Risk Factors Comparison 2024-02-22 to 2023-02-23 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Business Operations We have experienced significant losses, expect losses to continue for the foreseeable future and may never achieve or maintain profitability. Although we have begun full scale marketing and sales of our RECELL ® System in the United States and other jurisdictions, ~~such sales have been limited to date and~~ we have not yet ~~obtained~~ **achieved** profitability. We had a total net loss of $ **35. 4 million and $** 26. 7 million ~~and $ 25. 1 million~~ for the year ~~-~~ ended December 31, ~~2022~~ **2023** and ~~the year- ended~~ December 31, ~~2021~~ **2022** , respectively. We have incurred a cumulative deficit of $ ~~262~~ **298** . ~~6~~ **0** million through December 31, ~~2022~~ **2023** . We anticipate that we may continue to incur losses at least until U. S. sales of the RECELL System are adequate to fund operating expenses. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure, including in new markets for which we are not presently approved. **Servicing our debt requires a significant amount of cash and we are subject to a number of restrictive covenants relating to our indebtedness, which may restrict our business and financing activities. Pursuant to the Credit Agreement that the Company entered with OrbiMed Advisors, LLC (" Credit Agreement") on October 18, 2023, we incurred $ 40. 0 million of indebtedness secured by substantially all of our assets and have the ability to incur an additional $ 50. 0 million of indebtedness. This level of debt could have significant consequences on future operations, including increasing our vulnerability to adverse economic and industry conditions and limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete. Our ability to make scheduled payments of interest depends on our future performance, which is subject to interest rate risk, economic, financial, competitive and other factors beyond our control. We are exposed to risks related to a potential rising interest rate environment for the debt, which could cause our borrowing costs to rise and impact our liquidity. Our business may not generate cash flow from operations in the future sufficient to service our debt in cash and make necessary capital expenditures. In addition, if the Company' s net revenue does not equal or exceed a certain amount for upcoming fiscal periods as set forth in the Credit Agreement, then the Company will be required to repay five percent of the outstanding principal amount of its indebtedness in equal quarterly installments, in addition to a repayment fee and a prepayment fee. If we are unable to generate sufficient cash flow to satisfy payment obligations under the Credit Agreement, we may be required to adopt one or more alternatives, such as obtaining additional equity capital on terms that may be onerous or highly dilutive. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. The restrictions and covenants in the Credit Agreement may also prevent us from taking actions that we believe would be in the best interests of our business, and may make it difficult for us to successfully execute our business strategy or effectively compete with companies that are not similarly restricted. Our ability to comply with these covenants in future periods will largely depend on the success of our products, and our ability to successfully implement our overall business strategy. We may be unsuccessful in obtaining waivers or amendments to restrictions and covenants in the agreements. The breach of any of these covenants and restrictions could result in a default under the Credit Agreement, which could result in an acceleration of the repayment of our indebtedness.** Provisions in our U. S. government contracts ~~, including our contracts with BARDA~~ , may affect our intellectual property rights. Certain of our activities have been funded, and may in the future be funded, by the U. S. government, including through ~~our~~ **previous** contracts with BARDA. When new technologies are developed with U. S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention and rights that may permit the government to disclose our confidential information to third parties and to exercise " march- in " rights. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the U. S. 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, U. S. government- funded inventions must be reported to the government, U. S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States. Development and commercialization of our products require successful completion of the regulatory approval process and may suffer delays or fail. We may be unsuccessful in obtaining additional approvals for our RECELL System for ~~soft tissue repair~~ **full thickness skin defects** and skin conditions such as vitiligo. In the United States, as well as other jurisdictions, we have been and will be required to apply for and receive regulatory authorization before we can market our products. ~~Although~~ **For instance,** our RECELL System has been approved **by the FDA and regulatory authorities in Australia, the EU and Japan** for use in ~~the~~ **certain** ~~treatment~~ **treatments** ~~of acute partial- thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full- thickness thermal burn wounds in pediatric and adult patients in the United States, we are looking to expand the indications of the product for use in soft tissue repair and vitiligo. In December 2022, the company submitted a PMA supplement to expand the use of RECELL for soft tissue repair and an original PMA application for the use of RECELL for treatment of vitiligo. While clinical trials for such uses are nearing completion, there can be no assurance that we will be successful in those clinical trials or ever receive approval by the FDA for the use of our RECELL System for such additional applications. Such a failure of approval would have a material negative effect on our future prospects. In Australia, the RECELL System is approved to use for the treatment~~ of burns, acute wounds, scars and vitiligo. **However** ~~In the EU the product has been approved for the treatment of burns~~ , **we** ~~chronic wounds, scars and vitiligo.~~

~~We worked with COSMOTEC to advance our application for approval of the RECELL System in Japan pursuant to Japan' s Pharmaceuticals and Medical Devices Act (" PMDA "). In February 2022, our application for regulatory approval was approved by the PMDA for both adult and pediatric burns. We~~ will require additional clinical data or approvals from regulatory authorities within these countries to market the product for the treatment of other indications, and from any other jurisdictions in which we seek to market the product. This process can be time ~~-~~ consuming and complicated and may be unsuccessful or otherwise result in unanticipated delays or fail altogether **. For example, on September 29, 2023, the Company received notice from the FDA that additional information regarding the Company' s PMA supplement for its latest device, RECELL GO is required for the continuation of the FDA' s review. This request, which is not unique to the Breakthrough Device Program, placed the application file on hold for approximately 4 to 6 months while the Company addresses the FDA' s questions** . To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting preclinical and clinical safety and effectiveness as well as detailed information on the manufacturing and control of the product, proposed labeling and other additional information. Before marketing authorization is granted, regulatory authorities may require the inspection of the manufacturing facility or facilities and quality systems (including those of third parties) at which the product candidate is manufactured and tested, as well as potential audits of the non- clinical and clinical trial sites that generated the data cited in the marketing authorization application. We cannot predict whether any additional marketing authorizations will ultimately be granted or how long the applicable regulatory authority or agency will take to do so. Regulatory agencies, including the FDA, have substantial discretion in the approval process. In addition, the approval process and the requirements governing clinical trials vary from country to country. The policies of the FDA or other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay the necessary approval of any products we may develop and commercialize. