made material misstatements or omissions regarding the

Company's business and operations, allegedly culminating in the Company's restatement of its consolidated financial statements, disclosed in a Form 8-K and filed on March 27, 2024. The Class Action asserts claims pursuant to the Securities Exchange Act of 1934, including Section 10(b), Rule 10b-5 promulgated thereunder and Section 20(a). The Class Action seeks to recover, among other remedies, compensatory damages. On March 4, 2025, the Plaintiff filed an amended complaint. The Company intends to vigorously defend the action.

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

Note 14. 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

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, 2024 and 2023, by level withing the fair value hierarchy. There were no non-recurring fair value measurements, as the Company does not have any long-lived assets, including fixed assets, intangible assets or goodwill which can require non-recurring measurements for impairment.

	Fair Value at December 31, 2024	Fair Value Measurements at December 31, 2024		
		(Level 1)	(Level 2)	(Level 3)
Liabilities:				
Liability classified warrants	$ 33	$ —	$ —	$ 33
	$ 33	$ —	$ —	$ 33

	Fair Value at December 31, 2023	Fair Value Measurements at December 31, 2023		
		(Level 1)	(Level 2)	(Level 3)
Liabilities:				
Convertible notes	$ 4,179	$ —	$ —	$ 4,179
Liability classified warrants	2,307	—	—	2,307
Total	$ 6,486	$ —	$ —	$ 6,486

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, 2024 and 2023 (in thousands):

Level 3 Rollforward ($ in thousands)	Forward Purchase Agreement Derivative Liability	Convertible Notes	Liability Classified Warrants
Balance January 1, 2023	**$ 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)
Balance December 31, 2023	**$ —**	**$ 4,373**	**$ 2,307**
Additions	—	501	586
Payments	—	(700)	—
Shares issued as payments	—	(4,922)	(3,107)
Changes in fair value	—	748	697
Exchange for short-term note payable	—	—	(450)
Balance December 31, 2024	**$ —**	**$ —**	**$ 33**

Level 3 Inputs

For assets or liabilities for which the Company is required to remeasure the fair value on a recurring basis at each reporting date, generally the Company is required to disclose certain quantitative data related to the inputs used at the most recent reporting period date. However, for those assets or liabilities for which the Company has elected to take the 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, 2024 and 2023:

	December 31, 2024	December 31, 2023	
	(&)	Minimum	Maximum
Expected volatility	130.00%	85.00%	90.00%
Equivalent term	2.825	4.04	4.65
Risk-free rate	4.27%	3.84%	3.90%
Dividend yield	0.00%	0.00%	0.00%
Stock price	$ 1.94	$ 0.44	$ 0.44
Strike price	$ 287.50	$ 0.50	$ 11.50

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

Note 15. Income Taxes

The Company recorded approximately $3 thousand and $0 of current income tax expense for the years ended December 31, 2024 and 2023, respectively.

The effective income tax rate of the Company's provision for income taxes differed from the federal statutory rate as follows:

	Year Ended December 31,	
($ in thousands)	**2024**	**2023**
Federal tax at statutory rate	21.00%	21.00%
State income tax	(3.12)%	3.26%
R&D tax credit	0.79%	0.65%
Stock compensation expense	(0.07)%	(0.26)%
Interest on convertible notes	0.00%	(0.87)%
Unrealized gains and losses, net, for liability classified warrants	(0.59)%	0.29%
Unrealized gains and losses, net, for convertible debt	(5.20)%	(8.24)%
Realized gains and losses, net, for extinguishment of convertible debt	0.00%	(2.09)%
Adjustment to prior period federal deferred tax assets	(0.38)%	4.55%
Non-deductible expenses	(0.03)%	(0.02)%
Other	(0.68)%	0.00%
Change in valuation allowance	(11.72)%	(18.27)%
Total effective income tax rate	0.00%	0.00%

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

($ in thousands)	**December 31, 2024**	**December 31, 2023**
Deferred tax assets:		
Net operating losses	$ 23,936	$ 21,911
Finance charges and origination fees	133	602
Accrued compensation	314	232
Stock-based compensation	47	83
Section 174 research and development capitalization	2,771	1,642
Capitalized start-up fees	209	231
Tax credits	1,103	903
Total deferred tax assets	28,513	25,604
Valuation allowance	(28,513)	(25,604)
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, 2024 and 2023, the net increase in the valuation allowance was approximately $2.8 million and $4.8 million, respectively.

As of December 31, 2024 and 2023, the Company had federal net operating loss carryforwards of approximately $108.4 million and $106.5 million, respectively, of which approximately $55.3 million of federal net operating loss carryforwards post 2017 will be carried forward indefinitely. The remaining $52.8 million of federal net operating loss carryforwards begin expiring in 2027. The Company has also generated approximately $8.9 million of net operating loss carryforwards in California in 2019 and carryforward for 20 years, $2.9 million of Florida net operating losses that carryforward indefinitely; $4.5 million of Illinois net operating loss carryforwards that carryforward for 20 years and $1.3 million of net operating loss carryforwards in Virginia that carryforward indefinitely. The Company has not used any net operating loss carryforwards to date.

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

The Company had federal energy credit carryforwards of approximately $0.6 million as of December 31, 2024 and 2023, which will expire starting in 2027 if not utilized. The Company has federal research and development credit carryforwards of approximately $0.5 million and $0.3 million as of December 31, 2024 and 2023, respectively, which will expire starting in 2042 if not utilized.

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

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

Uncertain Tax Benefits

The Company uses the "more likely than not" criterion for recognizing the income tax benefit of uncertain income tax positions and establishing measurement criteria for income tax benefits. As of December 31, 2024, the Company has approximately $0.9 thousand of uncertain tax benefits, all of which are accounted for as contra deferred tax assets. The following schedule provides the roll forward of the Company's uncertain tax positions in 2024:

($ in thousands)	**Uncertain Tax Position**
Balance as of December 31, 2023	$ 110
Increase due to previously unrecognized tax benefits from prior years	749
Increase due to current year unrecognized tax benefits	85
Balance as of December 31, 2024	$ 944

The increase in the prior year uncertain tax position relates to Colorado net operating losses as it is more likely than not that the Colorado apportionment percentage was overstated in prior years. The Company has no accrued interest related to the uncertain tax benefits. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months as of December 31, 2024.

