Risk Factors Comparison 2024-04-16 to 2023-03-30 Form: 10-K

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Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under " Cautionary Note Regarding Forward- Looking Statements, " you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described herein in any document incorporated by reference herein are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business. **Risk Factor Summary • The Company has incurred significant losses since its inception and may continue to incur significant losses for the foreseeable future. • The Company has not generated any significant revenue and may never be profitable. • The Company has a limited operating history. • If the Company fails to obtain additional financing, it would be forced to delay, reduce or eliminate its product development program. • The Company may not use its net operating losses to offset future taxable income Risks Related to the Company' s Business Operations. • The Company may not receive approval from the FDA to market its product. • The Company is subject to certain risks relating to pursuing an FDA approval process. • The Company may not be able to manage its growth effectively. • The Company will initially depend on revenue generated from a single product. • The Company may fail to comply with extensive regulations of United States and foreign regulatory agencies. • Delays in successfully completing the Company' s planned clinical trials could jeopardize its ability to obtain regulatory approval. • The Company has limited experience in identifying and working with large- scale contracts with medical device manufacturers. • Difficulties in manufacturing the Company' s SCD could have an adverse effect upon its revenue and expenses. • The Company faces intense competition in the medical device industry. • The Company outsources many of its operational and development activities for which it may not have full control. • The Company may be subject to enforcement action if it engages in improper marketing or promotion of its products. • The Company is subject to stringent and changing privacy laws, regulations and standards • The Company depends on key personnel and its inability to attract and retain qualified personnel could impede its ability to achieve its business objectives. • The Company' s products may in the future be subject to product recalls. • The Company' s business is subject to risks arising from future pandemics. • The Company' s forecasted operating and financial results may not be accurate • The Company' s estimates of market opportunity, industry projections and forecasts of market growth may prove to be inaccurate. • The Company relies upon exclusively licensed patent rights from third parties which are subject to termination or expiration. • If the Company is unable to obtain and maintain sufficient patent protection for its products, the Company' s ability to commercialize such products successfully may be adversely affected. • The Company may not be able to obtain protection under the Hatch- Waxman Act and similar non-United States legislation for extending the term of patents covering its products • The Company could become involved in intellectual property litigation that could be costly, result in the diversion of management' s time and efforts. • Issued patents covering one or more of the Company' s products could be found invalid or unenforceable if challenged in patent office proceedings, or in court. • If the Company is unable to protect the confidentiality of its trade secrets, the value of its technology could be adversely and materially affected, and its business could be harmed. • Competitors may develop superior products based on new technologies. • Changes to the patent law in the United States and other jurisdictions could diminish the value of the Company' s patents in general, thereby impairing the Company' s ability to protect its products. • Intellectual property rights do not necessarily address all potential threats to the Company' s competitive advantage. • The Company may obtain only limited geographical protection with respect to certain patent rights, • The Company does not have long- term experience operating as a United States public company. • The Company' s Common Stock may be delisted from Nasdaq if we do not maintain compliance with Nasdaq' s continued listing requirements. If our Common Stock is delisted, it could negatively impact the Company. • The Company identified a material weakness in its internal control over financial reporting, which may result in restatements of financial statements. • The Company may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless. • The trading price of our Common Stock has been volatile and is likely to be volatile in the future. • If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. • Future sales, or the possibility of future sales, of a substantial number of shares of our Common Stock could adversely affect the price of the shares and dilute stockholders. • We have not paid cash dividends in the past and do not expect to pay dividends in the future** Risks Relating to the Company' s Financial Condition ~~SeaStar Medical~~ **The Company** has incurred significant losses since its inception and anticipates that it will continue to incur significant losses for the foreseeable future. The Company is a medical technology company focused primarily on developing and commercializing its lead product candidate, the SCD, for pediatric and adult AKI indications. The Company ~~has submitted an~~ **applied for a** HDE ~~application with the FDA~~ for **SCD in June 2022 for the treatment of** pediatric patients with AKI on CRRT. **On September 29, 2023, the Company received a correspondence from the FDA indicating that this HDE is approvable for use in children weighing 10 kilograms or more with AKI and sepsis or a septic condition requiring CRRT in the hospital ICU. On October 30, 2023, the Company announced that it received the approvable letter from the FDA, which outlined remaining administrative steps that must**

be finalized before the HDE can be approved and active for commercialization. On February 22, 2024, the Company announced the receipt of the approval order from the FDA. The Company believes the approval of its HDE will confirm SCD and its technology as an effective tool to treat hyperinflammation related diseases, which will enable us to successfully execute our business and growth strategies. In addition, on February 9, 2023, the Company received approval from the FDA of its IDE application to conduct a pivotal study evaluating the effectiveness of its SCD in reducing hyperinflammation in adults with AKI requiring CRRT. The Company ~~plans to begin~~ **began** enrollment in ~~Q2~~ **June** 2023 and ~~expect~~ **expects** to generate interim study results **by mid-** ~~during the fourth quarter of 2023~~ **2024** and topline study results and submission of a PMA application ~~in~~ **by** the **end** ~~second half~~ of 2024 **, and the Company is targeting FDA approval by the end of 2025** . However, there is no guarantee that the Company will complete any planned clinical trial in a timely manner, or at all, nor will there be any assurance that positive data will be generated from such **a** trial. Even if the Company is able to generate positive results from this trial, the FDA and other regulatory agencies may require the Company to conduct additional trials to support the study or disagree with the design of the trial and request changes or improvements to such design. To date, the Company has not obtained regulatory approval to commercialize or sell any of its SCD product candidates, and it does not expect to generate any significant revenue for the foreseeable future. ~~SeaStar Medical~~ **The Company** has incurred significant net losses since its inception and had an accumulated deficit of $ ~~99~~ **106** . ~~3~~ **1** million and ~~,~~$ ~~76~~ **69** . ~~3~~ million as of December 31, **2023 and** 2022 ~~and 2021~~ , respectively. The Company has devoted most of its financial resources to research and development, including clinical trials and non- clinical development activities, and to obtain regulatory approval of its SCD product candidates. Since the completion of the Business Combination, the Company relied primarily on the sales of securities to fund its operations ~~,~~and are limited as the Company needs to meet certain conditions before such funding becomes available. The size of its future net losses will depend, in part, on the rate of future expenditures and its ability to generate revenues. To date, none of its product candidates have generated ~~significant~~ revenue, and if its product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, it will not achieve profitability and its business may fail. Even if the Company successfully obtains regulatory approval to market its product candidates in the United States, its revenues are also dependent upon the size of the markets outside of the United States, regulatory approval outside of the United States, and its ability to obtain market approval and achieve commercial success. The Company expects to continue to incur substantial and increased expenses as it expands research and development activities and advances clinical programs through the regulatory approval process. The Company also expects an increase in its expenses associated with preparing for the potential commercialization of its products and creating additional infrastructure to support operations as a public company. As a result of the foregoing, it expects to continue to incur significant and increasing losses and negative cash flows for the foreseeable future ~~. The Company has not generated any significant revenue and may never be profitable~~ . The Company' s ability to generate revenue and achieve profitability depends on its ability, alone or with collaborators, to successfully complete the development, obtain the necessary regulatory approvals of and commercialize its lead product candidate, the SCD. It does not anticipate generating revenues from its product candidates' sales for the foreseeable future. Its ability to generate future revenues from product sales depends heavily on its success with the following items: • completing the clinical development of its SCD, initially for the treatment of adult AKI in the hospital setting; • obtaining regulatory approval for its SCD for the designated indication, including the HDE in pediatrics and PMA for adults; • launching and commercializing its SCD, including building a hospital- directed sales force and collaborating with third parties; • obtaining third party reimbursement status from government agencies and insurance carriers; and • entering into collaboration agreement and partnerships to commercialize its products. Because of the numerous risks and uncertainties associated with medical device product development, the Company is unable to predict the timing or amount of increased expenses, when, or if, it will be able to achieve or maintain profitability. In addition, its expenses could increase beyond expectations if it is required by the FDA to perform additional, unanticipated studies. Even if its product candidates are approved for commercial sale, the Company anticipates incurring significant costs associated with commercializing any approved product candidate. In the case of its SCD product candidate for the treatment of pediatric AKI, even if the Company receives approval from the FDA for its HDE application, the Company will be limited in its ability to sell and distribute its SCD units due to certain restrictions under the HDE requirements that limit the number of units that can be sold on an annual basis, which will further limit the amount of revenue that could be generated by the Company. Even if it is able to generate revenues from the sale of its products, the Company may not become profitable and may need to obtain additional funding to continue operations. The Company has a limited operating history, which makes it difficult to forecast its future results of operations. The Company has not received approval from the FDA and other regulatory authorities to sell its SCD product candidates and therefore it has a limited commercial operating history. According, the Company' s ability to accurately forecast future results of its operations is limited and subject to a number of uncertainties and risks, including its ability to plan for and model future growth. If the Company receives regulatory approval to market and sell its SCD product candidates, its revenue growth could slow in the future, or its revenue could decline or fluctuate for a number of reasons, including slowing demand for its products, increasing competition, changing demand in the markets, new scientific or technological developments, a decrease in the growth of its overall market, its failure to attract more customers, the inability to obtain reimbursement for its products by government agencies and insurers, or its failure, for any reason, to continue to take advantage of growth opportunities. If its assumptions regarding these risks and uncertainties and its future revenue growth are incorrect or change, or if it does not address these risks successfully or forecast its results accurately, the Company' s operating and financial results could differ materially from its expectations, and its business could suffer. If the Company fails to obtain additional financing, it would be forced to delay, reduce or eliminate its product development program, which may result in the cessation of its operations. Developing medical device products, including conducting preclinical studies and clinical trials, is expensive. The Company expects its research and development expenses to substantially increase in connection with its ongoing activities, particularly as it advances its clinical programs. As