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are slow or unable to adapt to new or changed requirements, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. Additionally, any future regulatory approvals that we receive may also contain requirements for costly post- marketing testing and surveillance to monitor the safety and effectiveness of the product. Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and ~~recordkeeping~~ **record keeping** for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post- marketing reports, registration, and continued compliance with good manufacturing practices for any clinical trials that we conduct post- approval. Finally, per FDA regulations, changes made to products, specifications, or test data evaluation methodology would generally require communication with the FDA. There are several pathways for communicating with the FDA of such changes. As part of such review, the FDA may request additional information, at which time the product may become temporarily unavailable. **Our success depends, in part, on our relationships with, and the efforts of, third- party distributors. We rely on third- party distributors for a portion of our sales in countries outside of the U. S. Our distributors may not commit the necessary resources to market and sell our products to the level of our expectations, and, regardless of the resources they commit, they may not be successful. If we are not able to maintain our distribution network, if our distribution network is not successful in marketing and selling our products, or if we experience a significant reduction in, cancellation, or change in the size and timing of orders from our distributors, our revenues could decline significantly and lead to an inability to meet operating cash flow requirements, which would have a material adverse effect on our business, financial condition, and results of operations.** Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate in other jurisdictions. Obtaining and maintaining regulatory approval for a product in one jurisdiction does not guarantee that we will be able to obtain or maintain similar approval in other jurisdictions, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even ~~if~~ **though** the FDA **has** ~~grants~~ **granted** marketing approval for use of our RECELL System for the treatment ~~soft tissue repair~~ **full- thickness skin defects** and ~~/ or~~ vitiligo, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries if not currently approved. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a medical device must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We are highly dependent on our regulatory approval in the United States and failure to maintain that approval would materially impact our business and prospects. Our business is highly dependent on the PMA we received in September 2018 from the FDA **including subsequent secondary approvals of the PMA outside of burns** . This PMA allows us to sell our RECELL System in the United States, our current primary market ~~. In addition, maintaining this PMA also increases the probability of approval of secondary indications for the PMA outside of burns~~ . While we intend to take every action and precaution to ensure that our PMA remains effective, it is possible that the FDA could take a position in the future that requires a modification, temporary suspension or revocation of our PMA. Any such action by the FDA would have a material adverse effect on our business. We may encounter substantial delays in any further clinical studies necessary to support any regulatory applications for additional commercial applications of our technology. We cannot guarantee that any preclinical testing or clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve the expected clinical milestones necessary for approval by the FDA, or other regulators, for the use of our RECELL System for additional applications in the United States or other countries. A failure in a clinical study or regulatory application can occur at

any stage. Events that may prevent successful or timely commencement, enrollment or completion of clinical development or a regulatory application include: • delays in raising, or inability to raise, sufficient capital to fund the planned trials; • delays in reaching a consensus with regulatory agencies on trial design; • changes in trial design; • inability to identify, recruit and train suitable clinical investigators; • inability to add new clinical trial sites; • delays in reaching agreement on acceptable terms for the performance of the trials with prospective clinical research organizations and clinical trial sites; • delays in recruiting suitable clinical sites and patients (i. e., subjects) to participate in clinical trials; • imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites; • failure by any relevant parties to adhere to clinical trial requirements; • failure to perform in accordance with the FDA' s Good Clinical Practice (" GCPs "), or applicable regulatory guidelines in other countries; • delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites; • delays caused by clinical trial sites not completing a trial; • failure to demonstrate adequate effectiveness; • occurrence of serious adverse events in clinical trials that are associated with the product candidates that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • adverse events, safety issues, product recalls, manufacturing or supply chain interruptions, or poor clinical outcomes where the RECELL System is being used commercially; and • disagreements with regulatory agencies in the interpretation of the data from our clinical trials. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete clinical trials for our product candidates. If we are not able to successfully complete clinical trials or are not able to do so in a timely and cost-effective manner, we will not be able to obtain regulatory approval for the use of our RECELL System for additional applications, all of which could have a material adverse effect on our business, financial condition and results of operations. We may be unsuccessful in commercializing our RECELL System, or other future products, due to unfavorable pricing regulations or third- party coverage and reimbursement policies. We cannot guarantee that we will receive favorable pricing and reimbursement for use of our products. The rules and regulations that govern pricing and reimbursement for medical products vary widely from country to country or from indication to indication, and within the United States, can also vary widely from one health system or hospital to the next. In some foreign jurisdictions, including the EU, the government largely controls pricing of medical products. In other countries, coverage negotiations must occur at the regional or hospital level. Pricing negotiations can take considerable time after the receipt of marketing approval for a medical product. As a result, even after obtaining regulatory approval for a product in a particular country, we may be subject to price regulations or limited reimbursement, which may delay or limit our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our total investment