Note 16. Net Loss Per Share

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

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

	2024	2023
Investor E (January 2024) warrants	650,446	—
July 2024 Warrants	1,014,219	—
Placement Agent warrants	21,682	—
Public Stockholders' warrants	422,000	414,000
Private Placement warrants	229,520	229,520
PIPE Investor warrants	20,000	28,000
Legacy warrants	1,957	2,789
Convertible Note warrants	—	106,493
Options to purchase common stock	21,617	20,178
Unvested restricted stock units	220,247	10,261
Total	2,601,688	811,242

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

($ in thousands except share and per share amounts)	2024	2023
Net loss	$ (24,830)	$ (26,232)
Weighted-average shares outstanding - basic and diluted	3,743,554	866,813
Basic and diluted net loss per share	$ (6.63)	$ (30.26)

Note 17. Segment Reporting

The Company is comprised of a single reportable segment, its Device Segment. This organizational structure aligns with how our Chief Operating Decision Maker ("CODM"), the Chief Executive Officer, manages the Company's business, including resource allocation and performance assessment. The Company is focused entirely on the development, regulatory approval and commercialization of the Company's adult and pediatric Selective Cytopheretic Devices (SCDs). The Company had a total of 19 employees at December 31, 2024, and total assets of $4.7 and $3.5 million, as of December 31, 2024 and 2023, respectively.

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

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

The following table represents the Company's sole segment's operating results for the years ended December 31, 2024 and 2023, respectively.

	Year Ended December 31,	
	2024	2023
Net Revenue	$ 135	$ —
Cost of goods sold	—	—
Gross profit	$ 135	$ —
Operating expenses		
Research and development	9,105	5,973
General and administrative	8,872	8,237
Total operating expenses	$ 17,977	$ 14,210
Loss from operations	$ (17,842)	$ (14,210)
Non-operating expenses (*)	(6,985)	(12,022)
Net loss before taxes	$ (24,827)	$ (26,232)

(*) - Non-operating expenses consist of interest expense, interest income, and gains and losses from changes in the fair value of liability classified financial instruments such as warrants and convertible debt.

Note 18. Subsequent Events

At-the-Market Offering

From January 2, 2025 through January 30, 2025, the Company raised approximately $0.9 million gross proceeds ($0.9 net of offering fees) from the sale of 483,755 shares of the Company's common stock through its At-the-Market offering program. As a result of the February 3, 2025 registered direct offering (see below), the Company cannot sell any shares under the At-the-Market offering program for a period of 60 days from the February 3, 2025. Since the initial shelf-registration in August 2024, the Company has, as of the date of this filing, raised approximately $5.5 million gross proceeds under the At-the-Market offering program, issuing approximately 2.3 million shares, for net proceeds of approximately $5.3 million.

February 2025 Registered Direct Offering

On January 31, 2025, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an institutional investor (the "Purchaser"), pursuant to which the Company issued to the Purchaser, (i) in a registered direct offering, 713,000 shares of the Company's common stock (the "Shares"), par value $0.0001 per share ("Common Stock"), and pre-funded warrants to purchase 2,816,412 shares of Common Stock with an exercise price of $0.001 per share, and (ii) in a concurrent private placement, warrants to purchase 3,529,412 shares of Common Stock (the "Common Warrants") with an exercise price of $1.70. Such registered direct offering and concurrent private placement are referred to herein as the "February 2025 Transaction." The offering was made without an underwriter or a placement agent and we are not paying underwriting discounts or commissions. We were required to pay to H.C. Wainwright & Co. a cash fee equal to 7.0% of the aggregate gross proceeds in this offering and issue Wainwright warrants to purchase 247,059 shares of Common Stock at an exercise price of $2.125 per share. The Company received aggregate gross proceeds from the February 2025 Transaction of approximately $6.0 million, before deducting estimated offering expenses payable by the Company.

Nasdaq Decision Letter

As disclosed in a current report on Form 8-K on March 13, 2025, on March 11, 2025, the Company received a decision letter (the "Letter") from the Nasdaq Hearings Panel (the "Panel"), granting the Company's request to continue its listing on The Nasdaq Stock Market ("Nasdaq"), subject to certain conditions. The Panel's decision provides the Company with an exception until June 22, 2025, to demonstrate compliance with Nasdaq Listing Rule 5550(b)(2) (the "MVLS Rule"), which requires a Market Value of Listed Securities of at least $35 million. The Panel reviewed the Company's compliance plan, which includes the continuation of fund-raising efforts that began in 2024, and strategies for achieving long-term compliance with the MVLS Rule. As part of the conditions outlined in the Panel's decision, the Company is required to, on or before June 22, 2025:

- file a public disclosure describing the transactions undertaken to increase its equity and providing an indication of its equity following those transactions, and

- provide the Panel with an update on its fundraising plans and updated income projections for the next 12 months, with all underlying assumptions clearly stated.

The Company is taking steps to address the conditions outlined in the Letter and remains confident in its ability to meet all applicable requirements within the specified timeframes.

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

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

	March 31, 2025 (unaudited)	December 31, 2024
ASSETS		
Current assets		
Cash	$ 5,296	$ 1,819
Accounts receivable, net	110	112
Inventory	44	—
Prepaid expenses	1,334	1,835
Total current assets	6,784	3,766
Other assets	813	892
Total assets	$ 7,597	$ 4,658
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 3,397	$ 3,046
Accrued expenses	3,255	3,188
Notes payable, net of deferred financing costs	363	574
Liability classified warrants	17	33
Total current liabilities	7,032	6,841
Total liabilities	7,032	6,841
Commitments and contingencies (Note 10)		
Stockholders' equity/(deficit)		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock - $0.0001 par value per share; 450,000,000 and 500,000,000 shares authorized at March 31, 2025 and December 31, 2024, respectively; 9,257,763 and 5,977,246 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	2	2
Additional paid-in capital	143,899	137,379
Accumulated deficit	(143,336)	(139,564)
Total stockholders' equity/(deficit)	565	(2,183)
Total liabilities and stockholders' equity/(deficit)	$ 7,597	$ 4,658

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

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

	Three Months Ended March 31,	
	2025	**2024**
Net revenue	$ 293	$ —
Cost of goods sold	—	—
Gross profit	293	—
Operating expenses		
Research and development	2,431	1,697
General and administrative	1,684	2,253
Total operating expenses	4,115	3,950
Loss from operations	(3,822)	(3,950)
Other income (expense)		
Interest expense	(11)	(143)
Interest income	48	—
Change in fair value of convertible notes	—	(5,758)
Change in fair value of liability classified warrants	16	(2,846)
Total other income (expense), net	53	(8,747)
Loss before provision for income taxes	(3,769)	(12,697)
Provision for income taxes	3	—
Net loss	$ (3,772)	$ (12,697)
Net loss per share of common stock, basic and diluted	$ (0.44)	$ (4.73)
Weighted-average shares outstanding, basic and diluted	8,617,932	2,684,243