of December 31, **2023 and** 2022 ~~and 2021~~, SeaStar Medical had negative working capital of $ **4.** 2 ~~.~~ **million and $** 3 ~~million and $ 2~~. ~~5~~ **8** million, respectively. The Company currently does not have sufficient capital to support its operations and complete its planned regulatory approval process. The Company will need to secure additional capital to continue its operation, and such funding may not be available on acceptable terms, or at all. In addition, the Company incurred a significant amount of debt in connection with the Closing, including the issuance of unsecured and secured promissory notes to LM Funding America, Inc. (" LMFA "), LMFAO Sponsor (the" Sponsor") and Maxim (" Maxim" **), and convertible notes to 3i LP (" 3i "), an affiliate of Tumim Stone Capital (" Tumim "**), and the Company may not have sufficient funds to repay these loans. Even if the Company obtains additional funding, the Company will be required to make certain mandatory payments under such promissory notes, which will reduce the amount of proceeds available for the Company to operate its business. On August 23, 2022, ~~LMAO~~ **LMF** and **the Predecessor** ~~SeaStar Medical, Inc.~~ entered into a Common Stock Purchase Agreement (the " Purchase Agreement ") with Tumim ~~Stone Capital LLC (" Tumim ")~~ for the purchase of up to $ 100. 0 million in shares of the common stock (~~"~~ **"** Common Stock") after the consummation of the Business Combination. There ~~are~~ **were** certain conditions and limitations on the Company' s ability to utilize the $ 100. 0 million equity line with Tumim. The Company **was** ~~will be~~ required to satisfy various conditions, which include, among others: (1) delivery of a compliance certificate; (2) filing of an initial registration statement; and (3) customary bring- down opinions and negative assurances, in order to commence the selling of Common Stock to Tumim under the Purchase Agreement. Once such conditions ~~are~~ **were** satisfied, Tumim' s purchases ~~are~~ **were** subject to various restrictions and other limitations, including a cap on the number of shares of Common Stock that we ~~can~~ **could** sell based on the trading volume of our Common Stock, as well as certain beneficial ownership restrictions of Tumim. ~~If any of these conditions are not satisfied or limitations are in effect, the Company may not be able to utilize all or part of the Tumim equity line, which would have an adverse impact on the Company' s ability to satisfy its capital needs and could have a material adverse impact on its business.~~ The Company has received a total of $ 1. 9 million from ~~these~~ -- **the** ~~forward purchase~~ **Purchase** ~~agreements~~ - **Agreement** through February **15, 2024, when the Purchase Agreement was terminated by mutual consent of the parties thereto pursuant to its terms. In March** 2023 ~~. However~~ , **the Company entered into a securities purchase agreement with an 3i (as amended from time to time, the " March 2023 SPA ") for the purchase and sale of convertible notes and warrants (together with the March 2023 SPA, the " Note Documents "). The Note Documents include various restrictions and covenants, including an optional redemption provision that provides such investor the right to require the Company to use up to 20 % of the proceeds of any subsequent financing, including** this ~~source~~ **offering, to repay outstanding balance** of ~~capital may be limited since~~ **the notes (the " Optional Redemption Rights "). In connection with this offering, the institutional investor agreed to waive** ~~it its depends substantially on~~ **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** ~~the~~ **then outstanding Conversion Amount (as defined in the Note Documents) within three (3)** trading ~~volume~~ **days after the Suspension Period at** ~~and~~ - **an** ~~price~~ **amount equal to 200 %** of **the Conversion Amount. As of the date of this Form 10- K, the aggregate Conversion Amount under the Note Documents is approximately $ 1. 0 million. Failure to meet the restrictions, obligations, and limitations under the Notes Documents** ~~our~~ - **or** ~~Common Stock~~ **the securities issued thereunder may result in an event of default in accordance with the terms of the convertible notes issued thereunder** . ~~In addition~~ **An event of default would** , **among** ~~the~~ **other** ~~Company recently completed a~~ **things, provide the noteholder with the right to increase the outstanding balance by 15 %. Additionally, upon an event of default, the noteholder may consider the** convertible note **immediately due and payable** ~~financing in which the Company may issue up to a principal amount of approximately $ 9~~ . **Furthermore** ~~8 million of convertible notes in four separate tranches subject to certain conditions~~ , **upon** ~~and~~ - **an event** ~~on March 15, 2023, the Company closed the first tranche~~ of **default** ~~the financing by issuing a convertible note in a principal amount of $ 3. 3 million~~ , ~~and a warrant to purchase up to 328, 352 shares of Common Stock. However, there~~ -- **the interest rate may also** ~~is no guarantee that the Company will~~ be ~~able~~ **increased** to **12 % per annum** ~~satisfy the conditions required to issue additional notes under the remaining three tranches, including the requirement to obtain stockholder approval of such financing at the next annual meeting of stockholders.~~ Even if the Company receives sufficient capital in the future, the Company will be required to raise additional funds to support its own operations and complete its planned regulatory approval process, and such funding may not be available in sufficient amounts or on acceptable terms to the Company, or at all. If it is unable to raise additional capital when required or on acceptable terms, the Company may be required to: • significantly delay, scale back or discontinue the development or commercialization of its product candidates; • seek corporate partners on terms that are less favorable than might otherwise be available; • relinquish or license on unfavorable terms, its rights to technologies or product candidates that it otherwise would seek to develop or commercialize itself; If it is unable to raise additional capital in sufficient amounts or on acceptable terms, the Company will be prevented from pursuing development and commercialization efforts, including completing the clinical trials and regulatory approval process for its SCD product candidates, which would have a material adverse impact on its business, results of operations and financial condition. The Company' s ability to use its net operating losses to offset future taxable income may be subject to certain limitations. As of December 31, ~~2022~~ **2023** , the Company had net operating loss (" NOL ") carryforwards for federal and state (Colorado, California, and Florida) income tax purposes of $ ~~82~~ **106** . ~~3~~ **2** million and $ ~~28~~ **2** . ~~9~~ **0** million, respectively, which may be available to offset taxable income in the future. Under the Tax Cuts and Jobs Act of 2017, as modified by the Coronavirus Aid, Relief, and Economic Security Act, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80 percent of taxable income. Federal NOLs incurred before 2018 may be carried forward 20 years but are not subject to the taxable income limitation. Under current law, California NOLs generally may be carried forward 20 years (with a limited extension for California NOLs incurred

in 2020- 2021) without a taxable income limitation. The Company' s federal NOLs include $ ~~29~~ **53** . 4 million that can also be carried forward indefinitely, and the remaining $ 52. 8 million of federal NOLs expire in various years beginning in 2027 for federal purposes. The California NOLs expire beginning in 2039 if not utilized. A lack of future taxable income would adversely affect the Company' s ability to utilize these NOLs before they expire. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change " (as defined in Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre- change NOLs to offset future taxable income. The Company may experience a future ownership change under Section 382 of the Code that could affect its ability to utilize the NOLs to offset its income. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of NOL and research tax credit carryforwards available to offset future taxable income and income tax liabilities in future years may be significantly restricted or eliminated. Further, deferred tax assets associated with such NOLs, and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382. Furthermore, the Company' s ability to utilize NOLs of companies that it may acquire in the future may be subject to limitations. There is also a risk that due to legislative or regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, the Company' s existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, the Company may not be able to utilize a material portion of the NOLs reflected on its balance sheet, even if it attains profitability, which could potentially result in increased future tax liability to the Company and could adversely affect its business, results of operations and financial condition . Risks Related to the Company'..... by the Sponsor or its permitted transferees . We may suffer from lack of availability of additional funds. We expect to have ongoing needs for working capital in order to fund operations, continue to expand our operations and recruit experienced personnel. To that end, we will be required to raise additional funds through equity or debt financing. However, there can be no assurance that we will be successful in securing additional capital on favorable terms, if at all. If we are successful, whether the terms are favorable or unfavorable, there is a potential that we will fail to comply with the terms of such financing, which could result in severe liability for us. If we are unsuccessful, we may need to (a) initiate cost reductions; (b) forego business development opportunities; (c) seek extensions of time to fund liabilities, or (d) seek protection from creditors. In addition, any future sale of our equity securities would dilute the ownership and control of your shares and could be at prices substantially below prices at which our shares currently trade. Our inability to raise capital could require us to significantly curtail or terminate our operations altogether. We may seek to increase our cash reserves through the sale of additional equity or debt securities. The sale of convertible debt securities or additional equity securities could result in additional and potentially substantial dilution to our shareholders. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations and liquidity. In addition, our ability to obtain additional capital on acceptable terms is subject to a variety of uncertainties. In addition, if we are unable to generate adequate cash from operations, and if we are unable to find sources of funding, it may be necessary for us to sell all or a portion of our assets, enter into a business combination, or reduce or eliminate operations. These possibilities, to the extent available, may be on terms that result in significant dilution to our shareholders or that result in our shareholders losing all of their investment in our Company. **.Risks Related to the Company' s Business Operations The Company has not received,and may never receive,approval from the FDA to market its product in** the United States or abroad.The Company may encounter various challenges and difficulties in its application to seek approval from the FDA to sell and market its SCD product candidates,including the application for HDE for pediatric AKI indication and the pivotal trial for adult AKI indication.The Company is required to submit a substantial amount of supporting documentation for its HDE application to demonstrate the eligibility of the SCD to treat pediatric patients ~~.The Company submitted an application for a HDE for SCD in June 2022 for the treatment of pediatric patients with AKI on CRRT.On September 29,2023,the Company received correspondence from the FDA indicating that this HDE is approvable for use in children weighing 10 kilograms or more with AKI and sepsis or a septic condition requiring CRRT in the hospital ICU.On October 30,2023,the Company announced that it received the approvable letter from the FDA.On February 22,2024,the Company announced the receipt of the approval order from the FDA.The Company believes the approval of its HDE will confirm SCD and its technology as an effective tool to treat hyperinflammation related diseases,which will enable us to successfully execute our business and growth strategies.The Company believes that its novel therapeutic device is readily applicable for use in other indications,which will require additional clinical studies and FDA approval.For example,on September 28,2023,the Company received Breakthrough Device Designation for our patented and cell- directed SCD for use with patients in the hospital ICU with acute or chronic systolic heart failure and worsening renal function due to cardiorenal syndrome or right ventricular dysfunction awaiting implantation of a left ventricular assist device,and on October 18,2023,the Company received Breakthrough Device Designation for our patented and cell- directed SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure.While the Company expects the Breakthrough Device Designation to expedite the clinical development and regulatory review of the SCD program for use in this patient population,there is no guarantee that the Company will be able to expedite the clinical development or obtain regulatory approval .~~While the Company recently obtained approval from the FDA to conduct the AKI adult pivotal trial for SCE,there is no guarantee that the Company will be able to complete such trial in a timely manner,or at all,nor will there be any assurance that positive data will be generated from such trials.Even if the Company is able to generate positive results from this trial,the FDA and other regulatory agencies may require the Company to conduct additional trials to support the study or disagree with the design of the trial and request changes or improvements to such design.The Company is also subject to numerous other risks relating to the regulatory approval process,which include but are not limited to:• an inability to secure and obtain support and references from collaborators and suppliers required by the FDA;• a disagreement with the FDA regarding the design of the trial,including the number of clinical study subjects and other data,which may require SeaStar Medical to conduct additional testing or increase the

size and complexity of its pivotal study;• a failure to obtain a sufficient supply of filters to conduct its trial;• an inability to enroll a sufficient number of subjects;• a shortage of necessary raw materials,such as calcium;and • delays and failures to train qualified personnel to operate the SCD therapy.Even if the Company obtains approval,the FDA or other regulatory authorities may require expensive or burdensome post- market testing or controls.Any delay in,or failure to receive or maintain,clearance or approval for its future products could prevent the Company from generating revenue from these products or achieving profitability.Additionally,the FDA and other regulatory authorities have broad enforcement powers.Regulatory enforcement or inquiries,or other increased scrutiny on the Company,could dissuade some physicians from using its products and adversely affect its reputation and the perceived safety and efficacy of its products.Delays or rejections may occur based on changes in governmental policies for medical devices during the period of product development.The FDA can delay,limit or deny approval of a PMA application for many reasons,including:• the Company' s inability to demonstrate the safety or effectiveness of the SCD or any other product it develops to the FDA' s satisfaction;• insufficient data from its preclinical studies and clinical trials,including for its SCD,to support approval;• failure of the facilities of its third- party manufacturers or suppliers to meet applicable requirements;• inadequate compliance with preclinical,clinical or other regulations;• its failure to meet the FDA' s statistical requirements for approval;and • changes in the FDA' s approval policies,or the adoption of new regulations that require additional data or additional clinical studies.If the Company is not able to obtain regulatory approval of its SCD in a timely manner or at all,it may not be able to continue to operate its business and may be forced to shut down its operations.The Company is subject to certain risks relating to pursuing an FDA approval via the HDE pathway,including limitations on the ability to profit from sales of the product.Except in certain circumstances,products approved under an HDE cannot be sold for an amount that exceeds the costs of the research and development,fabrication,and distribution of the device (i.e.,for profit).Currently,under section 520 (m) (6) (A) (i) of the Food,Drug,and Cosmetic Act,as amended (the " FD & C Act ") by the Food and Drug Administration Safety and Innovation Act,a Humanitarian Use Device (" HUD ") is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation,and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs;or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible,highly impracticable,or unsafe.If an HDE- approved device does not meet this eligibility criteria,the device cannot be sold for profit.With enactment of the FDA Reauthorization Act of 2017,Congress provided that the exemption for the HUD / HDE profitability is available as long as the request for an exemption is submitted on or before October 1,2022.Not receiving an exemption for the HUD / HDE profitability would have a material adverse effect on the Company' s business,results of operations and financial condition.In addition,if the FDA subsequently approves a PMA or clears a 510 (k) for the HUD or another comparable device with the same indication,the FDA may withdraw the HDE.Once a comparable device becomes legally marketed through PMA approval or 510 (k) clearance to treat or diagnose the disease or condition in question,there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520 (m) (2) (B) of the FD & C Act.The Company plans to expand its operations and it may not be able to manage its growth effectively,which could strain its resources and delay or derail implementation of its business objectives.The Company will need to significantly expand its operations to implement its longer- term business plan and growth strategies,including building and expanding its internal organizational infrastructure to complete the regulatory approval process with the FDA.The Company will also be required to manage and form new relationships with various strategic partners,technology licensors,customers,manufacturers and suppliers,consultants and other third parties.This expansion and these new relationships will require the Company to significantly improve or replace its existing managerial,operational and financial systems,and procedures and controls;to improve the coordination between its various corporate functions;and to manage,train,motivate and maintain a growing employee base.The time and costs to effectuate these steps may place a significant strain on its management personnel,systems and resources,particularly if there are limited financial resources and skilled employees available at the time.The Company cannot assure that it will institute,in a timely manner or at all,the improvements to its managerial,operational and financial systems,procedures and controls necessary to support its anticipated increased levels of operations and to coordinate its various corporate functions,or that it will be able to properly manage,train,motivate and retain its anticipated increased employee base.If it cannot manage its growth initiatives,the Company will be unable to commercialize its products on a large- scale in a timely manner,if at all,and its business could fail.The Company will initially depend on revenue generated from a single product and in the foreseeable future will be significantly dependent on a limited number of products.If the Company receives approval from the FDA and other regulatory authorities,the Company will initially depend on revenue generated from its SCD product candidate for pediatric and adult patients with AKI and in the foreseeable future will be significantly dependent on a single or limited number of products.Given that,for the foreseeable future,the Company' s business will depend on a single or limited number of products,to the extent a particular product is not well- received by the market,the Company' s sales volume,prospects,business,results of operations and financial condition could be materially and adversely affected.If the Company fails to comply with extensive regulations of United States and foreign regulatory agencies,the commercialization of its products could be delayed or prevented entirely.The Company' s SCD product candidate and research and development activities are subject to extensive government regulations related to its development,testing,manufacturing and commercialization in the United States and other countries.The determination of when and whether a product is ready for large-scale purchase and potential use in the United States will be made by the United States government through consultation with a number of governmental agencies,including the FDA,the National Institutes of Health and the Centers for Disease Control and Prevention.The Company' s SCD has not received regulatory approval from the FDA,or any foreign regulatory agencies,to be commercially marketed and sold.The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations in the United States and in foreign countries is costly,time consuming,uncertain and subject to

