Risk Factors Comparison 2024-02-29 to 2023-03-01 Form: 10-K

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Below is a summary of the principal factors that make an investment in our Class A common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading ~~“~~ **"** Risk Factors ~~”~~ **"** and should be carefully considered, together with other information in this Form 10- K and our other filings with the SEC before making an investment decision regarding our Class A common stock. • Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control. • We have incurred significant losses in past years, and, notwithstanding our reported net income ~~for~~ **since** the **year ended December 31,** 2020 ~~, 2021 and 2022 fiscal years~~ , we may incur losses in the future. • Our success will depend in part on the extent to which coverage and adequate reimbursement for the costs of our products and related services will be available from government payers, private health insurers, and other third- party payers and we do not know whether such reimbursement will be available or, if such reimbursement is available, the rate at which it will be available. The rate of reimbursement and coverage for the use of our products has been and may continue to be unstable, unpredictable and subject to changes in government and private payer policies **(including the adoption of new LCDs)** that could adversely affect our business, results of operations, and financial condition. Currently, not all of our products are covered by all payers. • If Medicare reproposes and finalizes a policy to stop making separate payment for skin substitutes **under the Medicare Physician Fee Schedule** in ~~calendar year 2024 or~~ calendar year 2025 **or thereafter** , reimbursement for our products may not be adequate and our business may be negatively affected. • If Medicare Part A / B Administrative Contractors finalize policies that ~~non-~~ **do not** cover some or all of our products, or limit the use of our products, our business could be adversely affected **. In addition, MA plans typically follow Medicare Part A / B LCDs and would not cover the same products as Part A / B** . • Many existing and potential customers for our products are members of GPOs and / or IDNs, including accountable care organizations or public- based purchasing organizations, and our business is partly dependent on major contracts with these organizations. Cost- containment efforts of our customers, GPOs, IDNs, third- party payers, and governmental organizations could adversely affect our business, results of operations, and financial condition. • Medicare, which is the major source of revenue for most of our customers, reimburses the same amounts for most of our products and the products of our competitors targeting the same indications in the hospital outpatient setting. Because in some sites of care the reimbursement amount is not based on the cost we charge our customers for our products or the cost our competitors charge for products targeting the same indication, our customers may elect to use products cheaper than ours in order to increase their margins, which could have a material adverse effect on our business, results of operations, and financial condition. • As of January 1, 2022, we began reporting ASP for all our skin substitute products that are paid separately as biologics. The first such ASP report was made on April 30, 2022 for Q1 2022. If we do not report ASP or if we incorrectly report ASP, we may have to restate ASP for prior quarters or may face penalties, including statutory and regulatory sanctions. • Section 90004 of the Infrastructure Investment and Jobs Act, enacted in November 2021, requires manufacturers to pay a refund to the federal government if more than a certain applicable percentage of their single- use product is not administered to a patient and is discarded (~~“~~ **"** wasted ~~”~~ **"**) by providers. Because there is a lack of consistency and uniformity in wound sizes, it is likely that some skin substitute product is discarded with every treatment. The rebate obligation took effect January 1, 2023 and CMS proposed a methodology to implement the rebate in the MPFS rulemaking. The applicable percentage is required to be at least 10 percent of total allowed charges for the drug in a given calendar quarter. CMS has the authority to increase the applicable percentage that applies to refunds for discarded product if there are ~~“~~ **"** unique circumstances. ~~”~~ **"** We submitted comments on the proposal noting the unique circumstances related to skin substitutes and asking CMS to apply a higher percentage. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not apply a higher applicable percentage to any products other than the hydrogel example they used in the proposed rule and stated that they plan to collect additional information about products that may have unique circumstances such that an increased applicable percentage (higher than 10 percent) would apply. CMS estimated the wastage percentage for three of our products- Apligraf, Dermagraft, and PuraPly- based on 2020 data. ~~We~~ **In the calendar year 2023 rulemaking, CMS exempted skin substitutes from this refund requirement. This exemption is based on the possibility that CMS will, in future rulemaking, stop paying for skin substitutes using the ASP methodology and bundle payment into the payment for the application of the product. However, because we do not know if or when CMS will begin bundled payment under the MPFS, this exemption may be rescinded and we may be required to refund payments made for the discarded portions of our products. If that happens, we** do not know if the refund amounts calculated in 2023 will be similar to these estimates but if they are then we may owe rebates, which could be material, on these products and possibly other products. The total amount of any **potential** discarded product rebate liability is not known at this time. • We have identified **a** material ~~weaknesses~~ -- **weakness** in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. While we have **remediated one** ~~successfully addressed certain~~ of the **previously reported material weaknesses, we are continuing to work on remediating the remaining** internal control deficiencies that ~~were included in the aggregation of the previously reported material weakness, we are continuing to work on remediating the remaining internal control deficiencies, as well as other internal control deficiencies identified during the current period, that~~ collectively are aggregating to form the **remaining** material ~~weaknesses~~ -- **weakness** in our internal controls over financial reporting that exists as of December 31, ~~2022~~ **2023** . However, we cannot **guarantee** ~~assure you~~ that additional material weaknesses or significant deficiencies will not occur in the future. If our internal