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

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

	For the three months ended March 31, 2025 and 2024				
	Common Shares		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2023	**2,016,078**	**$ 1**	**$ 100,863**	**$ (114,734)**	**$ (13,870)**
Issuance of shares - conversion of convertible notes	507,912	—	9,389	—	9,389
Issuance of shares - exercise of warrants	352,074	—	3,959	—	3,959
Issuance of shares - equity offering (including pre-funded warrants), net of issuance costs	252,182	—	8,309	—	8,309
Stock-based compensation	—	—	434	—	434
Net loss	—	—	—	(12,697)	(12,697)
Balance, March 31, 2024	**3,128,246**	**$ 1**	**$ 122,954**	**$ (127,431)**	**$ (4,476)**
Balance, December 31, 2024	**5,977,246**	**$ 2**	**$ 137,379**	**$ (139,564)**	**$ (2,183)**
Issuance of shares - exercise of warrants	2,070,412	—	2	—	2
Issuance of shares - equity offering (including pre-funded warrants), net of issuance costs	1,202,133	—	6,351	—	6,351
Issuance of shares - vesting of restricted stock units	7,972	—	—	—	—
Stock-based compensation	—	—	167	—	167
Net loss	—	—	—	(3,772)	(3,772)
Balance, March 31, 2025	**9,257,763**	**$ 2**	**$ 143,899**	**$ (143,336)**	**$ 565**

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

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

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (3,772)	$ (12,697)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	11	27
Change in fair value of convertible notes (issued, converted and outstanding)	—	5,758
Change in fair value of liability classified warrants (exercised and outstanding)	(16)	2,846
Stock-based compensation	167	434
Change in operating assets and liabilities		
Accounts receivables, net	2	—
Inventory	(44)	—
Prepaid expenses	501	614
Other assets	79	2
Accounts payable	351	(493)
Accrued expenses	67	21
Net cash used in operating activities	(2,654)	(3,488)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	—	979
Proceeds from issuance of shares, net of issuance costs	1,566	4,543
Proceeds from sale of pre-funded warrants	4,785	3,769
Proceeds from exercise of warrants	2	853
Payment of notes payable	(222)	(1,813)
Net cash provided by financing activities	6,131	8,331
Net increase in cash	3,477	4,843
Cash, beginning of period	1,819	176
Cash, end of period	$ 5,296	$ 5,019
Supplemental disclosure of cash flow information		
Exercise of pre-funded warrants	$ —	$ 3,106
Shares issued as payment of convertible notes	$ —	$ 9,387
Issuance of convertible note warrants	$ —	$ 586

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

SeaStar Medical Holding Corporation
Notes to the Condensed Consolidated Financial Statements (Unaudited)
March 31, 2025

Note 1. Description of Business

Organization and Description of Business

SeaStar Medical Holding Corporation, a Delaware corporation ("SeaStar") and its wholly owned subsidiary, SeaStar Medical, Inc., are collectively referred to as the "Company". SeaStar Medical, Inc. was incorporated as a Delaware corporation in June 2007, and it is headquartered in Denver, Colorado. 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 patients with acute kidney injuries ("AKI"), but through additional Breakthrough Design Designation ("BDD") from the Food and Drug Administration ("FDA"), has expanded into treatments of patients with cardiorenal syndrome awaiting left ventricular assist device implantation, patients with hepatorenal syndrome, patients with end stage renal disease and adult and pediatric patients undergoing cardiac surgery. The BDD enables the potential for a speedier pathway to approval and the ability to have more frequent and flexible meetings with the FDA.

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

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

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules and regulations, certain notes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the Company's results for the interim periods presented. The results from operations for the three months ended March 31, 2025, are not necessarily indicative of the results to be expected for the year ending December 31, 2025, or for any future annual or interim period.

The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with the annual consolidated financial statements and the related notes for the year ended December 31, 2024. There have been no material changes in our significant accounting policies as described in our Annual Report on Form 10-K for the year ended December 31, 2024.

The interim unaudited condensed consolidated financial statements include the consolidated accounts of the Company's wholly owned subsidiary, SeaStar Medical, Inc. All significant intercompany transactions have been eliminated in consolidation.

On June 7, 2024, the Company effected a 1-for-25 reverse stock split (the "Reverse Stock Split") of its issued and outstanding shares of common stock, par value $0.0001 (the "common stock"). Following the effect of the Reverse Stock Split, each 25 shares of the Company's common stock that were issued and outstanding automatically converted into one outstanding share of common stock. All stock options and warrants of the Company outstanding immediately prior to the Reverse Stock Split were proportionally adjusted except for the Listed Warrants and the private placement warrants that were issued as part of the SPAC transaction that closed on October 28, 2022, which total 16,788,000 outstanding warrants in the aggregate (the "Unadjusted Warrants"). The Unadjusted Warrants retained an $11.50 exercise price each and require the exercise of 25 warrants to purchase one share of common stock. Unless otherwise indicated, all other share and per share amounts in this prospectus reflect the effect of the Reverse Stock Split. The par value of the Company's common stock remained unchanged at $0.0001 per share and the number of authorized shares of common stock remained the same after the Reverse Stock Split.

Segment Information

The Company is comprised of a single reportable segment, its Device Segment. This organizational structure aligns with how our Chief Operating Decision Maker ("CODM"), the Chief Executive Officer, manages the Company's business, including resource allocation and performance assessment. The Company is focused entirely on the development, regulatory approval and commercialization of the Company's adult and pediatric Selective Cytopheretic Devices (SCDs). The Company had a total of 19 employees at March 31, 2025, and total assets of $7.6 million and $4.7 million, as of March 31, 2025, and December 31, 2024, respectively.

For segment reporting purposes, the CODM uses operating profit/(loss) to evaluate segment performance and allocate resources. As a Company that only recently began limited commercial sales of QUELIMMUNE, the CODM is primarily focused on evaluating the overall spending for research and development activities needed to fund further development of the SCDs, and general and administrative activities incurred to support the research and development activities of the Company. Accounting policies associated with the Company's sole segment are the same as those described in Note 2.

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

Liquidity and Going Concern

The Company incurred losses of $3.8 million for the three months ended March 31, 2025. As of March 31, 2025, the Company has an accumulated deficit of $143.3 million and cash of $5.3 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 unaudited condensed consolidated financial statements. The Company believes that these conditions raise substantial doubt about its ability to continue as a going concern.

The Company's need for additional capital will depend in part on the scope and costs of its development activities. To date, the Company has generated very little revenue from the sales of its commercialized product, QUELIMMUNE. Its ability to generate meaningful product revenue will depend on the successful launch of QUELIMMUNE and development and eventual commercialization of the adult SCD. Until such time, if ever, it expects to finance its operations through the sale of equity or debt, 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 unaudited condensed 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

Use of Estimates

The preparation of the unaudited condensed 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 unaudited condensed consolidated financial statements and reported amounts of revenues and expenses during the period. Significant estimates include the (i) valuation of the liability classified warrants, (ii) provision for income taxes, (iii) convertible debt measured at fair value, (iv) unbilled clinical trial costs, and (v) 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.

Concentrations of Credit Risk

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

Accounts Receivable, net

The need for a credit loss allowance is evaluated each reporting period based on the Company's assessment of the credit worthiness of its customers or any other potential circumstances that could result in a credit loss. The Company uses an aging schedule method for estimating expected credit losses. As the Company just commenced commercial operations since July 1, 2024, with a limited customer base, the Company's estimates are based on customer specific facts, until such time that the Company has developed sufficient collection history data in which to apply a portfolio-wide expected credit loss estimate based on an aging schedule (see Note 4).