unanticipated delays.Obtaining such regulatory approvals,if any,can take several years.Despite the time and expense exerted,regulatory approval is never guaranteed.The Company is also subject to the following risks and obligations,among others:• the FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied;• the FDA may require additional testing for safety and effectiveness;• the FDA may interpret data from pre- clinical testing and clinical trials in different ways than the Company interprets them;• if regulatory approval of a product is granted,the approval may be limited to specific indications or limited with respect to its distribution;and • the FDA may change its approval policies and / or adopt new regulations.Failure to comply with these or other regulatory requirements of the FDA may subject the Company to administrative or judicially imposed sanctions,including:• warning letters,untitled letters or other written notice of violations;• civil penalties;• criminal penalties;• injunctions;• product seizure or detention;• product recalls;and • total or partial suspension of productions. **Delays in successfully completing the Company' s planned clinical trials could jeopardize its ability to obtain regulatory approval.** The Company' s business prospects will depend on its ability to complete studies,clinical trials,including its planned pivotal trials of its SCD for adult AKI indication,obtain satisfactory results,obtain required regulatory approvals and successfully commercialize its SCD product candidate.The completion of the Company' s clinical trials,the announcement of results of the trials and its ability to obtain regulatory approvals could be delayed for a variety of reasons,including:• slow patient enrollment;• serious adverse events related to its medical device candidates;• ~~insufficient funding to engage or continue to engage contract research organization to execute the trials;•~~ unsatisfactory results of any clinical trial;• the failure of principal third- party investigators to perform clinical trials on the Company' s anticipated schedules;and • different interpretations of the Company' s pre- clinical and clinical data,which could initially lead to inconclusive results.The Company' s development costs will increase if it has material delays in any clinical trial or if it needs to perform more or larger clinical trials than planned.If the delays are significant,or if any of its product candidates do not prove to be safe or effective or do not receive regulatory approvals,the Company' s financial results and the commercial prospects for its product candidates would be harmed.Furthermore,the Company' s inability to complete its clinical trials in a timely manner could jeopardize its ability to obtain regulatory approval.Delays,interruptions,or the cessation of production by its third- party suppliers of important materials or delays in qualifying new materials,may prevent or delay the Company' s ability to manufacture or process its SCD device.The Company currently relies on a single supplier for the filters used in the SCD device for the pediatric AKI indications pursuant to a supply agreement.In the event the current supplier is unable to provide filters for the SCD device or otherwise fails to meet its obligations under the agreement,the Company may not be able to obtain a sufficient number of filters to conduct its trials and commercialize its products.In addition,the supplier may decide to discontinue or terminate the specific type of filters that are required for its SCD for reasons beyond the Company' s control,in which case the Company will be forced to identify and secure an alternative source that may not be available immediately or at all.FDA review and approval of a new supplier may be required if these materials become unavailable from the Company' s current suppliers.Although there may be other suppliers that have equivalent materials that would be available to the Company,FDA review of any alternate suppliers,if required,could take several months or more to obtain,if it is able to be obtained at all.Any delay,interruption,or cessation of production by the Company' s third- party suppliers of important materials,or any delay in qualifying new materials,if necessary,would prevent or delay the Company' s ability to manufacture its SCD.The Company believes that it has sufficient access to the SCD inventory to conduct its current and near future clinical trials,but it is possible that the need for its SCD could increase that may require the Company to acquire more filters than it is currently able to purchase under its agreement with its supplier,and the Company may not be able to negotiate a new supply agreement successfully.If the Company is unable to find alternative sources of supply in a timely manner,any such delay could limit the Company' s ability to meet demand for the SCD and delay its ongoing clinical trials,which would have a material adverse impact on its business,results of operations and financial condition **.The Company has limited experience in identifying and working with large- scale contracts with medical device manufacturers** .To achieve the levels of production necessary to commercialize its SCD and any other future products,the Company will need to secure large- scale manufacturing agreements with contract manufacturers that comply with the manufacturing standards prescribed by various federal,state,and local regulatory agencies in the United States and any other country of use.The Company has limited experience coordinating and overseeing the manufacturing of medical device products on a large- scale.Manufacturing and control problems could arise as the Company attempts to commercialize its products and manufacturing may not be completed in a timely manner or at a commercially reasonable cost.In addition,the Company may not be able to adequately finance the manufacturing and distribution of its products on terms acceptable to the Company,if at all.If the Company cannot successfully oversee and finance the manufacturing of its products after receiving regulatory approval,it may not generate sufficient revenue to become profitable. **Difficulties in manufacturing the Company' s SCD could have an adverse effect upon its revenue and expenses.** The Company currently outsources all of the manufacturing of its SCD.The manufacturing of its SCD is difficult and complex.To support its current clinical trial needs,the Company complies with and intends to continue to comply with current Good Manufacturing Practice (" cGMP ") in the manufacturing of its products.The Company' s ability to adequately manufacture and supply its SCD in a timely matter is dependent on the uninterrupted and efficient operation of its third- party manufacturers,and those of the third parties producing raw materials and supplies upon which it relies on for the manufacturing of its products.The manufacturing of the Company' s products may be impacted by:• the availability or contamination of raw materials and components used in the manufacturing process,particularly those for which it has no other supplier;• its ability to comply with new regulatory requirements and cGMP;• potential facility contamination by microorganisms or viruses;• updating of its manufacturing specifications;• product quality success rates and yields;and • global viruses and pandemics,including the current COVID- 19 pandemic.If efficient manufacture and supply of its SCD is interrupted,the Company may experience delayed shipments or supply constraints.If it is at any time unable to provide an uninterrupted supply of its products,the Company' s ongoing clinical trials may be delayed,which could materially and adversely affect its business,results of operations and

financial condition.The Company' s SCD technology may become obsolete.The Company' s SCD product candidates may become obsolete prior to commercialization by new scientific or technological developments,or by others with new treatment modalities that are more efficacious and / or more economical than the Company' s products.Any one of the Company' s competitors could develop a more effective product which would render the Company' s technology obsolete.In addition,it is possible that competitors may use similar technologies,equipment or devices,including using certain " off- the- shelf " filters unauthorized by the FDA,to attempt to create a similar treatment mechanism as the SCD.Further,new technological and scientific developments within the hospital setting could cause the Company' s SCD product candidates to become obsolete.For example,the SCD relies on the existing footprint of CRRT pump systems in ICUs,as well as the growing use and adoption of regional citrate as an anticoagulant.Further developments in these areas could require the Company to reconfigure its SCD product candidates,which may not be commercially feasible,or cause them to become obsolete.Lastly,the Company' s ability to achieve significant and sustained growth in its key target markets will depend upon its success in hospital penetration,utilization,publication,its SCD' s reimbursement status and medical education.The Company' s products may not remain competitive with products based on new technologies.If it fails to sell products that satisfy its customers' demands or respond effectively to new product announcements by its competitors,then market acceptance of the Company' s products could be reduced and its business,results of operations and financial condition could be adversely affected **.The Company faces intense competition in the medical device industry** .The Company competes with numerous United States and foreign companies in the medical device industry,and many of its competitors have greater financial,personnel,operational and research and development resources than the Company.The Company believes that multiple competitors are or will be developing competing technologies to address cytokine storms.Progress is constant in the treatment of the immune system,which may reduce opportunities for the SCD.The Company' s commercial opportunities will be reduced or eliminated if its competitors develop and market products for any of the diseases it targets that:• are more effective;• have fewer or less severe adverse side effects;• are better tolerated;• are easier to administer;or • are less expensive than SeaStar Medical' s products or its product candidates.Even if the Company is successful in developing the SCD and any other future products and obtains FDA and other regulatory approvals necessary for commercializing them,its products may not compete effectively with other products.Researchers are continually learning more about diseases,which may lead to new technologies for treatment.The Company' s competitors may succeed in developing and marketing products that are either more effective than those that it may develop or that are marketed before any SeaStar Medical products.The Company' s competitors include fully integrated pharmaceutical & medical device companies and biotechnology companies,universities,and public and private research institutions.Many of the organizations competing with the Company have substantially greater capital resources,larger research and development staffs and facilities,greater experience in product development and in obtaining regulatory approvals,and greater marketing capabilities.If the Company' s competitors develop more effective treatments for infectious disease or hyperinflammation or bring those treatments to market before the Company can commercialize the SCD for such uses,it may be unable to obtain any market traction for its products,or the diseases it seeks to treat may be substantially addressed by competing treatments.If the Company is unable to successfully compete against larger companies in the pharmaceutical industry,it may never generate significant revenue or be profitable.If the Company' s products,or the malfunction of its products,cause or contribute to a death or a serious injury,the Company will be subject to medical device reporting regulations,which can result in voluntary corrective actions or agency enforcement actions.Under the FDA medical device reporting regulations,medical device manufacturers are required to report to the FDA that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury.If the Company fails to report these events to the FDA within the required timeframes,or at all,the FDA could take enforcement action against the Company.Any such adverse event involving the Company' s products could also result in future voluntary corrective actions,such as recalls or customer notifications,or agency action,such as inspection or enforcement action.Any corrective action,whether voluntary or involuntary,as well as defending against potential lawsuits,will require the dedication of the Company' s time and capital,distract management from operating its business,and may harm the Company' s reputation and financial results.The Company **outsources many of its operational and development activities for which it may not have full control.The Company** relies on third- party consultants or other vendors to manage and implement much of the day- to- day responsibilities of conducting clinical trials and manufacturing its current product candidates.Accordingly,the Company is and will continue to be dependent on the timeliness and effectiveness of the efforts of these third parties.The Company' s dependence on third parties includes key suppliers and third- party service providers supporting the development,manufacturing,and regulatory approval of its SCD,as well as support for its information technology systems and other infrastructure.While its management team oversees these vendors,the failure of any of these third parties to meet their contractual,regulatory,and other obligations,or the development of factors that materially disrupt the performance of these third parties,could have a material adverse effect on the Company' s business,results of operations and financial condition.It is possible that the current COVID- 19 pandemic might constrain the ability of third- party vendors to provide services that the Company requires.If a clinical research organization that the Company utilizes is unable to allocate sufficient qualified personnel to its studies in a timely manner or if the work performed by it does not fully satisfy the requirements of the FDA or other regulatory agencies,the Company may encounter substantial delays and increased costs in completing its development efforts.Any manufacturer of the Company' s products may encounter difficulties in the manufacturing of enough new product to meet demand,including problems with product yields,product stability or shelf life,quality control,adequacy of control procedures and policies,compliance with FDA regulations and the need for FDA approval of new manufacturing processes and facilities.If any of these occur,the development and commercialization of the Company' s product candidates could be delayed,curtailed,or terminated because the Company may not have sufficient financial resources or capabilities to continue such development and commercialization on its own.If the Company or its contractors or service providers fail to comply with laws