control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price. • We face significant and continuing competition, which could adversely affect our business, results of operations, and financial condition. • Rapid technological change could cause our products to become obsolete, and if we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete. • To be commercially successful, we must convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures. • Our failure to comply with regulatory obligations could result in negative effects on our business. • The FDA may determine that certain of our products that are, or are derived from, human cells or tissues, such as Affinity, Novachor, and NuShield, do not qualify for regulation solely under Section 361 of the Public Health Services Act, or PHSA. To the extent that any of these products are deemed not to be HCT / Ps or Section 361 HCT / Ps, the FDA may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA approval is obtained, which could adversely affect our business, results of operations, and financial condition. • The FDA may determine that our suspension of NuCel and ReNu commercialization on May 31, 2021 was not conducted in a timely or otherwise proper manner. To the extent that our suspension of any of these products is determined not to comply with the 361 HCT / P Guidance, we may be subject to regulatory sanctions, which could adversely affect our business, results of operations, and financial condition. • Because we depend upon a limited group of suppliers and manufacturers for our products, including Apligraf, Affinity, **CYGNUS,** Novachor, NuShield and PuraPly Antimicrobial products, we may incur significant product development costs or experience material delivery delays if there is an interruption in supply from any one of these suppliers or manufacturers, which could materially impact sales of our products. • We are dependent on the proper functioning of our and third- party manufacturing facilities, our supply chain and our sales force, all of which could be negatively impacted by public health emergencies, including the global COVID- 19 pandemic, or other factors, in a manner that could materially adversely affect our business, financial condition or results of operations. • Uncertainty and adverse changes in the general economic conditions, including ~~inflation~~ **recent turmoil in the global banking system** , may negatively affect our business. • Significant disruptions of our information technology systems or breaches of information security could adversely affect our business, results of operations, and financial condition. • Our patents and other intellectual property rights may not adequately protect our products. • We engage in transactions with related parties and the transactions present possible conflicts of interest that could have an adverse effect on our business, results of operations, and financial condition. • The Inflation Reduction Act of 2022 **(IRA)** , signed into law on August 16, 2022, includes several provisions to lower prescription costs for people with Medicare and reduce health care spending by the federal government. Among these is a requirement for manufacturers to pay a rebate to the federal government if prices for single- source biologicals covered under Medicare Part B, such as our products, increase faster than the rate of inflation. You should carefully consider the risks and uncertainties described below, together with the information included elsewhere in this Annual Report on Form 10- K and other documents we file with the SEC. The risks and uncertainties described below are those that we have identified as material, but are not the only risks and uncertainties facing us. Our business is also subject to general risks and uncertainties that affect many other companies, such as overall U. S. and non- U. S. economic and industry conditions including a global economic slowdown, geopolitical events, changes in laws or accounting rules, fluctuations in interest and exchange rates, terrorism, international conflicts, major health concerns, natural disasters or other disruptions of expected economic and business conditions. Additional risks and uncertainties not currently known to us or that we currently believe are immaterial also may impair our business operations and liquidity. Risks Related to Organogenesis and its business We are subject to the following factors, among others, that may negatively affect our operating results: • the announcement or introduction of new products by our competitors; • failure of government healthcare programs and private health plans to cover our products or to timely and adequately reimburse the users of our products; • the rate of reimbursement by government and private insurers for use of our products; • any change in Medicare payment policy which provides a competitive advantage to our competitor' s products; • any change in government healthcare programs' and private health plans' policies regarding sales and reimbursement of durable medical equipment (~~"~~DME ~~"~~), including a prohibition on physician- owned DME supplier entities; • whether our products or our competitors' products are granted pass- through reimbursement status or included in the ~~"~~ **"** bundled ~~"~~ **"** reimbursement structure; • our ability to upgrade and develop our systems and infrastructure to accommodate growth; • our ability to attract and retain key personnel in a timely and cost- effective manner; • our ability to offer our wound care and surgical products and supplies using our existing sales force and distribution network; • the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations, and infrastructure; • changes in, or enactment of new laws or regulations promulgated by federal, state, or local governments; • cost containment initiatives or policies developed by government and commercial payers that create financial incentives not to use our products; • our inability to demonstrate that our products are cost- effective or superior to competing products; • our ability to develop new products; • discovery of product defects during the manufacturing process; • initiation of a government investigation into potential non- compliance with laws or regulations; • issuance of government advisory opinions or program bulletins that could negatively affect one or more of our sales models; • sanctions imposed by federal or state governments due to non- compliance with laws or regulations; • recall of one or more of our products by the FDA due to noncompliance with FDA requirements; and • general economic conditions as well as economic conditions specific to the healthcare industry. We have based our current and future expense levels largely on our investment plans and estimates of future events, although certain of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenue relative to our planned expenditures would have an immediate adverse effect on our business, results of operations, and financial condition. Further, as a strategic response to changes in the competitive environment or to changes in laws and regulations, we may from time to time make certain pricing, service, or

marketing decisions (e. g., reduce prices) that could have a material and adverse effect on our business, results of operations, and financial condition. Due to the foregoing factors, our revenue and operating results are and will remain difficult to forecast. We have incurred significant losses in past..... of operations, and financial condition. A “ " material weakness ” " is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. We did not design and maintain effective controls ~~(i) to properly identify and assess significant non- routine transactions and (ii)~~ over information technology general controls and proper segregation of duties to support the proper initiation and recording of transactions and the resulting impact on business process controls and applications that rely on such data. **While we have remediated one of the previously reported material weaknesses, we are continuing to work on remediating the remaining internal control deficiencies that collectively aggregate to form the remaining material weakness in our internal controls over financial reporting that exists as of December 31, 2023. However, we cannot assure you that additional material weaknesses or significant deficiencies will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.