Fair Value of Financial Instruments

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

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

Revenue Recognition

Overall

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

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

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

Product Sales Revenue

The Company sells its products directly to end-user qualified customers using the Company's own internal commercial/sales resources.

- Timing of Revenue Recognition – During the brief history (commenced July 2024) of selling QUELIMMUNE, revenue has been recognized based on a *freight-on-board destination (*"FOB Destination") requirement, except in limited cases where they are sold *freight-on-board shipping point* ("FOB Shipping Point").

- Chargebacks, Government Rebates and Discounts – During the brief history of selling QUELIMMUNE commercially, the Company has not agreed to chargebacks, government rebates or discounts.

- Returns – Returns are specific to each order, but generally the Company allows for returns of any damaged or non-conforming product within 30 days of receipt of product. Given the (i) overall rate of product shipped that is defective/damaged, (ii) overall volume of sales to individual end-user customers, (iii) expected supply in the customer channel, and (iv) expected usage by customers, the Company does not anticipate that there will be significant risk of material product returns that require recognition.

- Variable Consideration – There are currently no other variable consideration elements outside of those already disclosed in this footnote.

- Transaction Price – Based on the above, as currently constructed, the Company's transaction price is fixed, based on the agreed-upon price per each purchase order submitted by each customer. Milestone or up-front payments unique to the distributor were disclosed in Note 3 (also see Notes 11 and 15), and are not expected to be recognized as revenue, but merely returned as a result of a settlement to cease the relationship with the distributor.

- Allocation of Consideration – Each sale of QUELIMMUNE is independent of any and all other sales. The entire transaction price for each QUELIMMUNE unit sold is allocated to that unit of QUELIMMUNE, and there are no allocations to services or other performance obligations, as there are no such services or other performance obligations that require the Company to allocate a portion of the transaction price.

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

Cost of Goods Sold

Prior to July 2024, the Company manufactured/assembled QUELIMMUNE and adult SCDs only for research oriented and/or clinical trial related activities. Inventory purchased prior to July 2024 was expensed as a period expense at the time of purchase as a research and development expense. Accordingly, all QUELIMMUNE units sold during the three months ended March 31, 2025 had no assigned value and the Company recognized no cost of goods sold.

As the Company procures inventory in the future, the Company will recognize the cost of materials to inventory. Use of inventory for QUELIMMUNE will be charged to cost of goods sold while inventory used for adult SCDs will be charged to research and development upon shipment.

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.

Recently issued accounting standards

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

Accounting Standards Update 2023-09 — In December 2023, the FASB issued ASU 2023-09 *Income Taxes (Topic 740) Improvements to Income Tax Disclosures*. ASU 2023-09 enhances the transparency and decision usefulness of income tax disclosures. The amendments in this update are effective for public business entities for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently assessing the impact of this guidance on its consolidated financial statements and disclosures, however the impact from the adoption of this guidance, if any, will not be reflected until the Company's Annual Report to Form 10-K for the year-ended December 31, 2025, due to the Company's net loss position and 100% valuation allowance for all deferred tax assets.

Note 3. Revenues and Contract Obligations

The Company currently only sells a single product, QUELIMMUNE, which has been approved under a Humanitarian Device Exemption ("HDE") by the FDA for use with pediatric patients for treatments allowed under approved therapeutic indications. The Company can only sell QUELIMMUNE kits directly to qualified healthcare facilities (the "Customers") that have qualified as capable of receiving and utilizing QUELIMMUNE in accordance with the terms of the HDE.

Each sale to a customer is independent from any past or future sales to that customer. Revenue is recognized at the point in time that control of the product transfers to the customer, which typically aligns with the shipping terms defined by each individual purchase order. Most sales are shipped "free-on-board" destination.

There are no up-front payments, material post-sale performance obligations, license agreements or other arrangements that could require the Company to defer a portion of the transaction price and recognize on a basis that is different from that of the physical transfer of QUELIMMUNE to the customer. See Note 2 for the Company's accounting policy relating to revenue recognition under ASC 606 - *Revenue from Contracts with Customers.*

The Company had no contract assets for the periods ended March 31, 2025 and December 31, 2024. The accounting policies used to measure the profit and loss of the segment are the same as those described in the summary of significant accounting policies.

Revenue by Geographic Location

The Company's sales are entirely in the United States of America, as it does not have any regulatory approval to sell elsewhere as of March 31, 2025.

Note 4. Accounts Receivable, net

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

($ in thousands)	Accounts Receivable, Gross	Expected Credit Losses	Accounts Receivable, Net
December 31, 2024	$ 112	$ —	$ 112
Change in accounts receivable, net	1	(3)	(2)
March 31, 2025	$ 113	$ (3)	$ 110

Note 5. Accrued Expenses

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

($ in thousands)	March 31, 2025	December 31, 2024
Accrued bonus	$ 1,621	$ 1,391
Accrued director compensation	487	391
Accrued research and development	830	1,023
Other	317	383
Total accrued expenses	$ 3,255	$ 3,188

Note 6. Notes Payable

Insurance Financing

In October 2024, the Company entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of $0.7 million. The Company paid approximately $0.2 million for the three months ended March 31, 2025, and will pay the remaining balance over five monthly installments of principal and interest totaling approximately $0.4 million with the last payment to be paid in August 2025.

Note 7. Equity Transactions

February 2025 Offering

In January 2025, the Company entered into a Securities Purchase Agreement with an institutional investor (the "Q1 2025 SPA"), pursuant to which the Company issued on February 3, 2025, to the investor, (i) in a registered direct offering, 713,000 shares of the Company's common stock, and pre-funded warrants to purchase 2,816,412 shares of Common Stock (the "February Pre-Funded Warrants") with an exercise price of $0.0001 per share, and (ii) in a concurrent private placement, warrants to purchase 3,529,412 shares of common stock with an exercise price of $1.70 ("February 2025 Common Warrants"). Such registered direct offering and concurrent private placement are referred to herein as the "February 2025 Offering".

The Company received aggregate gross proceeds from the February 2025 Offering of approximately $6.0 million, before deducting fees to H.C. Wainwright & Co. ("Wainwright") and other estimated offering expenses payable by the Company. The Pre-Funded Warrants will not expire and are exercisable upon issuance and at any time until all of the Pre-Funded Warrants are exercised in full. As of March 31, 2025, a total of 2,070,412 pre-funded warrants were exercised, leaving 746,000 pre-funded warrants outstanding. The February 2025 Common Warrants became exercisable on March 28, 2025, the effective date of stockholder approval for the issuance of the shares of common stock issuable upon exercise of the warrants and expire on March 28, 2030.