and regulations,it or they could be subject to regulatory actions,which could affect its ability to develop,market and sell its product candidates and any other future product candidates and may harm its reputation.If the Company or its manufacturers or other third- party contractors fail to comply with applicable federal,state or foreign laws or regulations,the Company could be subject to regulatory actions,which could affect its ability to successfully develop,market and sell its SCD product candidate or any future product candidates under development and could harm its reputation and lead to reduced or non- acceptance of its proposed product candidates by the market.Even technical recommendations or evidence by the FDA through letters,site visits,and overall recommendations to academia or biotechnology companies may make the manufacturing of a clinical product extremely labor intensive or expensive,making the product candidate no longer viable to manufacture in a cost- efficient manner.The mode of administration or the required testing of the product candidate may make that candidate no longer commercially viable.The conduct of clinical trials may be critiqued by the FDA,or a clinical trial site' s Institutional Review Board or Institutional Biosafety Committee,which may delay or make impossible the clinical testing of a product candidate.For example,the Institutional Review Board for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing.This would have a material adverse effect on the value of the product candidate and the Company' s business,results of operations and financial condition.If the Company obtains approval for its products,SeaStar Medical may still be subject to enforcement action if it engages in improper marketing or promotion of its products.The Company is not permitted to promote or market its product candidates until FDA approval is obtained.After approval,its promotional materials and training methods must comply with the FDA and other applicable laws and regulations,including the prohibition of the promotion of unapproved or off- label use.Practitioners may use the Company' s products off- label,as the FDA does not restrict or regulate a practitioner' s choice of treatment within the practice of medicine.However,if the FDA determines that the Company' s promotional materials or training constitutes promotion of an off- label use,it could request that the Company modify its training or promotional materials or subject the Company to regulatory or enforcement actions,including the issuance of an untitled letter,a warning letter,injunction,seizure,civil fine,or criminal penalties.Other federal,state,or foreign enforcement authorities might also take action if they consider the Company' s promotional or training materials to constitute promotion of an off- label use,which could result in significant fines or penalties under other statutory authorities,such as laws prohibiting false claims for reimbursement.In that event,the Company' s reputation could be damaged,which may lead to reduced or non- acceptance of its proposed product candidates by the market.In addition,the off- label use of the Company' s products may increase the risk of product liability claims.Product liability claims are expensive to defend and could divert the attention of the Company' s management,result in substantial damage awards against the Company,and harm its reputation.The Company intends to outsource and rely on third parties for the clinical development and manufacture,sales and marketing of its SCD or any future product candidates that it may develop,and its future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.The Company does not have the required financial and human resources to carry out on its own all the pre-clinical and clinical development for its SCD product candidate or any other or future product candidates that it may develop,and do not have the capability and resources to manufacture,market or sell its SCD product candidate or any future product candidates that it may develop.The Company' s business model calls for the partial or full outsourcing of the clinical,development,manufacturing,sales,and marketing of its product candidates in order to reduce its capital and infrastructure costs as a means of potentially improving its financial position.The Company' s success will depend on the performance of these outsourced providers.If these providers fail to perform adequately,the Company' s development of product candidates may be delayed and any delay in the development of the Company' s product candidates may have a material and adverse effect on its business,results of operations and financial condition.The Company is and will be exposed to product liability risks,and clinical and preclinical liability risks,which could place a substantial financial burden upon it should it be sued.The Company' s business exposes it to potential product liability and other liability risks that are inherent in the testing,manufacturing,and marketing of medical devices.Claims may be asserted against it.A successful liability claim or series of claims brought against it could have a material adverse effect on the Company' s business,results of operations and financial condition.The Company may not be able to continue to obtain or maintain adequate product liability insurance on acceptable terms,if at all,and such insurance may not provide adequate coverage against potential liabilities.Claims or losses in excess of any product liability insurance coverage that the Company may obtain could have a material adverse effect on its business,results of operations and financial condition.The Company' s SCD product candidate may be used in connection with medical procedures where those products must function with precision and accuracy.If medical personnel or their patients suffer injury as a result of any failure of the Company' s products to function as designed,or its products are designed inappropriately,the Company may be subject to lawsuits seeking significant compensatory and punitive damages.The risk of product liability claims,product recalls and associated adverse publicity is inherent in the testing,manufacturing,marketing,and sale of medical products.The Company intends to obtain general clinical trial liability insurance coverage;however,its insurance coverage may not be adequate or available.In addition,the Company may not be able to obtain or maintain adequate product liability insurance on acceptable terms,if at all,and such insurance may not provide adequate coverage against potential liabilities.Any product recall or lawsuit in excess of any product liability insurance coverage that the Company may obtain could have a material adverse effect on its business,results of operations and financial condition.Moreover,a product recall could generate substantial negative publicity about the Company' s products and business and inhibit or prevent commercialization of other future product candidates.United States legislative or FDA regulatory reforms may make it more difficult and costly for the Company to obtain regulatory approval of its product candidates and to manufacture,market and distribute its products after approval is obtained.From time to time,legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval,manufacture and marketing of regulated products or the reimbursement thereof.In addition,FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect the Company' s business and its products.Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen

review times of future products.It is impossible to predict whether legislative changes will be enacted,or FDA regulations,guidance or interpretations will be changed,and what the impact of such changes,if any,may be on the Company' s new product development efforts.The Company is subject to stringent and changing privacy laws,regulations and standards as well as policies,contracts and other obligations related to data privacy and security.The Company collects,receives,stores,processes,uses,generates,transfers,discloses,makes accessible,protects,and shares personal information and other information (" Process " or " Processing "),including information it collects in connection with clinical trials,as necessary to operate its business,for legal and marketing purposes,and for other business- related purposes.There are numerous federal,state,local and international laws,regulations and guidance regarding privacy,information security and Processing,the number and scope of which is changing,subject to differing applications and interpretations,and which may be inconsistent.The Company is subject,and may become subject in the future,to certain of these laws,regulations,and guidance,and it is also subject to the terms of its external and internal privacy and security policies,representations,certifications,standards,publications,frameworks,and contractual obligations to third parties related to privacy,information security and Processing.If the Company fails,or is perceived to have failed,to address or comply with such obligations,it could:• increase its compliance and operational costs;• expose it to regulatory scrutiny,actions,fines and penalties;• result in reputational harm;interrupt or stop its clinical trials;• result in litigation and liability;result in an inability to process personal data or to operate in certain jurisdictions;or • harm its business operations or financial results or otherwise result in a material harm to its business.Additionally,given that these obligations impose complex and burdensome obligations and that there is substantial uncertainty over the interpretation and application of these obligations,the Company may be required to incur material costs,divert management attention,and change its business operations,including its clinical trials,in an effort to comply,which could materially adversely affect its business,results of operations and financial condition.The California Consumer Privacy Act of 2018 (" CCPA ") is an example of the increasingly stringent data protection legislation in the United States.The CCPA gives California residents expanded rights to access and require deletion of their personal information,opt- out of certain personal information sharing,and receive detailed information about how their personal information is used.The CCPA created civil penalties for violations,as well as a private right of action for data breaches and statutory damages ranging from $ 100 to $ 750 per violation,which is expected to increase data breach class action litigation and result in significant exposure to costly legal ~~judgments~~ **judgements** and settlements.Although there are limited exemptions for clinical trial data under the CCPA,the CCPA and other similar laws could impact the Company' s business activities depending on how they are interpreted.The Company' s business operations will be adversely affected if its security measures,or those maintained on its behalf,are compromised,limited or fails.In the ordinary course of its business,the Company handles and processes proprietary,confidential and sensitive information,including personal data,intellectual property,trade secrets,and proprietary business information owned or controlled by us or other third parties,or collectively.The Company may use and share such sensitive information with service providers and other third parties.If the Company,its service providers,partners,or other relevant third parties have experienced,or in the future experience,any security incident or incidents that result in any data loss;deletion or destruction;unauthorized access to;loss,unauthorized acquisition,disclosure,or exposure of,confidential and sensitive information,it may adversely affect SeaStar Medical' s business,results of operations and financial condition,including the diversion of funds to address the breach,and interruptions,delays,or outages in its operations and development programs.Cyberattacks,malicious internet- based activity and online and offline fraud are prevalent and continue to increase,including the possibility that the ongoing conflict between Russia and Ukraine could result in cyberattacks or cybersecurity incidents that may have a direct or indirect impact on our operations.In addition to threats from traditional computer " hackers," threat actors,software bugs,malicious code (such as viruses and worms),employee theft or misuse,denial- of- service attacks (such as credential stuffing) and ransomware attacks,sophisticated nation- state and nation- state supported actors now engage in attacks (including advanced persistent threat intrusions).The Company may also be the subject of phishing attacks,viruses,malware installation,server malfunction,software or hardware failures,loss of data or other computer assets,or other similar issues any of which could have a material and adverse effect on its business,results of operations and financial condition.Should the Company' s products be approved for commercialization,a lack of third- party coverage and reimbursement for the Company' s devices could delay or limit their adoption.In both the United States and international markets,the use and success of medical devices is dependent in part on the availability of reimbursement from third- party payors,such as government and private insurance plans.Healthcare providers that use medical devices generally rely on third- party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services.Should the Company' s products under development be approved for commercialization by the FDA,reimbursement may not be available in the United States or other countries or,even if approved,the amount of reimbursement may not be sufficient to allow sales of the Company' s future products,including the SCD,on a profitable basis.The coverage decisions of third- party payors will be significantly influenced by the assessment of the Company' s future products by health technology assessment bodies.These assessments are outside the Company' s control,and any such evaluations may not be conducted or have a favorable outcome.If approved for use in the United States,the Company expects that any products that it develops,including the SCD,will be purchased primarily by medical institutions through their operations budget.Payors may include the Centers for Medicare & Medicaid Services (" CMS "),which administers the Medicare program and works in partnership with state governments to administer Medicaid,other government programs and private insurance plans.The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive.Further,Medicare coverage is based on the Company' s ability to demonstrate that the treatment is " reasonable and necessary " for Medicare beneficiaries.Even if products utilizing the Company' s SCD technology receive FDA and other regulatory clearance or approval,they may not be granted coverage and reimbursement by any payor,including by CMS.For some governmental programs,such as Medicaid,coverage and adequate reimbursement differ from state to state and some state