** Although we have made certain progress in remediating ~~these~~ -- **the remaining** material ~~weaknesses~~ -- **weakness** , we concluded that the material ~~weaknesses~~ -- **weakness** described above continued to exist as of December 31, ~~2022~~ **2023** . We have taken actions to remediate the deficiencies in our internal controls over financial reporting and implemented additional processes and controls designed to address the underlying causes of the above- mentioned **remaining** material ~~weaknesses~~ -- **weakness** . If we do not successfully remediate the material ~~weaknesses~~ -- **weakness** described above, or if other material weaknesses or other deficiencies arise in the future, we may be unable to accurately report our financial results, which could cause our financial results to be materially misstated and require restatement. The technologies underlying our products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop. Any such occurrence could have a material and adverse effect on our business, results of operations, and financial condition. We plan to enhance and broaden our product offerings in response to changing customer demands and competitive pressure and technologies, but we may not be successful. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to: • properly identify and anticipate physician and patient needs; • develop and introduce new products or product enhancements in a timely manner; • adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; • demonstrate the safety and efficacy of new products, including through the conduct of additional clinical trials; • obtain the necessary regulatory clearances or approvals for new products or product enhancements; • achieve adequate coverage and reimbursement for our products; and • compete successfully against other skin substitutes and other modalities for treating wounds such as negative- pressure wound therapy and hyperbaric oxygen. If we do not develop and, when necessary, obtain regulatory clearance or approval for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not be covered or reimbursed by government healthcare programs such as Medicare or private health plans, may not produce sales in excess of the costs of development and / or may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. We believe physicians will only adopt our products if they determine, based on experience, clinical data and published peer- reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to conventional methods. Physicians also are more interested in using cost- effective products and may practice in settings like Accountable Care Organizations, or ACOs, or Medical Homes, where they face considerable cost- containment pressure. In general, physicians may be slow to change their medical treatment practices and use of our products for the following reasons, among others: • their lack of experience using our products; • lack of evidence supporting additional patient benefits from use of our products over conventional methods; • pressure to contain costs; • preference for other treatment modalities or our competitors’ products; • perceived liability risks generally associated with the use of new products and procedures; • limited availability of coverage and / or reimbursement from third- party payers; and • the time that must be dedicated to training. The degree of market acceptance of our products will continue to depend on a number of factors, including: • the safety and efficacy of our products; • the potential and perceived advantages of our products over alternative treatments; • clinical data and the clinical indications for which our products are approved; • product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in approved labeling; • the cost of, and relative reimbursement rate for, using our products relative to the use of our competitors’ products or alternative treatment modalities; • relative convenience and ease of administration; • the strength of marketing and distribution support; • the quality of the service and support provided to our customers; • the timing of market introduction of competitive products; • publicity concerning our products or competing products and treatments; • our reputation and the reputation of the products; • the shelf life of our products and our ability to manage the logistics of the end- user supply chain; and • sufficient and readily accessible third- party insurance coverage and reimbursement. In addition, we are currently conducting clinical studies for some of our products that were brought to market as 361 HCT / Ps to generate efficacy data in various clinical applications. Unfavorable results from these 361 HCT / P clinical trials such as lack of clinical efficacy or serious treatment- related side effects could negatively affect the use and adoption of our products by physicians and hospitals, thereby compromising our market acceptance. We believe recommendations for, and support of our products by,

influential physicians are essential for market acceptance and adoption. If we do not receive this support (e. g., because we are unable to demonstrate favorable long- term clinical data), physicians and hospitals may not use our products, which would significantly reduce our ability to achieve expected revenue and would prevent us from sustaining profitability. In the course of conducting our business, we must comply with regulatory quality requirements, and adequately address quality issues that may arise with our products, as well as defects in third- party components included in our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate these risks and quality issues may arise in which case we would be subject to liability. If the quality of our products does not meet the expectations of regulators, physicians, or patients, then we could be subject to regulatory sanctions and our brand and reputation could suffer and our business, results of operations, and financial condition could be adversely impacted. We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance. Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating, and marketing of medical devices and human tissue products. We are, and may in the future be, subject to product liability claims and lawsuits, including potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers, or others selling our products. Defending a lawsuit, regardless of merit, could be costly, divert management attention, and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: • harm to our business reputation; • investigations by regulators; • significant defense costs; • distraction of management' s attention from our primary business; • substantial monetary awards to patients or other claimants; • loss of revenue; • exhaustion of any available insurance and our capital resources; and • decreased demand for our products. Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage or be excluded from coverage under our policy. If we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims or we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could cause our stock price to decline and, if our liability exceeds our insurance coverage, could adversely affect our business, results of operations, and financial condition. Interruptions in the supply of our products or inventory loss may adversely affect our business, results of operations, and financial condition. Our products are manufactured 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 and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non- compliance with regulatory requirements including stability requirements or specifications. Most of our products must be stored and transported within a specified temperature range. For example, if environmental conditions deviate from that range, our products' remaining shelf- lives could be impaired or their safety and efficacy could be adversely affected, making them unsuitable for use. These deviations may go undetected. The occurrence of actual or suspected production and distribution problems can lead to lost inventories, and in some cases recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays and result in substantial additional expenses. Production of our Affinity product, for example, was suspended in the first quarter of 2019 due to production issues at one of our suppliers. As a result, we identified an alternate supplier, and were only able to resume commercial- scale production in the second quarter of 2020. Subsequently, we have added a second source to provide additional capacity and redundancy in supply. This disruption in supply resulted in reduced Affinity revenue. Although we were able to partially offset the lost Affinity revenue by increasing production of our other products, there can be no assurance that we will be able to do so in the event of any future suspensions or failures in the storage or manufacturing of Affinity, Dermagraft or our other products. Any future failure in the storage or manufacture of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations. As noted above, manufacturing of Dermagraft was suspended in the fourth quarter of 2021, and sales of Dermagraft were suspended in the second quarter of 2022. We plan to transition our Dermagraft manufacturing to a new manufacturing facility or engage a third- party manufacturer, which we expect will result in substantial long- term cost savings. In the period when Dermagraft is not available, we expect that customers will be willing to substitute Apligraf for Dermagraft and that the suspension of Dermagraft sales will not have a material impact on our net revenue. However, if we do not realize the expected substantial long- term cost savings or if customers are unwilling to substitute Apligraf for Dermagraft during the period in which Dermagraft is unavailable, it could have an adverse effect on our net revenue and results of operations. Because we depend upon a limited group of suppliers and manufacturers for our products, including our **Apligraf, Affinity, CYGNUS, Novachor,** NuShield ~~, Affinity, Apligraf~~ and PuraPly Antimicrobial products, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially impact sales of our products. We obtain some of the components for our products from a limited group of suppliers. **These** ~~For us to be successful, our~~ suppliers must be able to provide us with these components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed- upon specifications, at acceptable costs, and on a timely basis. Our efforts to maintain a continuity of supply and high quality and reliability may not be successful. Manufacturing disruptions experienced by our suppliers may jeopardize our supply of these components. Due to the stringent regulations and requirements of the FDA regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology. A reduction or interruption in manufacturing (including the

current suspension of Dermagraft manufacturing pending its transition to a new manufacturing facility or engagement of a third-party manufacturer), or an inability to secure alternative sources of raw materials or components, could have a material effect on our business, results of operations, and financial condition. In addition, one or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing equipment, supplies, products, or components, or may only agree to extend us credit on significantly less favorable terms or subject to more onerous conditions. This could significantly disrupt our ability to purchase or lease required equipment, supplies, products and components in a cost- effective and timely manner and could have a material adverse effect on our business, results of operations, and financial condition. Any casualty, natural disaster, other disruption of any of our sole- source suppliers' operations, or any unexpected loss of any existing exclusive supply contract, could have a material adverse effect on our business, results of operations, and financial condition. Our products are dependent on the availability of tissue from human donors, and any disruption in supply could adversely affect our business, results of operations, and financial condition. Many of the products that we manufacture require that we obtain human tissue. The success of our business depends upon, among other factors, the availability of tissue from human donors. Any failure to obtain tissue from our sources will interfere with our ability to effectively meet the demand for our products incorporating human tissue. The processing of human tissue for our products is very labor- intensive and it is therefore difficult to maintain a steady supply stream. The availability of donated tissue could also be adversely impacted by regulatory changes, public opinion of the donor process as well as our own reputation in the industry. The challenges we may face in obtaining adequate supplies of human tissue involve several risks, including limited control over the availability, quality, and delivery schedules. In addition, any interruption in the supply of any human tissue component could materially harm our ability to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations, and financial condition. Increased prices for, or unavailability of, raw materials used in our products could adversely affect our business, results of operations, and financial condition. Our profitability is affected by the prices of the raw materials used in the manufacture of our products. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel- related delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates, and government regulation. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third- party payers, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. If the cost of key components or raw materials increases, and we are unable fully to recover these increased costs through price increases or offset these increases through other cost reductions, we could experience lower margins and profitability. Significant increases in the prices of raw materials, due to inflation or otherwise, that cannot be recovered through productivity gains, price increases or other methods could adversely affect our business, results of operations, and financial condition. We continue to invest significant capital to maximize our sales and marketing infrastructure, and there can be no assurance that these efforts will result in significant increases in sales. We are committed to maximizing our internal sales and marketing capabilities, including by optimizing our sales force to further support the marketing and sales of the products acquired in connection with our 2017 acquisition of NuTech Medical and our 2020 acquisition of CPN Biosciences. As a result, we continue to invest in sales and marketing resources for our products to allow us to reach new customers and potentially increase sales. These expenses impact our operating results, and there can be no assurance that we will continue to be successful in significantly increasing the sales of our products. The impairment or termination of our relationships with independent sales agencies, whom we do not control, could materially and adversely affect our ability to generate revenues and profits. We intend to develop additional relationships with independent sales agencies in order to increase revenue from certain of our products; our inability to do so may prevent us from increasing sales. We derive a portion of our revenues through our relationships with independent sales agencies. The impairment or termination of these relationships for any reason could materially and adversely affect our ability to generate revenues and profits. Because the independent sales agency often controls the customer relationships within its territory, there is a risk that if our relationship with the independent sales agency ends, our relationship with the customer will be lost. Also, because we do not control