In connection with the February 2025 Offering, the Company amended the exercise price of the warrants issued in conjunction with the January 2024 Offering, (the "Series A and Series B common warrants" (collectively "January 2024 Warrants"), issued in a financing transaction with the institutional investor in January 2024, to $1.70 from the original exercise price of $20.76. Furthermore, the original expiration date of June 4, 2025, for the 216,816 Series B warrants of the January 2024 Warrants was extended to January 30, 2029, upon stockholder approval on March 28, 2025. With the amendment to the expiration date, all of the January 2024 Warrants now expire in 2029.

The Company paid approximately $0.4 million in fees to Wainwright and issued 247,059 warrants (the "February 2025 PA Warrants") to purchase shares of the Company's common stock at an exercise price of $2.13. The 2025 PA Warrants were exercisable upon issuance and expire on January 30, 2029. The 2025 PA Warrants and February 2025 Common Warrants are herein defined as the "February 2025 Warrants".

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

August 2024 At-The-Market Offering

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

Through March 31, 2025, the Company has raised approximately $5.5 million utilizing the ATM since inception in August 2024, issuing 2,263,643 shares of the Company's Common Stock. During the three months ended March 31, 2025, the Company raised approximately $0.9 million, net of offering costs, issuing 483,755 shares of the Company's common stock.

Note 8. Warrants

The Company issued warrants in connection with various financing transactions. The Company had the following warrants outstanding at March 31, 2025, and December 31, 2024:

	March 31, 2025	December 31, 2024
Liability Classified Warrants		
Private Placement Warrants	229,520	229,520
PIPE Investor Warrants	20,000	20,000
Subtotal	249,520	249,520
Equity Classified Warrants		
February 2025 Warrants	3,776,471	—
February 2025 Pre-Funded Warrants	746,000	—
July 2024 Warrants	1,014,219	1,014,219
January 2024 Warrants	672,129	672,129
Public Stockholders' Warrants	422,000	422,000
Legacy Warrants	1,957	1,957
Subtotal	6,632,776	2,110,305
Grand Total	6,882,296	2,359,825

The following tables provide the weighted-average strike price and time to maturity for each warrant share equivalent outstanding for each warrant tranche as of March 31, 2025 and December 31, 2024:

March 31, 2025	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Maturity
Liability Classified Warrants			
Private Placement Warrants	229,520	$ 287.50	2.58
PIPE Investor Warrants	20,000	$ 287.50	2.58
Equity Classified Warrants			
February 2025 Warrants	3,776,471	$ 1.73	4.99
February 2025 Pre-Funded Warrants	746,000	$ 0.00	(*)
July 2024 Warrants	1,014,219	$ 10.72	4.28
January 2024 Warrants	672,129	$ 2.38	4.19
Public Stockholders' Warrants	422,000	$ 287.50	2.58
Legacy SeaStar Inc. Warrants	1,957	$ 250.00	1.13

(*) - the February 2025 Pre-Funded Warrants have a strike price of $0.001 and do not expire.

December 31, 2024	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Maturity
Liability Classified Warrants			
Private Placement Warrants	229,520	$ 287.50	2.82
PIPE Investor Warrants	20,000	$ 287.50	2.82
Equity Classified Warrants			
July 2024 Warrants	1,014,219	$ 10.72	4.53
January 2024 Warrants	672,129	$ 20.83	3.01
Public Stockholders' Warrants	422,000	$ 287.50	2.82
Legacy SeaStar Inc. Warrants	1,957	$ 250.00	1.38

Below is the warrant activity for the three months ended March 31, 2025, for those warrants with activity during the three months ended March 31, 2025:

	February 2025 Warrants	February 2025 Pre-Funded Warrants
Outstanding as of December 31, 2024	—	—
Issuance	3,776,471	2,816,412
Exercised	—	(2,070,412)
Forfeited / cancelled	—	—
Outstanding as of March 31, 2025	3,776,471	746,000

During the three months ended March 31, 2025, the Company incurred a gain of approximately $16 thousand from the mark-to-market adjustment for all remaining liability classified warrants.

Note 9. Stock-Based Compensation Awards

The following table sets forth the total stock-based compensation cost included in the Company's unaudited condensed consolidated statements of operations for the periods indicated:

	Three Months Ended March 31,	
($ in thousands)	**2025**	**2024**
Research and development	$ 23	$ 119
General and administrative	145	315
Total stock-based compensation	$ 168	$ 434

Equity Incentive Plan - Summary

2022 Omnibus Incentive Plan

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

2019 Stock Incentive Plan

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

Stock Options

Option activity for the period ended March 31, 2025, is as follows:

2022 Omnibus Incentive Plan - Stock Options

	Options	Weighted-Average Exercise Price	Total Intrinsic Value	Weighted-Average Remaining Contractual Life (Years)
Outstanding at December 31, 2024	13,114	$ 46.00	$ —	8.2
Exercised	—			
Issued	—			
Forfeited / cancelled	—			
Outstanding at March 31, 2025	13,114	$ 46.00	$ —	8.0
Vested and exercisable at March 31, 2025	13,114	$ 46.00	$ —	8.0

2019 Omnibus Incentive Plan - Options

	Options	Weighted-Average Exercise Price	Total Intrinsic Value	Weighted-Average Remaining Contractual Life (Years)
Outstanding at December 31, 2024	8,817	$ 44.30	$ —	5.5
Exercised	—			
Issued	—			
Forfeited / cancelled	—			
Outstanding at March 31, 2025	8,817	$ 44.30	$ —	5.2
Vested and exercisable at March 31, 2025	8,662	$ 44.90	$ —	5.2

Restricted Stock Units

A summary of the Company's restricted stock unit ("RSU") activity is as follows:

2022 Omnibus Incentive Plan - RSUs

	Number of RSU	Weighted-Average Grant Date Fair Value (per share)
Outstanding at December 31, 2024	219,500	$5.09
Granted	—	
Vested	(7,417)	
Forfeited / cancelled	—	
Outstanding at March 31, 2025	212,083	$ 4.64

2019 Stock Incentive Plan - RSUs

	Number of RSU	Weighted-Average Grant Date Fair Value (per share)
Outstanding at December 31, 2024	747	$ 200.00
Granted	—	
Vested	(555)	
Forfeited / cancelled	—	
Outstanding at March 31, 2025	192	$ 200.00

Note 10. Commitments and Contingencies

Lease Agreements

The Company is part of a membership agreement for shared office space and can cancel at any time. Rent expense was approximately $21 thousand and $8 thousand for the three months ended March 31, 2025 and 2024, respectively.

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.

2024 Securities Class Action Lawsuit

On July 5, 2024, Forrest A K Wells (the "Plaintiff"), a purported stockholder of the Company, filed a putative class action complaint in the United States District Court for the State of Colorado, captioned Wells v. SeaStar Medical Holding Corporation et al, Case No. 1:24-cv-0187 (D. Colorado) (the "Class Action"). The Class Action alleges that the Company, its Chief Executive Officer and former Chief Financial Officer made or caused to be made material misstatements or omissions regarding the Company's business and operations, allegedly culminating in the Company's restatement of its consolidated financial statements, disclosed in a Form 8-K and filed on March 27, 2024. The Class Action asserts claims pursuant to the Securities Exchange Act of 1934, including Section 10(b), Rule 10b-5 promulgated thereunder and Section 20(a). The Class Action seeks to recover, among other remedies, compensatory damages. The Company intends to vigorously defend the action.