Medicaid programs may not pay adequate amounts for the procedure products utilizing the Company' s technology system,or any payment at all.Moreover,many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies and amounts.However,no uniform policy for coverage and reimbursement of medical devices exists among third- party payors in the United States.Therefore,coverage and reimbursement can differ significantly from payor to payor.If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals,this may affect coverage and reimbursement determinations by many private payors for any future SeaStar Medical products.Should any of its future products,including the SCD,be approved for commercialization,adverse changes in reimbursement policies and procedures by payors may impact the Company' s ability to market and sell its products.Healthcare costs have risen significantly over the past decade,and there have been and continue to be proposals by legislators,regulators and third- party payors to decrease costs.Third- party payors are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services.For example,in the United States,the Patient Protection and Affordable Care Act,as amended by the Health Care and Education Reconciliation Act of 2010 (collectively,the " ACA "),among other things,reduced and / or limited Medicare reimbursement to certain providers.However,on December 14,2018,a Texas United States District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress as part of legislation enacted in 2017,informally titled the Tax Cuts and Jobs Act of 2017.Additionally,on June 17,2021,the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress.Thus,the ACA remains in effect without the " individual mandate." Further,prior to the United States Supreme Court ruling,on January 28,2021,President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace,which began on February 15,2021 and remained open through August 15,2021.The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare,including among others,reexamining Medicaid demonstration projects and waiver programs that include work requirements,and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.It is possible that the ACA will be subject to judicial or Congressional challenges in the future.It is unclear how any such challenges and litigation,and the healthcare reform measures of the Biden administration will impact the ACA and the Company' s business.The Budget Control Act of 2011,as amended by subsequent legislation,further reduces Medicare' s payments to providers by 2 % through fiscal year 2031.However,COVID- 19 relief legislation suspended the 2 % Medicare sequester from May 1,2020 through March 31,2022.Under current legislation,the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 3 % in the final fiscal year of this sequester.These reductions may reduce providers' revenues or profits,which could affect their ability to purchase new technologies.Furthermore,the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers.In addition,Congress is considering additional health reform measures.Legislation could be adopted in the future that limits payments for the Company' s products from governmental payors.It is also possible that additional governmental action is taken in response to the COVID- 19 pandemic.Furthermore,commercial payors such as insurance companies,could adopt similar policies that limit reimbursement for medical device manufacturers' products.Therefore,it is possible that SeaStar Medical' s products or the procedures or patient care performed using its products will not be reimbursed at a cost- effective level.The Company faces similar risks relating to adverse changes in reimbursement procedures and policies in other countries where it may market its products.Reimbursement and healthcare payment systems vary significantly among international markets.The Company' s inability to obtain international reimbursement approval,or any adverse changes in the reimbursement policies of foreign payors,could negatively affect its ability to sell its products in foreign markets and have a material adverse effect on its business,results of operations and financial condition.The Company **depends on key personnel and its inability to attract and retain qualified personnel could impede its ability to achieve its business objectives.The Company** ' s success depends on the continuing service of key employees,especially its Chief Executive Officer,Eric Schlorff.The loss of any of these individuals could have a material and adverse effect on the Company' s business,results of operations and financial condition.The Company will also be required to hire and recruit highly skilled managerial,scientific,and administrative personnel to fully implement its business plan and growth strategies.Due to the specialized scientific nature of its business,the Company is highly dependent upon its ability to attract and retain qualified scientific,technical and managerial personnel.Competition for these individuals is intense and the Company may not be able to attract,assimilate or retain additional highly qualified personnel in the future.The Company may not be able to engage the services of qualified personnel at competitive prices or at all,particularly given the risks of employment attributable to its limited financial resources and lack of an established track record.Also,if the Company is required to attract personnel from other parts of the United States or abroad,it may have significant difficulty doing so because of the costs associated with moving personnel to the area.If the Company cannot attract and retain qualified staff and executives,it may be unable to develop its products and achieve regulatory clearance,and its business could fail **.The Company' s products may in the future be subject to product recalls** .The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in their design or manufacture.For the FDA,the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death.Manufacturers may,under their own initiative,recall a product if any material deficiency in a device is found.The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.A government- mandated or voluntary recall could occur as a result of an unacceptable risk to health,component failures,malfunctions,manufacturing errors,design or labeling defects or other deficiencies and issues.Recalls of any of the Company' s products would divert managerial and financial resources and have an adverse effect on the Company' s

reputation,business,results of operations and financial condition,which could impair its ability to produce its products in a cost-effective and timely manner in order to meet its customers' demands.The Company may also be subject to liability claims,be required to bear other costs,or take other actions that may have a negative impact on its future sales and its ability to generate profits.Companies are required to maintain certain records of recalls,even if they are not reportable to the FDA or the competent authority of another country.The Company may initiate voluntary recalls involving its products in the future that it determines do not require notification of the FDA or the competent authority of another country.If the FDA disagrees with the Company' s determinations,they could require the Company to report those actions as recalls.A future recall announcement could harm the Company' s reputation with customers and negatively affect its sales.Moreover,the FDA could take enforcement action for failing to report recalls.The Company is also required to follow detailed recordkeeping requirements for all firm- initiated medical device corrections and removals. **The Company' s business is subject to risks arising from future pandemics.** Worldwide pandemics have presented substantial public health and economic challenges and has affected the Company' s employees,patients,communities,and business operations,as well as the United States and global economy and financial markets.A future pandemic may directly or indirectly impact the timeline for the launch of its SCD product candidate.The Company may experience disruptions that could severely impact its business,clinical trials,and manufacturing and supply chains,including:• further delays or difficulties in enrolling patients in its clinical trials;• delays or difficulties in clinical site initiation,including difficulties in recruiting clinical site investigators and clinical site staff;• the diversion of healthcare resources away from the conduct of clinical trials,including the diversion of hospital staff supporting the conduct of its clinical trials;• the interruption of key clinical trial activities,such as clinical trial site monitoring,due to limitations on travel imposed or recommended by federal or state governments,employers and others or interruption of clinical trial subject visits and study procedures,which may impact the integrity of subject data and clinical study endpoints;• the interruption of,or delays in receiving,supplies of its product candidates from its contract manufacturing organizations due to staffing shortages,production slowdowns or stoppages and disruptions in delivery systems;• delays in clinical sites receiving the supplies and materials needed to conduct its clinical trials and interruptions in global shipping may affect the transport of clinical trial materials;• limitations on employee resources that would otherwise be focused on the conduct of its clinical trials,including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;• delays in receiving feedback or approvals from the FDA or other regulatory authorities with respect to future clinical trials or regulatory submissions;• changes in local regulations as part of a response to a future pandemic,which may require it to change the ways in which its clinical trials are conducted,resulting in unexpected costs,or discontinuing the clinical trials altogether;• delays in necessary interactions with local regulators,ethics committees and other important agencies and contractors due to limitations on employee resources or the forced furlough of government employees;• the refusal of the FDA to accept data from clinical trials in affected geographies;and • difficulties launching or commercializing products,including due to reduced access to doctors as a result of social distancing protocols.In addition,the spread of a future pandemic may negatively impact the Company' s ability to raise additional capital on a timely basis or at all.The extent to which a future pandemic may impact the Company' s business,including its clinical trials,manufacturing and supply chains and financial condition will depend on future developments,which are highly uncertain and cannot be predicted with confidence,such as the continued geographic spread of the disease,the duration of the pandemic,travel restrictions and social distancing in the United States and other countries,continued business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.A small number of the Company' s stockholders,including its major stockholders,the Dow Pension Funds,could significantly influence its business.The Company has a few significant stockholders who own a substantial percentage of its outstanding shares of Common Stock,including Dow Employees' Pension Plan Trust and Union Carbide Employees' Pension Plan Trust.These few significant shareholders,either individually or acting together,may be able to exercise significant influence over matters requiring shareholder approval,including the election of directors and approval of significant corporate transactions,such as a merger or other sale of the Company or its assets.This concentration of ownership may make it more difficult for other shareholders to effect substantial changes in the Company,may have the effect of delaying,preventing or expediting,as the case may be,a change in control of the Company and may adversely affect the market price of the Common Stock.Further,the possibility that one or more of these significant shareholders may sell all or a large portion of their Common Stock in a short period of time could adversely affect the trading price of our Common Stock.The Company' s forecasted operating and financial results rely in large part upon assumptions and analyses developed by the Company.If these assumptions and analyses prove to be incorrect,the Company' s actual operating and financial results may be significantly below its forecasts.The Company has previously provided projected financial and operating information that reflected its estimates of future performance.Whether actual operating and financial results and business developments will be consistent with the Company' s expectations and assumptions as reflected in its forecast depends on a number of factors,many of which are outside the Company' s control,including,but not limited to:• whether the Company can obtain sufficient capital to develop and commercialize its SCD product candidate and grow its business;• whether the Company can manage relationships with key suppliers;• the ability to obtain necessary regulatory approvals;• demand for the Company' s products;• the timing and costs of new and existing marketing and promotional efforts;• competition,including from established and future competitors;• the Company' s ability to retain existing key management,to integrate recent hires and to attract,retain and motivate qualified personnel;• the overall strength and stability of the economies in the markets in which it operates or intends to operate in the future;and • regulatory,legislative and political changes.Unfavorable changes in any of these or other factors,most of which are beyond the Company' s control,could materially and adversely affect its business,results of operations and financial condition.The **Company' s estimates of market opportunity,industry projections and forecasts of market growth may prove to be inaccurate.The** market opportunity estimates and growth forecasts included in this Annual Report,including information concerning the Company' s industry and the markets in which the Company intends to operate,are obtained from

publicly available information released by independent industry and research organizations and other third party sources.Although the Company is responsible for the disclosure provided in this Annual Report and believes such third- party information is reliable,the Company has not independently verified any such third- party information.In addition,projections,assumptions and estimates of the future performance of the industry in which the Company operates are subject to uncertainty and risk due to a variety of factors.As a result,inaccuracies in third- party information,or in the projections,may adversely impact the assumptions that are relied upon for the Company' s internal business planning and in the analysis of investors.Risks Relating to the Company' s Intellectual Property The Company relies upon exclusively licensed patent rights from third parties which are subject to termination or expiration.If licensors terminate the licenses or fail to maintain or enforce the underlying patents,the Company' s competitive position could be materially harmed.The Company relies in part upon exclusively licensed patent rights for the development of its SCD technology.For example,the Company co-owns with,and exclusively licenses from,the University of Michigan patents related to the SCD technology.If UOM were to terminate its license with the Company,it would no longer have exclusive rights to the co- owned patents and UOM would be free to license UOM' s interest in the co- owned patents to a competitor of the Company.The Company may become reliant in the future upon licenses to certain third- party patent rights and proprietary technologies necessary to develop and commercialize its SCD technology or other technologies.If the Company is unable to timely obtain these licenses on commercially reasonable terms,if at all,its ability to commercially exploit such products may be inhibited or prevented.If these licenses do not provide exclusive rights to use the subject intellectual property in all relevant fields of use and all territories in which the Company chooses to develop or commercialize its technology and products,it may not be able to prevent competitors from developing and commercializing competitive products in such territories.Even if the Company is able to obtain necessary licenses,it may be required to pay significant licensing fees in order to market its products.Should any of the Company' s current or future licenses be prematurely terminated for any reason,or if the patents and intellectual property owned by its licensors are challenged or defeated by third parties,the Company' s research and commercialization efforts could be materially and adversely affected.The Company' s licenses may not continue in force for as long as is required to fully develop and market its products.It is possible that if the licenses are terminated or the underlying patents and intellectual property are challenged or defeated,suitable replacements may not be obtained or developed on terms acceptable to the Company,if at all.There is also the related risk that the Company may not be able to make the required payments under any patent license,in which case the licensor may terminate the license.Further,the Company' s licensors may not successfully prosecute the patent applications which it has licensed and on which the Company' s business depends or may prosecute them in a manner not in the best interests of the Company.Further,licensors may fail to maintain licensed patents,may decide not to pursue litigation against third- party infringers,may fail to prove infringement or may fail to defend against counterclaims of patent invalidity or unenforceability.In addition,despite of the Company' s best efforts,a licensor could claim that the Company has materially breached a license agreement and terminate the license,thereby removing the Company' s ability to obtain regulatory approval for and to market any product covered by such license.If the Company' s licenses are terminated,or if the underlying patents fail to provide the intended market exclusivity,competitors would have the freedom to seek regulatory approval of,and to market,identical products.Disputes may arise regarding intellectual property subject to a licensing agreement,including:• the scope of rights granted under the license agreement and other interpretation related issues;• the extent to which the Company' s technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;• the sublicensing of patent and other rights under any collaboration relationships the Company might enter into in the future;• the Company' s diligence obligations under the license agreement and what activities satisfy those diligence obligations;• the ownership of inventions and know how resulting from the joint creation or use of intellectual property by the Company and its licensors;and • the priority of invention of patented technology.If disputes over intellectual property that the Company has licensed prevent or impair its ability to maintain its current licensing arrangements on acceptable terms,it may be unable to successfully develop and commercialize the affected product candidates.If the Company is unable to obtain and maintain sufficient patent protection for its products,if the scope of the patent protection is not sufficiently broad,or if the combination of patents,trade secrets and contractual provisions upon which it relies to protect its intellectual property are inadequate,its competitors could develop and commercialize similar or identical products,and the Company' s ability to commercialize such products successfully may be adversely affected.The Company' s success depends in large part on its ability to protect its proprietary rights to the technologies incorporated into its products,including its ability to obtain and maintain patent protection in the United States and other countries related to its SCD technology and other technologies that it deems important to its business.The Company relies on a combination of patent protection,trade secret laws and nondisclosure,confidentiality,and other contractual restrictions to protect its proprietary technology.If the Company does not adequately protect its intellectual property,competitors may be able to erode or negate any competitive advantage it may have,which could harm its business,result of operations and financial condition.To protect the Company' s proprietary technologies,it has pursued patent protection in the United States and abroad related to its SCD technology and other technologies that are important to its business.The patent application and approval process are expensive and time- consuming.The Company may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.Failure to protect,obtain,maintain,or extend adequate patent and other intellectual property rights could materially adversely affect the Company' s ability to develop and market its products.The enforcement,defense and maintenance of such patents and other intellectual property rights may be challenging and costly.The Company cannot be certain that any patents that it has been issued or granted will not later be found to be invalid and / or unenforceable.The Company cannot be certain that pending patent applications will be issued in a form that provides it with adequate protection to prevent competitors from developing competing products.As a medical device technology company,the Company' s patent position is uncertain because it involves complex legal and factual considerations.The standards applied by United States Patent and Trademark Office (" USPTO "),and foreign patent offices in granting patents are not always applied