an independent sales agency' s field sales agents, there is a risk we will be unable to ensure that our sales processes, regulatory compliance, and other priorities will be consistently communicated and executed by the distributor. If we fail to maintain relationships with our key independent sales agencies, or fail to ensure that our independent sales agencies adhere to our sales processes, regulatory compliance, and other priorities, this could have an adverse effect on our business, results of operations, and financial condition. We may have liability for the actions of independent sales agencies in marketing our products and our lack of control over their activities impedes our ability to prevent, detect or address such non- compliance. We intend to develop relationships and arrangements with additional independent sales agencies in order to increase our sales with respect to certain of our products. However, we may fail to develop such relationships, in which case we may not be able to increase our sales. Our success is partially dependent upon our ability to retain and motivate our independent sales agencies and their representatives to sell our products in certain territories. They may not be successful in implementing our marketing plans. Some of our independent sales agencies may not sell our products exclusively and may offer similar products from other companies. Our independent sales agencies may terminate their contracts with us, may devote insufficient sales efforts to our products, or may focus their sales efforts on other products that produce greater commissions for them, which could have an adverse effect on our business, results of operations, and financial condition. We also may not be able to find additional independent sales agencies who will agree to market and / or distribute those products on commercially reasonable terms, if at all. If we are unable to establish new independent sales agency relationships or renew current sales agency agreements on commercially acceptable terms, our business, results of operations, and financial condition could be materially and adversely affected. In addition, because we do not control these independent sales agencies as closely as our employees, while we may take steps to mitigate the risks associated with noncompliance by independent sales agencies, there remains a risk they do not

comply with regulatory requirements or our requirements or our policies which could also adversely affect our business. We will need to continue to expand our organization, and managing growth may be more difficult than expected. Managing our growth may be more difficult than we expect. We anticipate that a period of significant expansion will be required to penetrate and service the markets for our existing and anticipated future products and to continue to develop new products. This expansion will place a significant strain on management, operational and financial resources. To manage the expected growth of our operations, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative, and operations staff. Management may be unable to hire, train, retain, motivate, and manage necessary personnel or to identify, manage, and exploit existing and potential strategic relationships and market opportunities. In addition to expanding our organization, we are expanding our manufacturing capabilities, which requires significant capital expenditures. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the expansion of our manufacturing facilities is delayed, for regulatory or other reasons, it may limit our ability to expand the size of our organization and to meet our corporate goals. Even if we are able to expand our manufacturing facilities as we plan, we may not realize the full expected benefit of our investment. We may expand our business through acquisitions, similar to our acquisitions of NuTech Medical and CPN Biosciences, licenses, investments, and other commercial arrangements in other companies or technologies. Such acquisitions or commercial arrangements may entail significant risks. We periodically evaluate strategic opportunities to acquire companies, divisions, technologies, products, and rights through licenses, distribution agreements, investments, and outright acquisitions to grow our business, such as our acquisitions of NuTech Medical and CPN Biosciences **and our License and Manufacturing Agreement with Vivex Biologics, Inc** . In connection with one or more of those transactions, we may: • issue additional equity securities that would dilute our stockholders' value; • use cash that we may need in the future to operate our business; • incur debt that could have terms unfavorable to us or that we might be unable to repay; • structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step- up in the tax basis for the assets acquired; • be unable to realize the anticipated benefits, such as increased revenues, cost savings, **economies of scale** or synergies from additional sales of existing or newly acquired products; • be unable to successfully integrate, operate, maintain, and manage our newly acquired operations **; • be unable to sell all of the products we are required to purchase under the Vivex agreement** ; • divert management' s attention from the existing business to integrate, operate, maintain, and manage our newly acquired operations and personnel; • acquire unknown liabilities that could subject us to government investigations and / or litigation or other actions that make it impossible to realize the anticipated benefits of the transaction; • be unable to secure the services of key employees related to the acquisition; and • be unable to succeed in the marketplace with the acquisition. Any of these items could materially and adversely affect our revenues, financial condition, and profitability. **Our November 2023 license and manufacturing agreement with Vivex to sell their Dual and Matrix products expanded our product Advanced Wound Care and Surgical & Sports Medicine product portfolio. However, we are required to pay a royalty on the net sales of the licensed products during the royalty term, and to meet certain minimum purchase commitments. If we are not able to sell sufficient quantities of the licensed products, we may not be able to sell all of the products we are required to purchase under the agreement, achieve economies of scale for this product line, or in general realize the full anticipated benefit of our investment in the arrangement with Vivex.** Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Our acquisition of NuTech Medical and CPN Biosciences expanded our wound care portfolio and our acquisition of NuTech Medical broadened our addressable market to include the Surgical & Sports Medicine market. We may not realize the increased revenues, cost savings, and synergies that we anticipate from this acquisition in the near term or at all due to many factors, including delays in the integration process, an inability to successfully penetrate the amniotic category of the wound care market or an inability to obtain necessary regulatory approvals. Additional liabilities related to acquisitions could include a lack of compliance with government regulations that could subject us to investigation and civil and criminal sanctions. For example, we may acquire a company that was not compliant with FDA quality requirements or was making payments or other forms of remuneration to physicians to induce them to use their products. Incurring unknown liabilities or the failure to realize the anticipated benefits of an acquisition could materially and adversely affect our business and we may lose our entire investment or be unable to recover our initial investment, which could include the cost of acquiring licenses or distribution rights, acquiring products, purchasing