in our RECELL System or other future products, even after obtaining regulatory approval. If we are unable to promptly obtain coverage and profitable payment rates from hospital budget, government- funded and private purchasers for the RECELL System or any future products, this could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. For example, we presently benefit from various reimbursement codes, including the following: • ~~Reimbursement~~ for hospitals in inpatient services using Medicare Severity Diagnosis- Related Groups (" MS- DRGs "). • Specific International Classification of Disease, 10th revision, Procedure Classification System (" ICD- 10- PCS ") code series describing our " cell suspension technique " for the use of the RECELL System. • ~~Current Procedural Terminology (" CPT ")~~ codes to support physician reimbursement for professional healthcare services, ambulatory surgical center (" ASCs ") reimbursement for facility services and hospital reimbursement for outpatient department services. Medicare reimburses ASCs for services using CPT codes and reimburses hospitals for outpatient services using Ambulatory Payment Classifications (" APCs "). In addition, in 2022, we were approved for a ~~Transitional Pass- through Payment (" TPT ")~~ C code to support additional Medicare payment in the outpatient hospital and the ASC setting. There can be no guarantee that the above reimbursement codes will not be withdrawn, reduced, consolidated or otherwise be altered in a manner which is not supportive of ongoing commercial use of the RECELL System. We **may** ~~have limited financial resources and will likely~~ require additional ~~financings~~ **financing in the future** to continue the development and commercialization of our RECELL System or any future products, which may cause dilution to our existing stockholders ~~or place restrictions on our operations~~. If additional financing is not available, we may have to postpone, reduce or cease operations. If we are unable to achieve profitability sufficient to permit us to fund our operations **, repay the indebtedness under our Credit Agreement with OrbiMed** and other planned actions, we may be required to raise additional capital. There can be no assurance that such capital would be available on favorable terms, or at all. If we raise additional capital through the issuance of equity ~~or convertible debt securities~~, the percentage ownership held by existing stockholders may be reduced, and the market price of our common stock or CDIs could fall due to an increased number of shares or CDIs available for sale in the market ~~. Debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with respect to certain business matters~~. If we are unable to secure additional capital as circumstances require, we may not be able to fund our planned activities or continue our operations. We face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results. Our success depends, in part, on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a manufacturing facility located in Ventura, California where we produce, package and warehouse the RECELL System. We also rely on global third- party manufacturers for production of some of the components used in the RECELL System. If our facility, or the facilities of our third- party contract manufacturers, suffer damage, or a force majeure event, this could materially impact our ability to operate. We are also subject to other risks relating to our manufacturing capabilities, including: • quality and reliability of components, sub- assemblies and materials that we source from third- party suppliers, who are required to meet our quality specifications, some of whom are our single- source suppliers for the products they supply; • failure to secure raw

materials, components and materials in a timely manner, in sufficient quantities or on commercially reasonable terms; • inability to secure raw materials, components and materials of sufficient quality to meet the exacting needs of medical device manufacturing; • inability to increase production capacity or volumes to meet demand; and As demand for our products increases, we will have to invest additional resources to purchase raw materials and components, sub- assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently to meet demand for our products, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. It may not be possible for us to manufacture our products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, we are continually identifying additional third- party suppliers who could serve if necessary as replacement manufacturers should the need arise. Certain of our products are dependent on specialized sources of supply potentially subject to disruption which could have a material, adverse impact on our business. **Due** ~~We expect recent supply chain disruptions as a result of the pandemic combined with raw material shortages, and inflationary pressures, to continue for the foreseeable future. These conditions have strained our suppliers and extended supplier delivery lead times. The Life Sciences industry is experiencing market wide shortages for resin products used in our packaging. As a result of recent inflation, we are seeing increases in the costs of raw materials. We have single- sourced some of our material components due~~ to the cost and regulatory requirements associated with qualifying multiple suppliers **, in the prior year we single- sourced some of our material components** . To the extent **that** any of these single **-** sourced suppliers **experience** ~~may have~~ disruptions in deliveries due to production, quality, or other issues, we ~~may also experience related~~ **are potentially subject to similar** production delays or unfavorable cost increases ~~associated with qualifying alternate~~ **. In the current year, we invested resources in obtaining additional** suppliers **for some** ~~. The impact~~ of ~~delays resulting from disruptions in~~ **our key raw materials, but these efforts only mitigate, and not eliminate, our** supply **chain risk** ~~for these items could negatively impact our revenue, our reputation with our customers, and our results of operations. In addition, significant price increases from single- source suppliers could have a negative impact on our profitability to the extent that we are unable to recover these cost increases on our fixed price contracts~~ . We rely on third parties to conduct, supervise and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug product candidates and our business could be substantially harmed. We rely on clinical research organizations (" CRO "), and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. CROs manage and monitor the clinical trials, duties and functions, and we will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with the FDA' s GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA, and comparable foreign regulatory authorities, enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. If any such event were to occur, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. ~~As a result of the ongoing COVID- 19 pandemic, other pandemics, inadequate funding or other reasons, the FDA and other government agencies may have resource constraints which could limit their ability to review and approve our applications in a timely manner, thus negatively impacting our business. The FDA' s ability to review and approve regulatory submissions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, federal government shutdowns, and other events that may otherwise affect the FDA' s ability to perform routine functions. The time to review submissions can vary from time to time. If a prolonged government shutdown occurs, or if global health concerns continue to prevent or delay the FDA or other regulatory authorities from conducting, at all or in a timely manner, their regular inspections, reviews, or other regulatory activities (including pre- submission engagements), it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.~~ Product recalls or inventory losses caused by unforeseen events may adversely affect our operating results and financial condition. Our products are manufactured, stored and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture, storage and