uniformly or predictably.For example,there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable as methods of medical treatment.Consequently,patents may not be issued from any applications that are currently pending or that are filed in the future.As such,the Company does not know the degree of future protection that it will have for its technology.As a result,the issuance,scope,validity,enforceability,and commercial value of the Company' s patent rights are highly uncertain.Only issued patents can be enforced against third parties practicing the technology claimed in such patents.Pending patent applications cannot be enforced unless and until patents get issued from such applications.Assuming the other requirements for patentability are met,currently,patents are granted to the party who was the first to file a patent application.However,prior to March 16,2013,in the United States,patents were granted to the party who was the first to invent the claimed subject matter.Publications of discoveries in the scientific literature often lag behind the actual discoveries,and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing,or in some cases not at all.Therefore,the Company cannot be certain that it was the first to make the inventions claimed in its patents or pending patent applications,or that it was the first to file for patent protection of such inventions.Moreover,because the issuance of a patent is not conclusive as to its inventorship,scope,validity or enforceability,the Company patents or pending patent applications may be challenged in the courts or by the USPTO or by foreign patent offices.For example,the Company may be subject to a third- party pre- issuance submission of prior art to the USPTO,or become involved in post- grant review procedures such as oppositions,derivations,reexaminations,inter parties review or interference proceedings,in the United States or elsewhere,challenging its patent rights or the patent rights of third parties.An adverse determination in any such challenges may result in the loss of exclusivity or in patent claims being narrowed,invalidated,or held unenforceable,in whole or in part,which could limit the Company' s ability to stop others from using or commercializing similar products,or limit the duration of the Company' s patent protection.In addition,given the amount of time required for the development,testing and regulatory review of medical devices,the Company' s patents might expire before or shortly after such products receive FDA approval and are commercialized,or before it receives approval to market its products in a foreign country.Patent applications may not result in patents being issued which protect any current and future product candidates,in whole or in part,or which effectively prevent others from commercializing competitive products.Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the Company' s patents or narrow the scope of its patent protection.In addition,the laws of foreign countries may not protect the Company' s rights to the same extent or in the same manner as the laws of the United States.For example,European patent law restricts the patentability of methods of treatment of the human body more than United States patent law.Although the Company believes that certain of its patents and applications,if they are granted,will help protect the proprietary nature of its SCD technology,this protection may not be sufficient to protect the Company during the development of that technology.Even if the Company' s patent applications are issued as patents,they may not be issued in a form that will provide it with any meaningful protection,prevent competitors from competing with it or otherwise provide it with any competitive advantage.The Company' s competitors may be able to circumvent its patents by developing similar or alternative technologies or products in a non- infringing manner.The Company' s competitors may also seek approval to market their own products similar to or otherwise competitive with any of the Company' s products.Thus,even if the Company has valid and enforceable patents,these patents still may not provide protection against competing products or technologies sufficient to achieve its business objectives.If the Company does not obtain protection under the Hatch- Waxman Act and similar non- United States legislation for extending the term of patents covering its products,its business,results of operations and financial condition may be materially harmed.Patents have a limited duration.In the United States,if all maintenance fees are timely paid,the natural expiration of a patent is generally 20 years from its earliest United States non- provisional filing date.Various extensions may be available,but the life of a patent,and the protection it affords,is limited.Even if patents related to the Company' s products,or their uses are obtained,once the patent life has expired,the Company may be open to competition from competitive products.Given the amount of time required for the development,testing and regulatory review of new product candidates,patents protecting the Company' s products might expire before or shortly after such products ~~receive~~ **received** FDA approval and are commercialized.As a result,the Company' s patent portfolio may not provide the company with sufficient rights to exclude others from commercializing similar or identical products.Depending upon the timing,duration and requirements of FDA marketing approval of the Company' s product candidates,its United States patents,if issued,may be eligible for a limited patent term extension under the Hatch- Waxman Act,or under similar legislation in other countries.However,the Company' s patent and patent applications are only eligible for a patent term extension under the Hatch Waxman Act if they relate to a medical device classified by the FDA as a Class III device.Therefore,if the Company' s product candidates are not classified as Class III devices,it will not be able to apply for an extension of term for any patents covering such approved products.If eligible,the Hatch- Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process.The patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product candidate approval,and only one patent related to an approved product candidate may be extended.However,the Company may not receive an extension if it fails to apply within applicable deadlines,fails to apply prior to expiration of relevant patents or otherwise fails to satisfy applicable requirements.Moreover,the length of the extension could be less than requested.Accordingly,if the Company is unable to obtain a patent term extension or the term of any such extension is less than requested,the period during which the Company can enforce its patent rights for that product will be shortened and competitors may obtain approval to market competing products sooner than expected.As a result,the Company' s business,results of operations and financial condition could be adversely and materially affected.The Company could become involved in intellectual property litigation that could be costly,result in the diversion of management' s time and efforts,require the Company to pay damages,prevent it from selling its commercially available products and / or reduce the margins it may realize from its products.The Company' s commercial success depends,in part,on its ability to develop and market its SCD

technology,as well as any future technologies that it develops,without infringing the intellectual property and other proprietary rights of third parties.The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights.Whether a product infringes a patent involves complex legal and factual issues,and the determination is often uncertain.There may be existing patents of which the Company is unaware that its products under development may inadvertently infringe.The likelihood that patent infringement claims may be brought against the Company increases as the number of competitors increases,as it introduces new products and achieves more visibility in the marketplace.Any infringement claim against the Company,even if without merit,may cause the Company to incur substantial costs,and would place a significant strain on its financial resources,divert the attention of management from its core business,and harm its reputation.In some cases,litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom the Company' s patents may provide little or no deterrence.If the Company is found to infringe any patents,the Company could be required to pay substantial damages,including triple damages if an infringement is found to be willful.The Company also could be forced,including by court order,to cease developing,manufacturing,or commercializing infringing products.The Company also could be required to pay royalties and could be prevented from selling its products unless it obtains a license or is able to redesign its products to avoid infringement.The Company may not be able to obtain a license enabling it to sell its products on reasonable terms,or at all.If the Company fails to obtain any required licenses or makes any necessary changes to its technologies or the products,the Company may be unable to commercialize one or more of its products or may have to withdraw products from the market,either of which would have a material adverse effect on its business,results of operations and financial condition.In the event a competitor infringes upon any of the Company' s patents or other intellectual property rights,enforcing its rights may be difficult,time consuming and expensive,and would divert management' s attention from managing its business.The Company may not be successful on the merits in any enforcement effort.In addition,the Company may not have sufficient resources to litigate,enforce or defend its intellectual property rights. **Issued patents covering one or more of the Company' s products could be found invalid or unenforceable if challenged in patent office proceedings,or in court.** Competitors may infringe the Company' s patents,trademarks,or other intellectual property.To counter infringement or unauthorized use of its intellectual property,the Company may be required to initiate legal proceedings against a third party to enforce its intellectual property rights.If the Company were to file a claim against a third party to enforce a patent covering one of its products,the defendant could counterclaim that the Company' s patent rights are invalid and / or unenforceable (a common practice in the United States).Grounds for a validity challenge could be an alleged failure to meet one or more statutory requirements for patentability,including,for example,lack of novelty,obviousness,lack of written description or non- enablement.In addition,patent validity challenges may,under certain circumstances,be based upon non- statutory obviousness- type double patenting,which,if successful,could result in a finding that the claims are invalid for obviousness- type double patenting or the loss of patent term,including a patent term adjustment granted by the USPTO,if a terminal disclaimer is filed to obviate a finding of obviousness- type double patenting.Grounds for an unenforceability assertion could be based on an allegation that someone connected with prosecution of the patent intentionally withheld relevant information from the USPTO or made a misleading statement,during prosecution.In any patent infringement proceeding,there is a risk that a court will decide that a Company patent is invalid or unenforceable,in whole or in part.There is also a risk that,even if the validity of such patents is upheld,the court will construe the patent' s claims narrowly or decide that the Company does not have the right to stop the other party from using the invention at issue on the grounds that the Company' s patent claims do not cover the invention at issue.An adverse outcome in a litigation or proceeding involving the Company' s patents could limit its ability to assert its patents against those other parties and other competitors,which may curtail or preclude its ability to exclude third parties from selling similar products.Any of these occurrences could adversely and materially affect the Company' s business,results of operations and financial condition.Even if the Company establishes infringement,the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages,which may or may not be an adequate remedy.Furthermore,because of the substantial amount of discovery required in connection with intellectual property litigation,there is a risk that some of the Company' s confidential information could be compromised by disclosure during litigation.Additionally,third parties are able to challenge the validity of issued patents through administrative proceedings in the patent offices of certain countries,including the USPTO and the European Patent Office.Although the Company believes that it has conducted its patent prosecution in accordance with the duty of candor and in good faith,the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable.With respect to the validity question,for example,the Company cannot be certain that there is no invalidating prior art,of which it and the patent examiner were unaware during prosecution.If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability,the Company would lose some or all of the patent protection for one or more of its products.Such a loss of patent protection could have a material adverse impact on its business,results of operations and financial condition.Further,intellectual property litigation could lead to unfavorable publicity that could harm the Company' s reputation.Other parties may challenge certain of the Company' s foreign patent applications.If any such parties are successful in opposing its foreign patent applications,the Company may not gain the protection afforded by those patent applications in particular jurisdictions and may face additional proceedings with respect to similar patents in other jurisdictions,as well as related patents.The loss of patent protection in one jurisdiction may influence the Company' s ability to maintain patent protection for the same technology in other jurisdictions. ~~In addition,the European Unified Patent Court,or the UPC,came into force during 2023.The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union.Although we have decided,and may continue to decide,to opt out certain of our European patents and patent applications from the UPC,if certain formalities and requirements are not met,then our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC.Thus,we cannot be certain that our European patents and patent applications will avoid falling under the~~