initial inventory, or investments in early- stage companies. Inability to recover our investment, or any write off of such investment, associated goodwill, or assets, could have a material and adverse effect on our business, results of operations, and financial condition. We have incurred significant losses in past years and,notwithstanding our reported net income for the ~~2020,2021,and 2022~~ fiscal years **since the year ended December 31,2020** ,we may incur losses in the future.To date,we have financed our operations primarily through debt and equity financings,and,with the exception of the fiscal years **since the year** ended December 31, ~~2022,2021,and~~ 2020 ~~,in which we reported net income of $ 15.5 million,$ 94.2 million and $ 17.2 million,respectively~~ ,we have incurred losses from operations in many years since our inception. **In the years ended December 31,2023,2022,and 2021,we reported net income of $ 4.9 million,$ 15.5 million and $ 94.2 million,respectively,** As of December 31, ~~2022~~ **2023** ,we had an accumulated deficit of $ ~~45~~ **41** . ~~3~~ **0** million ~~.We expect to incur significant sales and marketing costs to support the sale of our products~~ .Our prior losses, ~~combined with any~~ **and the possibility of** potential future losses,may have an adverse effect on our business,results of operations, **and financial condition.** New lines of business or new products and services may subject us to additional risks. From time to time, we may implement or may acquire new lines of business, such as our Surgical & Sports Medicine products that were acquired in connection with our acquisition of NuTech Medical, or we may offer new products and services within existing lines of business. There are risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed or are evolving. In developing and marketing new lines of business and new products and services, we may invest significant time and resources. External factors, such as regulatory compliance obligations, competitive

alternatives, lack of market acceptance, and shifting market preferences, may also affect the successful implementation of a new line of business or a new product or service. Failure to successfully manage these risks in the development and implementation of new lines of business or new products or services could have a material adverse effect on our business, results of operations, and financial condition. Significant disruptions of information technology systems or breaches of information security could adversely affect our business, results of operations, and financial condition. ~~We rely to a large extent upon sophisticated~~ **Our business depends on the availability, reliability, and security of our** information ~~technology~~ systems ~~to operate our business~~ **, networks, data, and intellectual property** . In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property) **. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, sales, competitive position, and privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share. Cyberattacks have become increasingly more prevalent and much harder to detect, defend against or prevent. As the frequency of cyberattacks and resulting breaches reported by other businesses and governments increases, we expect to continue to devote significant resources to improve and maintain our information technology (IT) infrastructure. We have incurred and may in the future incur significant costs in order to implement, maintain and / or update security systems we believe are necessary to protect our IT infrastructure. As the techniques used to obtain unauthorized access or to sabotage systems change frequently and are often not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventive measures. A breakdown in existing controls and procedures around our cyber- security environment may prevent us from detecting, reporting or responding to cyber incidents in a timely manner and could have a material adverse effect on our financial position and value of our stock. We cannot guarantee that our implemented processes for IT and risk mitigation measures will be effective for IT systems under our control** . We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third- party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever- increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. For example, in August 2020, our information technology (~~“~~IT ~~”~~) systems were exposed to a ransomware attack, which partially impaired certain IT systems for a short period of time. We finished investigating the incident, together with legal counsel and other incident response professionals. We did not experience any material losses related to the ransomware attack and were able to recover all data quickly, with only a minimal and temporary interruption to our business. While we have implemented measures to protect our data security and information technology systems, such measures may not prevent these events. Although we have cyber- insurance coverage that may cover certain events described above, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage. ~~Any interruption or breach in our systems could adversely affect our business operations and / or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities.~~ If a breach of our measures protecting personal data covered by HIPAA, the HITECH Act, or the CCPA occurs, we may incur significant liabilities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to ~~“~~ **"** covered entities ~~”~~ **"** (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA’ s requirements and restrictions with respect to handling such protected health information, and have executed business associate agreements with certain customers. In addition, California has enacted the California Consumer Privacy Act (~~“~~CCPA ~~”~~), which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt- out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt- in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non- compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply. Aside from California, Texas and several other major states impose rigorous local medical privacy requirements. It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result

in government- imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Further, compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and / or criminal penalties, as well as private litigation and / or adverse publicity that could negatively affect our operating results and business. We engage in transactions with related parties and such transactions present possible conflicts of interest that could have an adverse effect on our business, results of operations, and financial condition. We have entered into a significant number of transactions with related parties. Related party transactions create the possibility of conflicts of interest with regard to our management, including that: • we may enter into contracts between us, on the one hand, and related parties, on the other, that are not as a result of arm' s- length transactions; • our executive officers and directors that hold positions of responsibility with related parties may be aware of certain business opportunities that are appropriate for presentation to us as well as to such other related parties and may present such business opportunities to such other parties; and • our executive officers and directors that hold positions of responsibility with related parties may have significant duties with, and spend significant time serving, other entities and may have conflicts of interest in allocating time. Such conflicts could cause an executive officer or a director to seek to advance his or her economic interests or the economic interests of certain related parties above ours. Conversely, we may not be able to enter into transactions with third parties on terms as favorable as the terms of existing transactions with related parties. Further, the appearance of conflicts of interest created by related party transactions could impair the confidence of our investors. It is possible that a conflict of interest could have a material adverse effect on our business, results of operations, and financial condition. Our financial performance may be adversely affected by medical device tax provisions in healthcare reform laws. The Patient Protection and Affordable Care Act (the ~~"~~PPACA ~~"~~) imposed, among other things, an excise tax of 2. 