distribution of our product candidates, subjects us to risks. In addition, process deviations or unanticipated effects of approved process changes may result in production runs of our RECELL System not complying with stability requirements or specifications. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. In the event our production efforts require a recall or result in an inventory loss, our operating results and financial condition may be adversely affected. A cyber security incident could be disruptive to our business, compromise confidential data, cause reputation harm, and subject us to litigation and federal and state governmental inquiries. We collect and store sensitive business and other information, including intellectual property and trade secrets, on our networks. Our business operations are dependent upon the secure maintenance of this information. Despite **the implementation of security measures,** our **internal computer and** ~~efforts to secure this~~ information **technology systems and those of our vendors and customers are vulnerable to attack and damage from computer viruses** , **malware, denial of service attacks, unauthorized access, or** ~~there~~ - **other** ~~can be no assurance~~ **harm, including from threat actors seeking to cause disruption to our business. We face risks related to the protection of information** that **we maintain — or engage a third- party to maintain on our behalf — including unauthorized access, acquisition, use, disclosure, or modification of such information.** ~~cyberattacks~~ **Cyberattacks are increasing in their frequency, sophistication and intensity and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering** and other **means to affect service reliability and** ~~threats~~ **threaten the confidentiality, integrity and availability of information. Beyond external criminal activity, systems that access or control access to our services and databases may be compromised as a result of human error, fraud or malice on the part of employees or third parties, or may result** from ~~malicious~~ **accidental technological failure. A material cyberattack or security incident could cause interruptions in our operations and could result in a material disruption of our business operations, damage to our reputation, financial condition, results of operations, cash flows and prospects. We receive, collect, process, use and store a large amount of information from our customers and our own employees, including** ~~persons~~ **personal information, protected health** and ~~groups~~ **other sensitive and confidential information. If threat actors are able to circumvent or breach our security systems, they could steal any information located therein or cause serious and potentially long- lasting disruption to our operations. Security breaches or attempts thereof could also damage our reputation and expose us to a risk of monetary loss and / or litigation, fines and sanctions. We also face risks associated with security breaches affecting third parties that conduct business with us or our customers and others who interact with our data. While we maintain insurance that covers certain security incidents, we may not carry appropriate insurance or maintain sufficient coverage to compensate for all potential liability. We are subject to diverse laws and regulations relating to data privacy and security, such as HIPPA and similar U. S. state data protection regulations, including the California Consumer Privacy Act (CCPA), and European data privacy laws, including the E. U.' s General Data Protection Regulation. Complying with these numerous and complex regulations is expensive and difficult, and failure to comply with these regulations could result in regulatory scrutiny, fines, civil liability or damage to our reputation. In addition, any security breach or attempt thereof could result in liability for stolen assets or information, additional costs associated with repairing any system damage, incentives offered to clients or other business partners to maintain business relationships after a breach, and implementation of measures to prevent future breaches, including organizational changes, deployment of additional personnel and protection technologies, employee training and engagement of third- party experts and consultants. Additionally, the costs incurred to remediate any security incident could be substantial. We cannot assure you that any of our third- party service providers with access to our, or our customers and / or employees' personally identifiable and other sensitive or confidential information** will not **experience security breaches** ~~cause harm to or disrupt our~~ - **or** ~~business and operations. As~~ **attempts thereof, which could have** a **corresponding** ~~result, cyber security and the continued development and enhancement of our controls, processes and practices designed to protect our information systems from attack, damage or unauthorized access remain a priority for us. We may be required to expend significant additional resources to protect against cyber threats. A cyber- attack may result in a material adverse~~ effect on our ~~financial position and results of operations and harm our~~ business ~~reputation~~ . We rely on information technology systems for critical business functions and the operations of our business. We rely upon complex, integrated information technology (**"** IT **"**) systems in our business functions including our quality systems to operate our business. If any of our IT systems were to be disrupted or fail, our business could suffer irreparable harm, financial loss, and our operations would be adversely impacted. The markets in which we operate are highly competitive and innovative. Our competitors may develop products that render our products less attractive or obsolete and our business may deteriorate. The markets for our products are highly competitive and our competitors may develop products that may more effectively compete with our products, thus negatively impacting our sales, financial conditions and business prospects. Our competitors may have significantly more financial and other resources to invest in product development. We must continue to develop and market new products, or we risk our products becoming obsolete, in which case, our revenues may decline, and our business prospects may suffer. Product development is an expensive, uncertain and lengthy process. We have significant product development projects ongoing that, if successful, are intended to improve the ease and use of our device in our current burn indication **,** as well as in ~~soft tissue repair~~ **full- thickness skin defects** , vitiligo and future indications. The costs, timeline and ultimate success of these product development programs are subject to risk and uncertainty. If **we are** ~~the Company is~~ not able to develop and obtain regulatory approval for these products in development in a timely fashion and within budget, our business prospects and financial condition may suffer. Compliance with environmental, health and safety requirements is costly and, if not achieved, could result in material financial fines and penalties, expensive lawsuits, cessation of business operations, and a material adverse impact on the business. Our manufacturing and other processes may involve the use of hazardous materials subject to federal,