~~jurisdiction of the UPC.This could enable third parties to seek revocation of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated.Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products.Moreover,the controlling laws and regulations of the UPC will develop over time,and may adversely affect our ability to enforce or defend the validity of our European patents.~~ Further,disputes may arise regarding the ownership or inventorship of the Company' s patents.While the Company has entered into assignment of intellectual property agreements with its employees,consultants,and collaborators and believes that it owns its patents and applications,the assignment and other ownership agreements that it relies on could be challenged.If a court or administrative body determined that the Company' s does not own certain of its patents or patent applications,or that inventorship of certain of its patents its incorrect,the Company' s title to its patents could be invalidated and its ability to develop and commercialize its technology could be materially **harmed.If the Company is unable to protect the confidentiality of its trade secrets,the value of its technology could be adversely and materially affected,and its business could be** harmed.The Company has also entered into non- disclosure and confidentiality agreements with all of its employees,advisors,consultants,contract manufacturers,clinical investigators and other third parties involved in the development and commercialization of its technology in order to protect its intellectual property and other proprietary technologies some of which may not be amenable to patent protection.However,these agreements may not be enforceable or may not provide meaningful protection for the Company' s trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.For example,trade secrets and confidential know- how can be difficult to maintain as confidential.Although the Company uses reasonable efforts to protect its trade secrets,any party with whom it has executed a confidentiality agreement could breach that agreement and disclose the Company' s confidential information.Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult,expensive,and time consuming,and the outcome is unpredictable.Accordingly,the Company may not be able to obtain adequate remedies for such breaches,despite any legal action it might take against persons making such unauthorized disclosure.In addition,courts outside the United States sometimes are less willing than in the United States to protect trade secrets.If any of the Company' s trade secrets were to be lawfully obtained or independently developed by a competitor,it would have no right to prevent such third party,or those to whom the third party communicates such technology or information,from using that technology or information to compete with the Company.If any of its trade secrets were to be disclosed to or independently developed by a competitor,its business,results of operations and financial condition.Those with whom the Company collaborates on research and development related to current and future technologies and products may have rights to publish data and other information to which the Company has rights.In addition,the Company sometimes engages individuals or entities to conduct research relevant to its business.The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations.But these contractual provisions may be insufficient or inadequate to protect the Company' s confidential information.If the Company does not apply for patent protection prior to such publication,or if it cannot otherwise maintain the confidentiality of its proprietary technology and other confidential information,then its ability to obtain patent protection or to protect its trade secret information may be jeopardized.New technology may lead to the Company' s competitors developing superior products which would reduce demand for its products regardless of any patent protection it may have.Research into technologies similar to the Company' s technologies is proceeding at a rapid pace,and companies and research institutions are actively engaged in the development of products similar to the Company' s products.These new technologies may,if successfully developed,offer significant performance or price advantages when compared with the Company' s technologies.The Company' s existing patents or its pending and proposed patent applications may not offer meaningful protection if a competitor develops a novel product based on a new technology.The United States government may exercise certain rights with regard to the Company' s inventions,or licensors' inventions,developed using federal government funding.The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (as amended,the " Bayh- Dole Act ").Certain of the Company' s exclusively owned patents and patent applications and those patents and applications that it co- owns with and exclusively licenses from the University of Michigan were developed using federal funding from the National Institutes of Health,the U.S.Department of Defense,and / or the U.S.Army Medical Research and Materiel Command.Consequently,pursuant to the Bayh- Dole Act,the U.S.government has certain rights in patents and applications that cover SeaStar Medical' s SCD technology,in particular,to those patents and applications identified in the section of this Annual Report titled " Business – Intellectual Property " belonging to Patent Families 1- 4.The U.S.federal government has certain rights,including so- called " march- in rights," to any patent rights that were funded in part by the U.S.government and any products or technology developed from such patent rights.When new technologies are developed with U.S.government funding,the U.S.government generally obtains certain rights in any resulting patents,including a non- exclusive license authorizing the U.S.government to use the invention for non- commercial purposes.These rights may permit the U.S.government to disclose the Company' s confidential information to third parties and to exercise march- in rights to use or to allow third parties to use the Company' s licensed patents,including certain patents relating to SCD product candidates.The U.S.government can exercise its march- in rights if it determines that action is necessary because the Company fails to achieve the practical application of government- funded technology,because action is necessary to alleviate health or safety needs,to meet requirements of federal regulations,or to give preference to U.S.industry.In addition,the Company' s rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States.Furthermore,the U.S.government may have the right to take title to government- funded inventions if the Company fails to disclose the inventions to the government in a timely manner or fails to file a patent application within specified time limits.If the U.S.government exercises such march- in rights,the Company may not be able to develop or commercialize its product candidates effectively or profitably,or at all,which could harm the Company' s business,results of operations and financial

condition.In addition,if any intellectual property owned or licensed by the Company becomes subject to any of the rights or remedies available to the U.S.government or third parties pursuant to the Bayh- Dole Act,this could impair the value of the Company' s intellectual property and could adversely affect its business.The Company also sometimes collaborates with academic institutions to accelerate its research or development.While the Company tries to avoid engaging its academic partners in projects in which there is a risk that federal funds may be co- mingled,it cannot be sure that any co- developed intellectual property will be free from government rights pursuant to the Bayh- Dole Act.If,in the future,the Company co- owns or licenses technology which is critical to its business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act,its ability to enforce or otherwise exploit patents covering such technology may be adversely and materially affected.Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general,thereby impairing the Company' s ability to protect its products.As is the case with other medical device companies,the Company' s success is heavily dependent on intellectual property,particularly patents.Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity and is therefore costly,time consuming and inherently uncertain.Patent reform legislation in the United States and other countries,including the Leahy- Smith America Invents Act,or the Leahy- Smith Act,signed into law in September 2011,could increase those uncertainties and costs.The Leahy- Smith Act included a number of significant changes to United States patent law.These include provisions that affect the way patent applications are prosecuted,redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents,such as through post grant and inter parties review proceedings at the USPTO.In addition,the Leahy- Smith Act transformed the United States patent system into a " first to file " system effective March 2013.The Leahy- Smith Act and its implementation could make it more difficult for the Company to obtain patent protection for its inventions and increases the uncertainties and costs surrounding the prosecution of the Company' s patent applications and the enforcement or defense of its issued patents,all of which could harm its business,results of operations and financial condition.The United States Supreme Court has ruled on several patent cases,either narrowing the scope of patent protection available or weakening the rights of patent owners in certain circumstances.Additionally,there have been proposals for additional changes to the patent laws of the United States and other countries that,if adopted,could impact the Company' s ability to enforce its proprietary technology.Depending on future actions by Congress,the United States courts,the USPTO and the relevant law- making bodies in other countries,the laws and regulations governing patents could change in ways that would weaken the Company' s ability to obtain new patents or to enforce its existing and future patents. **Intellectual property rights do not necessarily address all potential threats to the Company' s competitive advantage.** The degree of future protection afforded by the Company' s intellectual property rights is uncertain because intellectual property rights have limitations,and may not adequately protect its business,or permit it to maintain its competitive advantage.The following examples are illustrative:• others may be able to make products that are the same as or similar to the Company' s products but that are not covered by the claims of patents that it owns or has rights to;• the Company or its licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by its patents or pending patent applications;• the Company or its licensors or any future strategic partners might not have been the first to file patent applications covering the inventions in the Company' s patents or applications;• others may independently develop similar or alternative technologies or duplicate any of the Company' s technologies without infringing the Company' s intellectual property rights;• the Company' s pending patent rights may not lead to issued patents,or the patents,if granted,may not provide it with any competitive advantage,or may be held invalid or unenforceable,as a result of legal challenges by its competitors;• the Company' s competitors might conduct research and development activities in countries where it does not have patent rights and then use the information learned from such activities to develop competitive products for sale in the Company' s major commercial markets;• third parties manufacturing or testing the Company' s products or technologies could use the intellectual property of others without obtaining a proper license;• the Company may not develop additional technologies that are patentable;and • third parties may allege that the Company' s development and commercialization of its products infringe their intellectual property rights,the outcome of any related litigation may have an adverse effect on the Company' s business,result of operations and financial condition.Obtaining and maintaining the Company' s patent protection depends on compliance with various procedural,document submissions,fee payment and other requirements imposed by governmental patent agencies,and its patent protection could be reduced or eliminated for noncompliance with these requirements.Periodic maintenance fees on any issued patent are owed to the USPTO and foreign patent agencies in several stages over the lifetime of the patent.The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural,documentary,fee payment and other similar provisions during the patent application process.While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules,there are situations in which noncompliance can result in abandonment or the lapse of a patent or patent application,resulting in the partial or complete loss of patent rights in the relevant jurisdiction.Noncompliance events that could result in abandonment or lapse of a patent or patent application include,but are not limited to,failure to respond to official actions within prescribed time limits,non- payment of fees and failure to properly legalize and submit formal documents.If the Company or its licensors fail to maintain the patents and patent applications covering the Company' s products,its competitive position would be adversely affected.The Company may obtain only limited geographical protection with respect to certain patent rights,which may diminish the value of its intellectual property rights in those jurisdictions and prevent it from enforcing its intellectual property rights throughout the world.Filing,prosecuting,and defending patents on product candidates in all countries throughout the world would be prohibitively expensive.Accordingly,the Company has not and in the future may not file for patent protection in all national and regional jurisdictions where such protection may be available.In addition,it may decide to abandon national and regional patent applications before grant,or to not pay maintenance fees on granted patents in certain jurisdictions.Finally,the grant proceeding of each national / regional patent office is an independent proceeding that may lead to situations in which applications in some jurisdictions are refused by the relevant patent