The Company has not recognized a contingent liability for this Class Action event as it does not qualify for the recognition criteria under ASC 450 - *Contingencies.*

Note 11. 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 warrants liability is classified as Level 3 in the fair value hierarchy.

Fair Value Measurement Hierarchy

The following table presents the Company's financial assets and/or liabilities that were accounted for at fair value on a recurring basis as of March 31, 2025 and December 31, 2024, 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.

Summary of Level 3 Input Changes

	Fair Value Measurements at March 31, 2025			
	(Level 1)	**(Level 2)**	**(Level 3)**	**Total**
Liabilities:				
Liability classified warrants	$ —	$ —	$ 17	$ 17
	$ —	$ —	$ 17	$ 17

	Fair Value Measurements at December 31, 2024			
	(Level 1)	**(Level 2)**	**(Level 3)**	**Total**
Liabilities:				
Liability classified warrants	$ —	$ —	$ 33	$ 33
Total	$ —	$ —	$ 33	$ 33

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 period ended March 31, 2025 (in thousands):

Level 3 Roll Forward	**Liability Classified Warrants**
Balance December 31, 2024	$ 33
Additions	—
Cash paid to settle	—
Shares issued upon conversion or exercise	—
Changes in fair value	(16)
Balance March 31, 2025	$ 17

Level 3 Inputs

For assets or liabilities for which the Company is required to remeasure the fair value on a recurring basis at each reporting date, generally the Company is required to disclose certain quantitative data related to the inputs used at the most recent reporting period date. However, for those assets or liabilities for which the Company has elected to take the FVO in accordance with ASC 825, Financial Instruments, then such quantitative disclosures are not required.

Liability Classified Warrants

The liability classified warrants as of March 31, 2025 and December 31, 2024, include three classes of warrants, and therefore, the range of assumptions used has been provided. Significant assumptions used in valuing warrants which require liability classification were as follows as of March 31, 2025 and December 31, 2024.

	March 31, 2025	December 31, 2024
Expected volatility	130.00%	130.00%
Equivalent term	2.575	2.825
Risk-free rate	3.89%	4.27%
Dividend yield	0.00%	0.00%
Stock price	$ 1.66	$ 1.94
Strike price	$ 287.50	$ 287.50

Note 12. Income Taxes

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. Except as noted below, 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. The Company has recognized an insignificant provision for certain minimum state taxes of approximately $3 thousand as of March 31, 2025.

The Company believes its tax filing position and deductions related to tax periods subject to examination will be sustained under audit and, therefore, has no reserve for uncertain tax positions.

Note 13. Net Loss Per Share

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

	Three Months Ended March 31,	
	2025	2024
Net loss	$ (3,772)	$ (12,697)
Weighted-average shares outstanding - basic and diluted	8,617,932	2,684,243
Basic and diluted net loss per share	$ (0.44)	$ (4.73)

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:

	As of March 31,	
	2025	**2024**
February 2025 warrants	3,776,471	—
July 2024 warrants	1,014,219	—
January 2024 warrants	672,129	672,129
Investor D warrants	—	126,323
Public Stockholders' warrants	422,000	422,000
Private Placement warrants	229,520	229,520
PIPE Investor warrants	20,000	20,000
Legacy warrants	1,957	1,957
Employee based options to purchase common stock	21,776	8,531
Unvested employee based restricted stock units	212,275	12,271
Total	6,370,347	1,492,731

Note 14. Segment Reporting

The Company is comprised of a single reportable segment, its Device Segment. This organizational structure aligns with how our Chief Operating Decision Maker ("CODM"), the Chief Executive Officer, manages the Company's business, including resource allocation and performance assessment. The Company is focused entirely on the development, regulatory approval and commercialization of the Company's adult and pediatric Selective Cytopheretic Devices (SCDs). The Company had total assets of $7.6 and $4.7 million, as of March 31, 2025 and December 31, 2024, respectively.

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

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

The following table represents the Company's sole segment's operating results for the three months ended March 31, 2025 and 2024, respectively.

	Three Months Ended March 31	
	2025	**2024**
Net Revenue	$ 293	$ —
Cost of goods sold	—	—
Gross profit	$ 293	$ —
Operating expenses		
Research and development	2,431	1,697
General and administrative	1,684	2,253
Total operating expenses	$ 4,115	$ 3,950
Loss from operations	$ (3,822)	$ (3,950)

(*) - Non-operating expenses consist of interest expense, interest income, and gains and losses from changes in the fair value of liability classified financial instruments such as warrants and convertible debt.

Note 15. Subsequent Events

At-the-Market Offering

From April 2, 2025 through May 12, 2025, the Company raised approximately $0.9 million gross proceeds $0.9 million net of offering costs from the sale of 623,647 shares of the Company's stock through its At-the-Market offering program.

Exercise of February 2025 Pre-Funded Warrants

On April 8, 2025, an investor exercised 402,000 of the February 2025 Pre-Funded Warrants, with proceeds from the exercise totaling $402.00. Only 344,000 February 2025 Pre-Funded Warrants remain unexercised.

Equity Line of Credit Purchase Agreement

As disclosed on a Form 8-K on April 25, 2025, the Company entered into a purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which Lincoln Park committed to purchase up to $15.0 million in shares of our common stock, $0.0001 par value per share.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million in shares of the Company's common stock. Such sales of the Company's common stock, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the date that a registration statement covering the resale by Lincoln Park of shares that have been and may be issued under the Purchase Agreement is declared effective by the Securities and Exchange Commission (the "SEC") and a final prospectus in connection therewith is filed and the other conditions in the Purchase Agreement are satisfied (the date on which all such conditions are satisfied, the "Commencement Date").

After the Commencement Date, on any business day, the Company may direct Lincoln Park to purchase up to 40,000 shares of our common stock (each, a "Regular Purchase"); provided that the share amount under a Regular Purchase may be increased to up to 50,000 shares, up to 60,000 shares or up to 75,000 shares if the closing sale price of our common stock is not below $1.00, $1.75 or $2.50, respectively, on the business day on which we initiate the Regular Purchase. However, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $500,000. Each Regular Purchase is subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement. The purchase price per share for each Regular Purchase will be 97% of the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the Regular Purchase and (ii) the average of the three lowest closing sale prices of our common stock during the 10-business day period immediately preceding the business day on which we initiate the Regular Purchase. In addition to Regular Purchases, we may also direct Lincoln Park to purchase other amounts of common stock as accelerated purchases and as additional accelerated purchases, subject to limits specified in the Purchase Agreement, at a purchase price per share calculated as specified in the Purchase Agreement.

Sales of shares of the Company's common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of our common stock and our determination as to the appropriate sources of funding for our operations. The Company expects that any proceeds it receives from such sales will be used for working capital and general corporate purposes.