state, and local and foreign environmental requirements. Under some environmental laws and regulations, we could be held responsible for costs at third- party sites that we have used for waste disposal, or for contamination at our past or present facilities. Failure to comply with current ~~environment~~ **environmental** laws, or future laws, could result in significant fines, penalties and expenses which could have an adverse impact on our financial condition. We may be subject to civil and criminal penalties if the FDA determines that we have marketed or promoted our products for off- label usage. We are prohibited from promoting our products for uses that are inconsistent with the uses that have been approved by the FDA- also known as " off- label " uses. More specifically, we may not make claims, in our promotion materials, website or otherwise, about the use of any RECELL products which are outside of their approved labeling and indications. If the FDA determines that our marketing activities constitute off- label promotion, the FDA could impose fines and penalties on the Company and our executives, withdraw or recall our approved product from the market, as well as limit our product from off- label usage. Risks Relating to our Industry and Intellectual Property We face competition from the existing standard of care and any future potential changes in medical practice and technology and the possibility that our competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours. The medical device, biotechnology and pharmaceutical industries, specifically relating to the areas where we currently or intend to market our RECELL System, are intensely competitive and subject to significant changes due to technology and medical practice standards. We may face competition from any number of different sources with respect to any products we develop and commercialize. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products, treatments or procedures that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our RECELL System or any future products we develop. Many of our current or future competitors may have significantly greater financial resources and experience and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we may have. Mergers and acquisitions in the pharmaceutical, medical device, and biotechnology industries or wound care markets may result in increased concentration of resources among a smaller number of our competitors. Other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We could be subject to product liability lawsuits, which could result in costly and time- consuming litigation and significant liabilities. The development of medical device products, such as our RECELL System, involves an inherent risk of product liability claims and associated financial liability and adverse publicity. Any products we may develop could be found to be harmful or to contain harmful substances and expose us to substantial liability and risk of litigation or may force us to discontinue production. We may be unable to obtain or maintain insurance on reasonable terms or otherwise protect ourselves against potential product liability claims that could impede or prevent further business development of any products we may create and commercialize. Furthermore, a product liability claim could damage our reputation, whether or not such claims are covered by insurance or have merit. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our business or financial condition. Furthermore, product liability lawsuits, regardless of their success, would likely be time consuming and expensive to resolve and would divert management' s time and attention, which could seriously harm our business. If we are unable to effectively protect our intellectual property, we may not be able to operate our business and third parties may be able to use and profit from our technology, both of which would impair our ability to be competitive. Our success will be heavily dependent on our ability to obtain and maintain meaningful patent protection for our technologies and products throughout the world. Patent law relating to the technology fields in which we will operate is still evolving. The amount of ongoing protection for our proprietary rights therefore is uncertain. We will rely on patents to protect a significant part of our intellectual property and to enhance our competitive position. However, our presently pending or future patent applications may be denied, and any patent previously issued to us or our subsidiaries may be challenged, invalidated, held unenforceable or circumvented. In ~~particular~~ **2019** , we filed a ~~patent~~ **Patent** Term Extension **(" PTE ")** application with the U. S. Patent and Trademark **for U. S.** ~~Office requesting an extension of our commercial patent~~ **Patent** ~~that~~ **No. 9, 029, 140, which** covers the RECELL System, **as a result of patent term lost to the FDA regulatory process. The PTE application was approved, and the patent term of** U. S. Patent No. 9, 029, 140 ~~. If the term extension is approved~~ , **has been** ~~the patent term will be~~ extended to April 9, 2024. ~~Without such approval~~ **Our other patents have expected expiration dates ranging from 2032 to 2033** , **while** our **pending** ~~RECELL System~~ patent **applications** ~~will expire in February 2024~~ , ~~which~~ **if granted,** ~~could~~ **would** ~~prevent us~~ **have expiration dates ranging** from **2032 to 2042** ~~defending our patent in the event a competitor infringes on our RECELL System by producing the same type of product~~ . Furthermore, the patent protections we have been granted may not be broad enough to prevent competitors from producing products similar to ours ~~. In markets other than the USA, where we continue to have patent protection on the RECELL System, the expiration of these patents means the Company may not be able to deter a competitor from introducing a product similar to the RECELL System in those jurisdictions. If this were to occur, our ability to successfully market and sell our products in such markets could be materially impaired~~ . In addition, the laws of various foreign countries in which we may compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive will be materially impaired. In the ordinary course of business and as appropriate, we intend to apply for additional patents covering both our technologies and products, as we deem appropriate. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or developing competing products and technologies. In addition, because patent law is evolving in the life science industry, the patent positions of companies like ours are uncertain. As a result, the validity and enforceability of our patents cannot be predicted with certainty. We may find it difficult to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on all of our technologies and