offices,while other applications are granted.It is also quite common that depending on the country,the scope of patent protection may vary for the same product candidate or technology.Competitors may use the Company' s technologies to develop their own products in jurisdictions where the Company has not obtained patent protection and,further,may export otherwise infringing products to territories where the Company has patent protection,but where patent enforcement is not as strong as that in the United States.These products may also compete with the Company' s products in jurisdictions where it does not have any issued or licensed patents or where the Company' s patent or other intellectual property rights are not effective or sufficient to prevent these products from competing with the Company.Additionally,some countries do not afford intellectual property protection to the same extent as the laws of the United States and Europe.Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions.The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights.This could make it difficult for the Company to stop the infringement of its patents or the misappropriation of its other intellectual property rights in these countries.For example,many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.In these countries,the patent owner may have limited remedies,which could materially diminish the value of such patent.If the Company or any of its licensors is forced to grant a license to third parties with respect to any patents relevant to its business,its competitive position may be impaired and its business,results of operations and financial condition may be adversely affected.Consequently,the Company may not be able to prevent third parties from practicing its inventions in certain countries outside the United States and Europe.Competitors may use the Company' s technologies to develop their own products in jurisdictions where the Company has not obtained patent protection.Furthermore,they may export otherwise infringing products to jurisdictions where the Company has patent protection,if the Company' s ability to enforce its patents to stop the infringing activities in those jurisdictions is inadequate.Proceedings to enforce the Company' s patent rights in foreign jurisdictions,whether or not successful,could result in substantial costs and divert its efforts and resources from other aspects of its business.Furthermore,while the Company intends to protect its intellectual property rights in major markets for its products,it may not be able to initiate or maintain similar efforts in all jurisdictions in which it wishes to market its products.Accordingly,the Company' s efforts to protect its intellectual property rights in such countries may be inadequate.Risks Related to Being a Public Company The Company does not have long- term experience operating as a United States public company and may not be able to adequately implement the governance,compliance,risk management and control infrastructure and culture required for a public company,including compliance with the Sarbanes Oxley Act.The Company is building experience operating as a United States public company,of which,the Company' s executive officers have limited experience in managing a United States public company,which makes their ability to comply with applicable laws,rules,and regulations uncertain.The Company' s failure to comply with all laws,rules and regulations applicable to United States public companies could subject the Company and its management to regulatory scrutiny or sanction,which could harm its reputation and share price. **Prior to the completion of the Business Combination in October 2022,the Company has not previously been required to establish and maintain the disclosure controls and procedures,and internal controls over financial reporting applicable to a public company in the United States,including the Sarbanes- Oxley Act.** Although the Company is developing and implementing governance,compliance,risk management and control framework and culture required for a public company,the Company may not be able to meet the requisite standards expected by the SEC and / or its investors.The Company may also encounter errors,mistakes,and lapses in processes and controls resulting in failures to meet the requisite standards expected of a public company.As a United States public reporting company,the Company incurs significant legal,accounting,insurance,compliance,and other expenses.The Company cannot predict or estimate the amount of additional costs it may incur or the timing of such costs.Compliance with reporting,internal control over financial reporting and corporate governance obligations may require members of its management and its finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled.If it fails to adequately implement the required governance and control framework,the Company could be at greater risk of failing to comply with the rules or requirements associated with being a public company.Such failure could result in the loss of investor confidence,could harm the Company' s reputation,and cause the market price of the Company' s securities to decline.Other challenges in complying with these regulatory requirements may arise because the Company may not be able to complete its evaluation of compliance and any required remediation in a timely fashion.Furthermore,any current or future controls may be considered as inadequate due to changes or increased complexity in regulations,the Company' s operating environment or other reasons.Due to inadequate governance and internal control policies,misstatements,or omissions due to error or fraud may occur and may not be detected,which could result in failures to make required filings in a timely manner and make filings containing incorrect or misleading information.Any of these outcomes could result in SEC enforcement actions,monetary fines,or other penalties,as well as damage to the Company' s reputation,business,financial condition,operating results and share price. **The Company** ~~Our Common Stock~~ may **not** be ~~delisted from~~ **able to consistently comply with all of** Nasdaq ~~if we do~~ **' s Listing Rules.As a public company,the Company is subject to Nasdaq listing rules.If it fails to meet the requirements of the applicable listing rules,such failure may result in the Company** not ~~maintain compliance with~~ **being listed by** Nasdaq ~~' s continued~~ **,a suspension of the trading of its shares,or** ~~listing~~ **delisting** ~~requirements~~ **in the future** . ~~If~~ **This may further result in legal** ~~our~~ - **or regulatory proceedings** ~~Common Stock is delisted~~ , ~~it could~~ **fines and other penalties,legal liability for the Company,the inability for the Company' s stockholders to trade their shares and** negatively impact the Company **' s share price** ~~.Continued listing of a security on Nasdaq is conditioned upon compliance with various continued listing standards.There can be no assurance that we will be able to comply with the applicable listing standards.On June 14~~ , ~~2023~~ **reputation** , **operations** ~~we received a letter from the Listing Qualifications Department of Nasdaq notifying us that the Market Value of Listed Securities (" MVLS ") of our Common Stock had been below the minimum $ 35~~ , ~~000~~ **and financial position** , ~~000 required for continued listing~~ as ~~set forth in Nasdaq Listing Rule 5550 (b) (2) (the " MVLS Requirement ").The letter also stated~~

~~that we would be provided 180 calendar days,or until December 11,2023,to regain compliance with the MVLS Requirement.On December 13,2023,we received a notification from the Listing Qualification Department of Nasdaq that we had not regain compliance with the MVLS Requirement and that our Common Stock would be subject to delisting unless we timely request a hearing before a Nasdaq Hearing Panel (the " Panel ").On December 19,2023,we submitted a hearing request to the Panel to appeal the delisting determination.On the same date,we received a notice from Nasdaq stating that its delisting action had been stayed pending a final written decision by the Panel and that a hearing would be held on March 12,2024.On February 6,2024,we received notification from Nasdaq that we had regained compliance with the MVLS Requirement.On June 26,2023,we received a letter from the Listing Qualifications Department of Nasdaq notifying us that the Company was not in compliance with the $ 1.00 per share minimum requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 555 (a) (2) (the " Bid Price Requirement ").This letter had no immediate effect on the listing of the Company' s Common Stock on Nasdaq and the Company had 180 calendar days from the date of the notice,or until December 26,2023,to regain compliance with the Bid Price Requirement.On December 27,2023,we received notification from Nasdaq that the Company had not regained compliance with the Bid Price Requirement and that the Panel will~~ **well** ~~consider this matter in rendering a determination regarding the Company' s continued listing on The Nasdaq Capital Market.Pursuant to Listing Rule 5810 (d),the Company should present its views with respect to this deficiency at its Panel hearing to be held on March 12,2024.If we fail to address the aforementioned issue,the Panel will consider the record~~ as ~~presented at the hearing and will make its determination based upon that information.There is~~ **its** ~~no guarantee that the Panel will render a favorable decision to permit the continuing list of our Common Stock,and failure to obtain such favorable decision will result in the delisting of our Common Stock,which will have a material adverse effect on our business operations and financial conditions.If the Company' s Common Stock ultimately were to be delisted for any reason,it could negatively impact the Company by (i) reducing the liquidity and market price of the Company' s Common Stock;(ii) reducing the number of investors willing to hold or acquire the Company' s Common Stock,which could negatively impact the Company' s~~ ability to **conduct future fundraising activities** ~~raise equity financing; (iii) limiting the Company' s ability to use a registration statement to offer and sell freely tradable securities,thereby preventing the Company from accessing the public capital markets;and (iv) impairing the Company' s ability to provide equity incentives to its employees~~ . ~~The Company~~ **SeaStar Medical** identified a material weakness in its internal control over financial reporting.If the Company is unable to develop and maintain an effective system of internal controls over financial reporting,the Company may not be able to accurately report its financial results in a timely manner,which may materially and adversely affect the Company' s business,results of operations and financial condition.The Company' s management is responsible for establishing and maintaining adequate internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S.GAAP.The Company' s management also evaluates the effectiveness of its internal controls,and the Company discloses any changes and material weaknesses identified through such evaluation of its internal controls.A material weakness is a deficiency,or a combination of deficiencies,in the internal controls over financial reporting,such that there is a reasonable possibility that a material misstatement of the Company' s annual or interim consolidated financial statements will not be prevented or detected on a timely basis.In the course of preparing the consolidated financial statements that are included in this Annual Report,SeaStar Medical has identified material weaknesses in its internal controls over financial reporting as of December 31, ~~2023 and~~ 2022,which relates to a deficiency in the design and operation of its financial accounting and reporting controls.Specifically,the material ~~weaknesses~~ -- **weakness** resulted from ~~(i)~~ a lack of segregation of duties within the financial accounting and reporting processes,including the absence of an independent review and approval process in recording transactions to the consolidated financial statements,disbursement and payroll systems ~~.and (ii) a lack of resources with the knowledge and experience to identify,analyze and conclude on the accounting for complex financial instruments in accordance with US GAAP~~ .While the Company intends to implement measures to remediate the material weakness including hiring additional **accounting staff with requisite experiences and skills,there is no guarantee that it can be remediated in a timely fashion or at all.The Company' s failure to correct this material weakness could result in inaccurate consolidated financial statements and could also impair its ability to comply with the applicable financial reporting requirements on a timely basis.These compliance issues could cause investors to lose confidence in the Company' s reported financial information and may result in volatility in and a decline in the market price of the Company' s securities.As discuss in Item 9A below,the Company was unable,without incurring unreasonable effort or expense,to conduct an assessment of our internal control over financial reporting as of December 31,2022.Accordingly,the Company is excluding management' s report on internal control over financial reporting pursuant to Section 215.02 of the SEC Division of Corporation Finance' s Regulation S- K Compliance & Disclosure Interpretations.While the Company is currently taking steps to develop and enhance its internal control process the Company' s management may conclude that its internal control over financial reporting is not effective,or the level at which the Company' s controls are documented,designed,or reviewed is not adequate,and may result in the Company' s independent registered public accounting firm issuing a report that is qualified.In addition,the reporting obligations may place a significant strain on the Company' s management,operational and financial resources and systems for the foreseeable future.The Company may be unable to complete its evaluation testing and any required remediation in a timely manner.During the course of documenting and testing the Company' s internal control procedures,in order to satisfy the requirements of Section 404,the Company may subsequently identify deficiencies in its internal control over financial reporting.Moreover,if the Company fails to maintain the adequacy of its internal control over financial reporting,as these standards are modified,supplemented,or amended from time to time,it may not be able to conclude on an ongoing basis that it has effective internal control over financial reporting in accordance with Section 404.If the Company fails to achieve and maintain an effective internal controls environment,it could result in material misstatements in its consolidated financial**

statements and a failure to meet its reporting obligations,which may cause investors to lose confidence in its reported financial information.This could in turn limit the Company' s access to capital markets and harm its results of operations.The Company may also be required to restate its consolidated financial statements from prior periods if such deficiencies are identified.Additionally,ineffective internal control over financial reporting could expose it to increased risk of fraud or misuse of corporate assets and subject it to potential delisting from Nasdaq,regulatory investigations and civil or criminal sanctions.All of these consequences could adversely impact the Company' s reputation,business,results of operations,financial condition and share price.The Company may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you,thereby making your warrants worthless.The Company has the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration,at a price of $ 0.01 per warrant,provided that the last reported sales price of our Common Stock equals or exceeds $ 18.00 per share (as adjusted for stock splits,stock dividends,reorganizations,recapitalizations and the like) for any 20 trading days within a 30 trading- day period ending on the third trading day prior to the date on which we give proper notice of such redemption and provided certain other conditions are met.If and when the warrants become redeemable by us,we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws.Redemption of the outstanding warrants could force you (i) to exercise your warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so,(ii) to sell your warrants at the then- current market price when you might otherwise wish to hold your warrants or (iii) to accept the nominal redemption price which,at the time the outstanding warrants are called for redemption,is likely to be substantially less than the market value of your warrants.None of the private placement warrants will be redeemable by us so long as they are held by the Sponsor or its permitted transferees Our management team has limited experience operating a public company. Most members of our management team have limited experience operating a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day- to- day management of our business, which could adversely affect our business, results of operations, cash flows and financial condition. ~~56~~ **Risks Related to Ownership of Our Common Stock 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. The trading market for our Common Stock is impacted by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgraded our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline. Future sales of a substantial number of shares of our Common Stock, or the perception that such sales will occur, could cause a decline in the market price of our Common Stock. This is particularly true if we sell our stock at a discount. If our stockholders sell substantial amounts of Common Stock in the public market, or the market perceives that such sales may occur, the market price of our Common Stock and our ability to raise capital through an issue of equity securities in the future could be adversely affected. In addition, in the future, we may issue additional shares of Common Stock or other equity or debt securities convertible into Common Stock in connection with financing, acquisition, litigation settlement, employee arrangements or otherwise. Any**

such issuance could result in substantial dilution to our existing stockholders and could cause the market price of our Common Stock to decline. We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our Common Stock. We have never paid cash dividends on our Common Stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our Common Stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors (the " Board ") may consider relevant. Further, the agreements governing our indebtedness limit our ability to make dividends on our Common Stock. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if our stock price appreciates. We are an " emerging growth company " as that term is used in the Jumpstart Our Business Startups Act of 2012 (the " JOBS Act "), and we intend to continue to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our Common Stock being less attractive to investors and adversely affect the market price of our Common Stock or make it more difficult to raise capital as and when we need it. We are an " emerging growth company " as that term is used in the Jumpstart Our Business Startups Act of 2012 (the " JOBS Act "), and we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved, and exemptions from any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor' s report on the financial statements. We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us under the JOBS Act and intend to continue to do so if we qualify as an " emerging growth company. " For example, so long as we qualify as an " emerging growth company, " we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would have otherwise been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate us. We cannot predict if investors will find our Common Stock less attractive because we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years. Because of the exemptions from various reporting requirements provided to us as an " emerging growth company, " we may be less attractive to investors, and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our business, results of operations, financial condition and cash flows, and prospects may be materially and adversely affected. 62