In addition, under applicable Nasdaq rules, the Company may not issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) the Company obtains stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds $1.25 per share (which represents the lower of (A) the official closing price of our common stock on Nasdaq immediately preceding the signing of the Purchase Agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the Purchase Agreement). In any event, the Purchase Agreement specifically provides that the Company may not issue or sell any shares of its common stock under the Purchase Agreement if such issuance or sale would breach any applicable Nasdaq rules.

Lincoln Park has no right to require the Company to sell any shares of its common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to the conditions and limitations in the Purchase Agreement including beneficial ownership limitations.

In connection with entering into the Purchase Agreement, on April 25, 2025, the Company issued 236,406 shares of its common stock to Lincoln Park in consideration for its commitment to purchase shares under the Purchase Agreement.

Up to 4,237,288 Shares of Common Stock and accompanying Warrants to Purchase Up to 4,237,288 Shares of Common Stock

or

Up to 4,237,288 Pre-Funded Warrants to Purchase Up to 4,237,288 Shares of Common Stock and accompanying Warrants to Purchase Up to 4,237,288 Shares of Common Stock

Up to 296,610 Placement Agent Warrants to Purchase Up to 296,610 Shares of Common Stock

Up to 4,533,898 Shares of Common Stock Issuable Upon Exercise of the Warrants, Pre-Funded Warrants and Placement Agent Warrants

PROSPECTUS

, 2025

You should rely only on the information contained. We have not authorized anyone to provide you with different information. You should not assume that the information contained is accurate as of any date other than the date of this prospectus. We are not making an offer of these securities in any state where the offer is not permitted.

PART II - INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses payable by us in connection with the registration and sale of the securities being registered. All expenses incurred with respect to the registration of the Common Stock will be borne by us. All amounts are estimated except the Securities and Exchange Commission registration fee.

SEC registration fee	$	766
Printing expense	$	
Accounting fees and expenses	$	15,000
Legal fees and expenses	$	100,000
Miscellaneous fees and expenses	$	
Total	$	115,766

(1) To be filed by amendment.

Item 14. Indemnification of Directors and Officers

We are incorporated under the laws of the State of Delaware. Under Delaware law, a corporation may indemnify any person who was or is a party or is threatened to be made a party to an action (other than an action by or in the right of the corporation) by reason of his or her service as a director or officer of the corporation, or his or her service, at the corporation's request, as a director, officer, employee or agent of another corporation or other enterprise, against expenses (including attorneys' fees) that are actually and reasonably incurred by him or her ("Expenses"), and judgments, fines and amounts paid in settlement that are actually and reasonably incurred by him or her, in connection with the defense or settlement of such action, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful. Although Delaware law permits a corporation to indemnify any person referred to above against Expenses in connection with the defense or settlement of an action by or in the right of the corporation, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests, if such person has been judged liable to the corporation, indemnification is only permitted to the extent that the Court of Chancery (or the court in which the action was brought) determines that, despite the adjudication of liability, such person is entitled to indemnity for such Expenses as the court deems proper. The DGCL also provides for mandatory indemnification of any director, officer, employee or agent against Expenses to the extent such person has been successful in any proceeding covered by the statute. In addition, the DGCL provides the general authorization of advancement of a director's or officer's litigation expenses in lieu of requiring the authorization of such advancement by the board of directors in specific cases, and that indemnification and advancement of expenses provided by the statute shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement or otherwise.

Our amended and restated bylaws and restated certificate of incorporation provide for indemnification of our directors and officers and for advancement of litigation expenses to the fullest extent permitted by current Delaware law.

We maintain a policy of directors and officers liability insurance which reimburses us for expenses which we may incur in connection with the foregoing indemnity provisions and which may provide direct indemnification to directors and officers where we are unable to do so.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the above, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Item 15. Recent Sales of Unregistered Securities

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 was not 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 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, we 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, bore interest at 7.0% per annum, had a maturity date of June 15, 2024, and required monthly installments of principal and interest. The First Investor D Note was 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 had an initial exercise price of $2.97 per share of common stock, an expiration date five years from their issuance date, and contained 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 comment stock at an initial conversion price of $2.70. The Second Investor D Notes were issued at an 8.0% discount and bore interest at 7.0% per annum and had maturity dates of June 15, 2024 and August 12, 2024. The Second Investor D Notes were 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 had an initial exercise price of $2.97 per share of common stock, an expiration date five years from their issuance date, and contained 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 were amended (the "First Amended Investor D SPA"). The institutional investor had 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, bore interest at 7.0% per annum and required monthly installments of principal and interest. Each tranche of the Third Investor D Notes was 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 included 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 four tranches of the Third Investor D Notes had maturity dates of 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 0f $0.20 per share of common stock as part of Letter Agreement (the "Investor D Letter Agreement Warrants").

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 was 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. We 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 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.

January 2024 Securities Purchase Agreement

On January 26, 2024, we entered into a Securities Purchase Agreement (the "January 2024 Purchase Agreement") with a single institutional investor (the "January 2024 Purchaser"), pursuant to which we issued to the January 2024 Purchaser: (i) in a registered direct offering, 252,182 shares of our Common Stock and pre-funded warrants to purchase 181,447 shares of Common Stock, each with an exercise price of $0.0001 per share, and (ii) in a concurrent private placement, series A warrants to purchase up to 433,631 shares of Common Stock (the "Series A Common Warrants") and series B warrants to purchase up to 216,816 shares of Common Stock (the "Series B Common Warrants," and together with the Series A Common Warrants, the "January 2024 Common Warrants"), each with an exercise price of $20.755 per share.

Maxim Group LLC ("Maxim") acted as the placement agent on a "reasonable best efforts" basis in connection with the transactions pursuant to a placement agency agreement, dated January 26, 2024 (the "Placement Agency Agreement"), by and between us Maxim. Pursuant to the Placement Agency Agreement, we issued to Maxim warrants to purchase up to 216,682 shares of Common Stock, each with an exercise price of $22.83 per share (the "January 2024 Placement Agent Warrants").

The January 2024 Common Warrants and the January 2024 Placement Agent Warrants were issued in reliance upon an exemption from the registration requirements under the Securities Act afforded by Section 4(a)(2) thereof.

July 2024 Securities Purchase Agreement

On July 10, 2024, we entered into a Securities Purchase Agreement (the "July 2024 Purchase Agreement") with certain institutional investors (the "July 2024 Purchasers"), pursuant to which we issued to the July 2024 Purchasers: (i) in a registered direct offering, 947,868 shares of our Common Stock, and (ii) in a concurrent private placement, warrants to purchase up to 947,868 shares of Common Stock (the "July 2024 Common Warrants") at an exercise price of $10.55 per share.