products in every jurisdiction is expensive. Competitors could reverse engineer our technologies in jurisdictions where we have not obtained patent protection to develop their own products. These products may compete with our products and may not be covered by any patent claims or other intellectual property rights. The laws of some countries do not protect intellectual property rights to the same extent as the laws of the United States and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. This lack of protection, particularly in relation to biotechnology, could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert the efforts and attention of key personnel from other aspects of our business. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology. If we choose to go to court to stop someone else from using the intellectual property claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and / or should not be enforced against that third party. These lawsuits are expensive and would distract our key personnel and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions or, even if the validity or enforceability of these patents is upheld, the court may refuse to stop the other party because the competitors' activities do not infringe our rights. If third parties make claims of intellectual property infringement against us, or otherwise seek to establish their intellectual property rights equal or superior to ours, we may have to spend time and money in response and potentially discontinue certain of our operations. While we currently do not believe it to be the case, third parties may claim that we are employing their proprietary technology without authorization or that we are infringing on their patents. If such claims were made, we could incur substantial costs coupled with diversion of our management and key technical personnel in defending against these claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively halt our ability to further develop, commercialize and sell products. In the event of a successful claim of infringement, courts may order us to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing available products and have a material negative effect on our business. Our current and future relationships with investigators, health care professionals, consultants, third- party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include: • the federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • the federal false claims laws including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making, or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on health plans, health care clearing houses, and certain health care providers, known as covered entities, and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors; • a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health data that are applicable to or affect our operations; • the federal transparency requirements, sometimes referred to as the " Sunshine Act, " under the Patient Protection and Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other" transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. ~~Beginning in 2022, applicable~~ **Applicable** manufacturers are also required to report such information regarding their relationships with physician assistants, nurse practitioners, clinical nurse

specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require medical device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, as well as state and local laws that require the registration of sales representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. The continued successful commercialization of the RECELL system for FDA approved and pending indications, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies. Continued sales of the RECELL System depend in part on the availability of coverage and reimbursement from third- party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Both the federal and state governments in the United States continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the RECELL System and may further limit our commercial opportunity. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. Accordingly, we continue to evaluate the effect that the Affordable Care Act has on our business. There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for our product and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. Cost control initiatives may decrease coverage and payment levels and, in turn, the price that we will be able to charge and / or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage, such as the Affordable Care Act, the IRA, as well as other federal, state, and foreign healthcare reform measures that have been and may be adopted in the future, or inadequate reimbursement could harm our business and reduce our revenue. Additionally, if rebate obligations associated with them are substantially greater than we expect, our future net revenue and profitability could be materially diminished.

Macroeconomic and Social Risks ~~Our business, results of operations and financial condition may be adversely impacted by the COVID- 19 pandemic. The ongoing COVID- 19 pandemic has negatively affected the U. S. and global economies, disrupted global supply chains, resulted in significant travel and transport restrictions, and created significant disruption of the financial markets. We continue to closely monitor the impact of the COVID- 19 pandemic on all aspects of our business, including how it is impacting our employees, product development, customers and supply chain. We continue to be unable to predict the ultimate impact that the COVID- 19 pandemic may have on our business, future results of operations, financial position or cash flows. The extent to which our operations may be impacted by the COVID- 19 pandemic and recovery will depend largely on future developments, which are highly uncertain and cannot be accurately predicted. We may experience additional operating costs due to increased challenges with our workforce (including as a result of illness, absenteeism or government orders), access to supplies, capital, and fundamental support services (such as shipping and transportation). Even after the COVID- 19 pandemic has subsided, we may experience materially adverse impacts to our business due to any resulting supply chain disruptions, economic recession or depression. Furthermore, the impacts of potential worsening of global economic conditions, inflation resulting from government interventions and stimulus, and continued disruptions to and volatility in the financial markets remain unknown. The impact of the COVID- 19 pandemic may also exacerbate other risks discussed in this section, any of which could have a material adverse effect on us. This situation continues to change rapidly, and additional impacts may arise that we are not aware of currently, including the emergence of additional variants which may or may not be resistant to currently available vaccines and therapeutic treatments.~~ Adverse changes in general economic conditions or uncertainty about future economic conditions, including economic uncertainty from the departures of critical personnel from the industry, could adversely affect us. We are subject to the risks arising from adverse changes in general economic market conditions ~~, including the negative impact to the U. S. and global economy from the COVID- 19 pandemic~~ . Uncertainty about future economic conditions could negatively affect our current and prospective customers causing them to delay the purchase of our products. Poor economic conditions could harm our business, financial condition, operating results and cash flows. In addition, a number of nurses and other critical personnel in burn centers who are trained and well versed in the use of the RECELL system have determined to change occupations ~~, possibly as a result of the ongoing pandemic~~ . Nationally, this has been termed the " great resignation ". The fact that many burn center employees have moved on to other positions or industries may limit our ability to increase adoption of our RECELL system as we will be required to train a new group of nurses and other personnel critical to the implementation of the RECELL system. Customer and consumer demand for our products may be impacted by weak economic conditions, recession, equity market volatility or other negative economic factors in the U. S. or other nations. The severity and