3 % on any entity that manufactures or imports medical devices offered for sale in the United States. Under these provisions, the Congressional Research Service predicted that the total cost to the medical device industry may be up to $ 20 billion over a decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which required, among other things, bi- monthly payments and quarterly reporting. The Consolidated Appropriations Act, 2016 (Pub. L. 114- 113), signed into law in December 2015, included a two- year moratorium on the medical device excise tax. A second two- year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115- 120), extending the moratorium through December 31, 2019. On December 20, 2019, President Trump signed into law a permanent repeal of the medical device tax under the PPACA, but there is no guarantee that Congress will not reverse course in the future. If such an excise tax on sales of our products in the United States is enacted, it could have a material adverse effect on our business, results of operations, and financial condition. We could incur asset impairment charges related to certain leasehold improvements **and construction in progress** , which could adversely affect our business, results of operations, and financial condition. Our long- term assets include property ~~, plant~~ and equipment of **$ 116. 2 million and** $ 102. 5 million ~~and~~ **, of which** $ ~~79~~ **60** . ~~2~~ **8** million **and $ 37. 6 million represents the value of improvements to our leased assets, and of which $ 59. 1 million and $ 65. 6 million represents construction in progress (each as described more fully in Note 8, Property and Equipment, Net, to our audited consolidated financial statements included in this Annual Report on Form 10- K),** as of December 31, **2023 and** 2022 ~~and 2021~~ , respectively. We review our long- lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based on appraised value. Any such impairment could result in a non- cash charge equal to the full value of these improvements. During the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , we did not recognize an impairment charge with respect to our long- lived assets. Changes in our assumptions with respect to our expected use of these assets may result in an impairment charge in the future, which could adversely affect our business, results of operations, and financial condition. We may be required to record a significant charge to earnings if our goodwill and other amortizable intangible assets, or other ~~investments~~ **assets** become impaired. We are required under generally accepted accounting principles **in the United States (GAAP)** to test goodwill for impairment at least annually and to review our goodwill, amortizable intangible assets, and other assets acquired through merger and acquisition activity, for impairment when events or changes in circumstance indicate the carrying value may not be recoverable. Factors that could lead to impairment of goodwill, amortizable intangible assets, and other assets acquired via acquisitions include significant adverse changes in the business climate and actual or projected operating results (affecting our company as a whole or affecting any particular segment) and declines in the financial condition of our business. We may be required in the future to record additional charges to earnings if our goodwill, amortizable intangible assets, or other investments become impaired. Any such charge would adversely impact our financial results. Our ability to use our net operating loss carryforwards may be subject to certain limitations. As of December 31, ~~2022~~ **2023** , we had approximately $ ~~44~~ **11** . ~~4~~ **7** million of federal net operating loss carry- forwards available for the reduction of future years' federal taxable income, all of which can be carried forward indefinitely. Under the Internal Revenue Code of 1986, as amended, or the Code, the deductibility of the net operating loss- carry- forward as of December 31, ~~2022~~ **2023** and all future net operating loss- carry- forwards is limited to 80 % of taxable income, limiting or delaying in part the use of net operating loss- carry- forwards. As of December 31, ~~2022~~ **2023** , we also had state net operating loss carry- forwards of approximately $ ~~14~~ **9** . ~~3~~ **4** million expiring from the year ended December 31, 2031 through 2038. It is uncertain whether and

to what extent applicable state tax laws will conform to the federal rule, though we are already subject to limitations in net operating loss utilization in certain states. In addition, our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Code. In the event of an “ " ownership change ” " , Section 382 imposes an annual limitation on the amount of post- ownership change taxable income that may be offset with pre- ownership change net operating losses of the loss corporation experiencing the ownership change. An “ " ownership change ” " is defined by Section 382 as a cumulative change in ownership of our company of more than 50 % within a three- year period. As of December 31, 2021, we performed a study and determined that there is no limitation on our federal net operating losses. Current or future changes in our stock ownership may trigger an “ " ownership change, ” " some of which may be outside our control. Accordingly, our ability to utilize our net operating loss carryforwards to offset federal taxable income, if any, could be limited by Section 382, which could potentially result in increased future tax liability to us. We are dependent on the proper functioning of our and third- party manufacturing facilities, our supply chain, and our sales force, all of which could be negatively impacted by public health emergencies, including the COVID- 19 pandemic, or other factors, in a manner that could materially adversely affect our business, financial condition or results of operations. We manufacture our non- placental- based products and use third- party manufacturers for our placental- based products and we use third- party raw material suppliers to support our internal manufacturing processes. If our manufacturing capabilities or the manufacturing capabilities of our suppliers are impacted as a result of a public health emergency, including a resurgence of the COVID- 19 pandemic, it may not be possible for us to timely manufacture relevant products at the required levels or at all. While the COVID- 19 pandemic has not had a material adverse effect on our business to date, a reduction or interruption in any of our manufacturing processes as a result of a public health emergency in the future (including a resurgence of the COVID- 19 pandemic) could have a material adverse effect on our business, results of operations, financial condition and cash flows. We also may be unable to obtain the raw materials necessary to support our internal manufacturing processes due to the additional constraints on suppliers. The manufacture of our products is dependent on the availability of sufficient quantities of source tissue, which is the primary component of our products. Source tissue includes donated human tissue, porcine