H.C. Wainwright & Co., LLC ("Wainwright") acted as the placement agent on a "reasonable best efforts" basis in connection with the transactions pursuant to an engagement letter, dated May 17, 2024 (the "Engagement Letter"), by and between us and Wainwright. Pursuant to the Engagement Letter, we issued to Wainwright warrants to purchase up to 66,351 shares of Common Stock at an exercise price of $13.1875 per share (the "July 2024 Placement Agent Warrants").

The July 2024 Common Warrants and the July 2024 Placement Agent Warrants were issued in reliance upon an exemption from the registration requirements under the Securities Act afforded by Section 4(a)(2) thereof.

January 2025 Securities Purchase Agreement

On January 31, 2025, we entered into a Securities Purchase Agreement (the "January 2025 Purchase Agreement") with a single institutional investor (the "January 2025 Purchaser"), pursuant to which issued to the January 2025 Purchaser: (i) in a registered direct offering, 713,000 shares of our Common Stock (the "Shares") and pre-funded warrants to purchase 2,816,412 shares of Common Stock, each with an exercise price of $0.001 per share, and (ii) in a concurrent private placement, warrants to purchase 3,529,412 shares of Common Stock (the "January 2025 Warrants") at an exercise price of $1.70 per share.

While Wainwright did not act as the placement agent, pursuant to the prior Engagement Letter, we issued to Wainwright warrants to purchase 247,059 shares of Common Stock at an exercise price of $2.125 per share (the "January 2025 Placement Agent Warrants").

The January 2025 Warrants and the January 2025 Placement Agent Warrants were issued in reliance upon an exemption from the registration requirements under the Securities Act afforded by Section 4(a)(2) thereof.

Equity Line of Credit

On April 25, 2025, we entered into a purchase agreement with Lincoln Park pursuant to which we have the right to sell to Lincoln Park up to $15.0 million in shares of Common Stock, subject to certain limitations, from time to time over the 36-month period commencing on the Commencement Date. We issued 236,406 Commitment Shares to Lincoln Park as consideration for its commitment to purchase shares of Common Stock under the Purchase Agreement. In the Purchase Agreement, Lincoln Park represented to us, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act).

The Commitment Shares were issued in reliance upon an exemption from the registration requirements under the Securities Act afforded by Section 4(a)(2) thereof.

Item 16. Exhibits.

(a)Exhibit Index

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1.

(b)Financial statement schedules

All schedules are omitted because the required information is inapplicable or the information is presented in the financial statements and the related notes.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(7) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit No.	Description
2.1†	Agreement and Plan of Merger, dated as of April 21, 2022, by and among LMF Acquisition Opportunities, Inc. ("LMAO"), LMF Merger Sub, Inc. and SeaStar Medical, Inc. (incorporated by reference to Exhibit 2.1 to Form 8-K filed by the registrant on April 26, 2022).
3.1	Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation, filed with the Secretary of State of Delaware on October 28, 2022 (incorporated by reference to Exhibit 3.1 to Form 8-K filed by the registrant on November 4, 2022).
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed September 20, 2023).
3.3	Second Certificate of Amendment of Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed by the registrant on June 7, 2024).
3.4	Third Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.4 to Form 10-K filed by registrant on March 27, 2025).
3.5	Second Amended and Restated Bylaws of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.1 of Form 8-K filed by the registrant on April 18, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the registrant on November 4, 2022).
4.2	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the registrant on January 28, 2021).
4.4	Form of Series A Common Stock Purchase Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of Form 8-K dated January 30, 2024).
4.5	Form of Series B Common Stock Purchase Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.3 of Form 8-K dated January 30, 2024).
4.6	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of Form 8-K filed by the registrant on July 11, 2024).
4.7	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 of Form 8-K filed by the registrant on July 11, 2024).
4.8	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of Form 8-K dated February 3, 2025).
4.9	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of Form 8-K filed by the registrant on February 3, 2025).
4.10	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 of Form 8-K filed by the registrant on February 3, 2025).
4.11**	Form of Pre-Funded Warrant to Purchase Common Stock
4.12**	Form of Common Stock Purchase Warrant
4.13**	Form of Placement Agent Warrant
5.1**	Opinion of Dorsey & Whitney LLP.

10.1	Amended and Restated SeaStar Medical Holding Corporation 2022 Omnibus Incentive Plan (incorporated by reference to Appendix A to Proxy Statement filed by the registrant on May 3, 2024).
10.2	SeaStar Medical Holding Corporation 2022 Employee Stock Purchase Plan (incorporated by reference to Annex E to Form S-4 filed by the registrant on May 16, 2022).
10.3+	Employment Agreement, dated January 10, 2024, by and between SeaStar Medical Holding Corporation and David Green (incorporated by reference to Exhibit 10.1 to Form 8-K dated January 11, 2024).
10.4	Warrant Redemption Agreement, dated June 28, 2024, by and between SeaStar Medical Holding Corporation and an institutional investor (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on July 2, 2024).
10.5	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on July 11, 2024).
10.6	At The Market Offering Agreement, dated August 20, 2024, by and between SeaStar Medical Holding Corporation, and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on August 21, 2024).
10.7	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on February 3, 2025).
10.8+	Employment Agreement, dated May 18, 2022, by and between SeaStar Medical Holding Corporation and Kevin Chung (incorporated by reference to Exhibit 10.27 to Form S-4/A filed by the registrant on August 24, 2022).
10.9+	Form of Amended and Restated Employment Agreement, by and between SeaStar Medical Holding Corporation and Eric Schlorff (incorporated by reference to Exhibit 10.32 to Form S-4/A filed by the registrant on August 24, 2022).
10.10	Purchase Agreement, dated April 25, 2025, by and between SeaStar Medical Holding Corporation and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on April 25, 2025).
10.11	Registration Rights Agreement, dated April 25, 2025, by and between SeaStar Medical Holding Corporation and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on April 25, 2025).
10.12**	Securities Purchase Agreement
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Form 8-K filed by the registrant on November 4, 2022).
23.1*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm.
23.2**	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on the signature page hereto).
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)
107*	Filing Fee Table

+ 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.

** To be filed by amendment.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Denver, Colorado, on June 16, 2025.

SEASTAR MEDICAL HOLDING CORPORATION

By: /s/ Eric Schlorff
Name: Eric Schlorff
Title: Chief Executive 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 Registration Statement on Form S-1, 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 Registration Statement on Form S-1 has been signed below by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ Eric Schlorff Eric Schlorff	Chief Executive Officer and Director (Principal Executive Officer)	June 16, 2025
/s/ David Green David Green	Chief Financial Officer (Principal Financial and Accounting Officer)	June 16, 2025
/s/ Rick Barnett Rick Barnett	Chairman of the Board of Directors	June 16, 2025
/s/ Kenneth Van Heel Kenneth Van Heel	Director	June 16, 2025
/s/ Jennifer A. Baird Jennifer A. Baird	Director	June 16, 2025
/s/ John Neuman John Neuman	Director	June 16, 2025
/s/ Bernadette N. Vincent Bernadette N. Vincent	Director	June 16, 2025