length of time that a downturn in economic and financial market conditions may persist, as well as the timing, strength and sustainability of any recovery from such downturn, are unknown and are beyond our control ~~. Many predict that the U. S. economy will enter a recession in fiscal year 2023. We continue to take precautions due to the COVID- 19 pandemic that could negatively impact our business. In response to the COVID- 19 pandemic, we have taken measures intended to protect the health and well- being of our employees, customers, and communities, which could negatively impact our business. While the COVID- 19 pandemic has not materially adversely affected our financial results and business operations through the fiscal year- ended December 31, 2022, we are unable to predict the impact that COVID- 19 will have on our business, operations, and financial results and condition because of the numerous uncertainties created by the unprecedented nature of the pandemic. We are closely monitoring the evolving impact of the pandemic on all aspects of our business. We have implemented a number of measures designed to protect the health and safety of our employees, support our customers and promote business continuity. We continue to evaluate the Company' s liquidity and operational performance, communicate with and monitor the actions of our customers, third- party manufacturers and suppliers, and review our near- term financial performance as we manage the Company through this period of uncertainty~~ . Risks Relating to Our Common Stock and CDIs We have never paid a dividend on our common stock and CDIs and do not intend to do so in the foreseeable future, and consequently, investors' only opportunity to realize a return on their investment in the Company is through the appreciation in the price of our common stock and CDIs. We do not anticipate paying cash dividends on our common stock and CDIs in the foreseeable future and intend to retain all earnings, if any, for our operations. If we decided to pay dividends at some future time, we may not have sufficient funds legally available to do so. Even if funds are legally available for distribution, we may be unable to pay any dividends to our stockholders because of limitations imposed by a lack of liquidity. Accordingly, our stockholders may have to sell some or all of their common stock or CDIs (as applicable) in order to generate cash flow from their investment. Our stockholders may not receive a gain on their investment when they sell their common stock or CDIs and may lose some or all of their investment. Any determination to pay dividends in the future on our common stock and CDIs will be made at the discretion of our Board of Directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable law, capital requirements, and other factors that our Board of Directors deems relevant. As long as we remain subject to the rules of the ASX and of Nasdaq, we will be unable to access equity capital without stockholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and consequently, we may be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite stockholder approvals. Our ability to access equity capital is currently limited by ASX Listing Rule 7. 1, which provides that a company must not, subject to specified exceptions, issue or agree to issue during any consecutive 12- month period any equity securities, or other securities with rights to conversion to equity, if the number of those securities in aggregate would exceed 15 % of the number of outstanding common shares at the commencement of that 12- month period unless stockholder approval is obtained. Our equity issuances will be limited by ASX Listing Rule 7. 1 so long as we continue to be listed on the ASX and this constraint may prevent us from raising the full amount of equity capital needed for operations without prior stockholder approval. In addition to ASX Listing Rule 7. 1, we are also subject to Nasdaq Listing Rule 5635 (d), commonly referred to as the Nasdaq 20 % Rule, which requires stockholder approval of a transaction other than a public offering involving the sale, issuance, or potential issuance by a company of common stock (or securities convertible into or exercisable for common stock) equal to 20 % or more of the common stock, or 20 % or more of the voting power outstanding before the issuance for less than the greater of book or market value of the shares. While less restrictive than ASX Listing Rule 7. 1, the operation of the Nasdaq 20 % rule could limit our ability to raise capital through issuance of common stock or convertible securities without jeopardizing our listing status. If we were to violate the Nasdaq 20 % rule, the Company would be subject to delisting from Nasdaq and share prices and trading volumes would likely suffer. There has been relatively limited trading volume in the markets for our common stock and CDIs, and more active, liquid trading markets for such securities may never develop. Trading in our common stock on Nasdaq and our CDIs on the ASX is often thin and susceptible to wide fluctuations in trading prices due to such limited trading volume and other factors, some of which may have little to do with our operations or business prospects. Limited liquidity in the trading markets for our common stock and CDIs may adversely affect a stockholder' s ability to sell its shares of our common stock or our CDIs at the time it wishes to sell them or at a price that it considers acceptable. In addition, if a more active, liquid public trading market does not develop we may be limited in our ability to raise capital by selling shares of common stock or CDIs. We cannot assure you that more active, liquid public trading markets for our common stock and CDIs will develop or, if developed, will be sustained. The market price and trading volume of our common stock and CDIs may be volatile and may be affected by variability in our performance from period to period and economic conditions beyond management' s control. The market price of our common stock (including common stock represented by CDIs) may be highly volatile and could be subject to wide fluctuations. This means that our stockholders could experience a decrease in the value of their common stock or CDIs regardless of our operating performance or prospects. The market prices of securities of companies operating in the medical device and biotech sectors have often experienced fluctuations that have been unrelated or disproportionate to the operating results of these companies. In addition, the trading volume of our common stock and CDIs may fluctuate and cause significant price variations to occur. If the market price of our common stock or CDIs declines significantly, our stockholders may be unable to resell our common stock or CDIs at or above their purchase price, if at all. There can be no assurance that the market price of our common stock and CDIs will not fluctuate or significantly decline in the future. Some specific factors that could negatively affect the price of our common stock and CDIs or result in fluctuations in their price and trading volume include: • actual or expected fluctuations in our operating results; • actual or expected changes in our growth rates or our competitors' growth rates; • results of clinical trials of our product candidates; • results of clinical trials of our competitors' products; • regulatory actions with respect to our products or our competitors' products; • reports of one or more patient serious adverse events; • publication of research reports by securities analysts about us or our competitors in the industry; • our failure or the

failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • fluctuations of exchange rates between the U. S. dollar and the Australian dollar; • issuances by us of debt or equity securities; • litigation involving our company, including stockholder litigation; • investigations or audits by regulators into the operations of our company; • proceedings initiated by our competitors or clients; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; • sales or perceived potential sales of the common stock or CDIs by us, our directors, executive management team or our stockholders in the future; • short selling or other market manipulation activities; • announcement or expectation of additional financing efforts; • terrorist acts, acts of war or periods of widespread civil unrest; • ~~economic and social effects of the COVID- 19 virus, including any emerging variants or other pandemics; •~~ natural disasters and other calamities; • changes in market conditions for biopharmaceutical stocks; • our inability to raise additional capital, limiting our ability to continue as a going concern; • changes in market prices for our product or for our raw materials; • changes in market valuations of similar companies; • changes in key personnel for us or our competitors; • speculation in the press or investment community; • changes or proposed changes in laws and regulations affecting our industry; and • conditions in the financial markets in general or changes in general economic conditions. The requirements of being a public company in the United States and listed on the ASX may strain our resources and divert management' s attention. As a public company, we are subject to the reporting requirements of the Exchange Act, the U. S. Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act "), the Dodd- Frank Act and the listing standards and the rules and regulations of Nasdaq. We are also subject to the reporting requirements under the ASX Listing Rules due to the listing of our CDIs on ASX. **The** ~~We expect that the~~ requirements of these rules and regulations will increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and **can** place significant strain on our personnel, systems and resources. As a result of our disclosure of information in filings required of a public company, our business and financial condition is more visible, which may result in threatened or actual litigation, including by competitors, stockholders or third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results. We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act of 2012 (" JOBS Act "). For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions and relief from various U. S. reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, (ii) having the option of delaying the adoption of certain new or revised financial accounting standards, (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iv) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We have taken, and in the future may take, advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information contained herein and in other reports we file with the SEC may be different than the information our investors receive from other public companies in which they hold stock. Further, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock and CDIs less attractive as a result, which may result in a less active trading market for our common stock and CDIs and higher volatility in our stock and CDI price. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act which, given the filing of the S- 8 Registration Statement on August 27, 2020, will be December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $ 1. 07 billion, (iii) the last day of the fiscal year in which we are deemed to be a " large accelerated filer " as defined in Rule 12b- 2 under the Exchange Act, or (iv) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period. If research analysts publish unfavorable commentary or downgrade our common stock or CDIs it could adversely affect our share price and trading volume. The trading market for our common stock and CDIs depends, in part, on the research and reports that research analysts publish about us and our business and industry. If one or more research analysts downgrade our shares or CDIs, publish unfavorable commentary about the Company or cease publishing reports about us or our business, the price of our common stock and CDIs could decline. If one or more of the research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our common stock and CDIs could decrease, which could cause our share price or trading volume to decline. General Risk Factors **The Company' s cash, cash equivalents and marketable securities could be adversely affected by bank failures or other events affecting financial institutions and could adversely affect our liquidity and financial performance. We regularly maintain domestic cash deposits in Federal Deposit Insurance Corporation (" FDIC ") insured banks, which exceed the FDIC insurance limits. We also maintain cash deposits in foreign banks where we operate, some of which are not insured or are only partially insured by the FDIC or other similar agencies. The failure or rumored failure of a bank, or events involving limited liquidity, defaults, non- performance, bankruptcy, receivership or other adverse developments in the financial or credit markets impacting financial institutions, may lead to disruptions in access to our bank deposits. These disruptions may adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U. S. or applicable foreign government, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government**

institutions or by acquisition in the event of a failure or liquidity crisis. As such, those funds in bank deposit accounts in excess of the standard FDIC insurance limits are uninsured and subject to the risk of bank failure. Currently, we have full access to all funds in deposit accounts or other money management arrangements. The failure of any bank in which we deposit our funds could reduce the amount of cash that we have available for our operations or delay our ability to access such funds. In the event of such failure, we may experience delays or other issues in meeting our financial obligations, our ability to access our cash and cash equivalents may be threatened and could have a material adverse effect on our business and financial condition. Future adverse developments with respect to specific financial institutions or the broader financial services industry may also lead to market- wide liquidity shortages. If we fail to manage our growth effectively, our business could be disrupted. Our future financial performance and ability to successfully commercialize our products, which is not guaranteed, and to compete in the market will depend, in part, on our ability to manage any future growth effectively. We expect to make significant investments to facilitate our future growth through, among other things: • new product development; • commercial development of our RECELL System to such areas ~~soft tissue repair~~ **full- thickness skin defects** and vitiligo; • clinical trials for additional indications; and • funding of our marketing and sales infrastructure. Any failure to manage future growth effectively could have a material adverse effect on our business and results of operations. Our growth and success depend on our ability to attract and retain additional highly qualified and skilled sales and marketing, research and development, operational, managerial and finance personnel. Competition for skilled personnel is intense and the unexpected loss of an employee with a particular skill could have a material adverse effect on our operations until a replacement can be found and trained. If we cannot attract and retain skilled scientific and operational personnel for our research and development and manufacturing operations on acceptable terms, we may not be able to develop and commercialize our products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company. Our operations are subject to anti- corruption laws, including Australian bribery laws, and the FCPA and other anti- corruption laws that apply in countries where we do business. Anti- corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti- corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws or other laws including trade related laws. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations and financial condition.