tissue, and bovine tissue. We acquire donated human tissue directly through institutional review board- approved protocols at multiple hospitals, as well as through tissue procurement firms engaged by us or by our contract manufacturers. Any failure to obtain tissue from our sources, including any failures related to public health emergencies, like the COVID- 19 pandemic, will interfere with our ability to effectively meet the demand for our products. Any interruption in the supply of source tissue could materially harm our ability to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations, and financial condition. Our current Advanced Wound Care portfolio is sold throughout the United States via an experienced direct sales force, which focuses its efforts on wound care in various sites of care. We use a mix of direct sales representatives and independent agencies to service the Surgical & Sports Medicine market. These sales representatives are supported by teams of professionals focused on sales management, sales operations and effectiveness, ongoing training, analytics and marketing. Our direct sales force functions by meeting in person with physicians and health care providers to discuss our products. Public health emergencies, like COVID- 19, may negatively affect demand for our products by limiting the ability of our sales personnel to maintain their customary contacts with physicians and health care providers. In such case, we cannot assure you that our direct sales representatives or independent agencies will increase or maintain our current sales levels, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. We may also experience significant and unpredictable reductions in demand for certain of our products if patients are unable to access certain advanced therapies due to stay- at- home orders or other governmental actions taken to address a public health emergency. **Risks Related to Regulation of** Our ~~ability~~ **Products and Other Government Regulations Our products are subject** to ~~comply to~~ the Infrastructure Investment and Jobs Act and rebate obligations that took effect on January 1,2023,and we may owe rebates,which could be material,on our Apligraf,Dermagraft,and PuraPly products and possibly other products.Section 90004 of the Infrastructure Investment and Jobs Act,enacted in November 2021,requires manufacturers to pay a refund to the federal government if more than a certain applicable percentage of their single- use product is not administered to a patient and is discarded (“ " wasted ” ") by providers.Because there is a lack of consistency and uniformity in wound sizes,it is likely that some skin substitute product is **discarded** with ~~financial covenants if more than a certain applicable percentage of their single- use product is not administered to a patient and is discarded (“ wasted ”) by providers.Because there is a lack of consistency and uniformity in wound sizes,it is likely that some skin substitute product is discarded with~~ every treatment.The rebate obligation took effect January 1,2023,and CMS proposed a methodology to implement the rebate in the MPFS rulemaking.The applicable percentage is required to be at least 10 percent of total allowed charges for the drug in a given calendar quarter.CMS has the authority to increase the applicable percentage that applies to refunds for discarded product if there are “ " unique circumstances. ” " We submitted comments on the proposal noting the unique circumstances related to skin substitutes and asking CMS to apply a higher percentage.In the 2023 MPFS final rule,published on November 1,2022,CMS did not apply a higher applicable percentage to any products other than the hydrogel example they used in the proposed rule and stated that they plan to collect additional information about products that may have unique circumstances such that an increased applicable percentage (higher than 10 percent) would apply.CMS estimated the wastage percentage for three of our products- Apligraf,Dermagraft,and PuraPly- based on 2020 data. ~~We~~ **In the calendar year 2023 rulemaking,CMS exempted skin substitutes from this refund requirement.This exemption is based on the possibility that CMS will,in future rulemaking,stop paying for skin substitutes using the ASP methodology and bundle payment into the payment for the application of the product.However,because we** do not know if **or when CMS** ~~the refund amounts calculated in 2023~~ will ~~be similar~~ **begin bundled payment** under **the MPFS, this exemption may be rescinded and we may be required to refund payments made for the discarded portions of our products. If that happens, we do not know if the refund amounts**

calculated in 2023 will be similar to these estimates but if they are then we may owe rebates, which could be material, on these products and possibly other products. The total amount of any potential discarded product rebate liability is not known at this time. We may encounter substantial delays ~~our~~ **or** ~~credit or~~ difficulties in our clinical trials.Before obtaining marketing approval from regulatory authorities for the sale of our product candidates,we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates.Clinical testing is expensive,time- consuming and uncertain as to the outcome.We have limited experience with clinical trials.We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule,if at all.A failure of one or more clinical trials can occur at any stage of testing.Events that may prevent successful or timely completion of clinical development include:• the FDA may require additional clinical trials in connection with the approval of product candidates;• delays in reaching a consensus with the FDA or other regulatory authorities on trial design;• delays in **reaching** agreement **on acceptable terms with prospective contract research organizations, or CROs,** and ~~raise capital may be materially~~ **clinical trial sites; • delays in opening clinical trial sites or obtaining required IRB or independent ethics committee approval at each clinical trial site; • our decision or the requirement of regulators or IRBs to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, a finding that the participants are being exposed to unacceptable health risks, or the imposition of a clinical hold as a result of a serious** ~~adversely~~ **adverse** ~~impacted by~~ **event or after an inspection of our clinical trial operations or clinical trial sites; • delays in recruiting suitable patients to participate in our future clinical trials, including, but not limited to challenges associated with any resurgence of** COVID- 19 **; • failure by us, any CROs we engage** or **any** other ~~any other~~ third parties to adhere to clinical trial or regulatory requirements;• failure by us,any CROs we engage or any other third parties to perform in accordance with Good Clinical Practice,or GCP,cGMPs,or applicable regulatory guidelines in the United States and other international markets;• failure by physicians to adhere to delivery protocols leading to variable results;• delays in the testing,validation,manufacturing and delivery of our product candidates to the clinical trial sites,including delays by third parties with whom we have contracted to perform certain of those functions due to COVID- 19 or other reasons;• insufficient or inadequate supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates;• delays in having patients complete participation in a clinical trial or return for post- treatment follow- up;• clinical trial sites or patients dropping out of a clinical trial at a rate higher than we anticipate;• selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;• receipt of negative or inconclusive clinical trial results;• occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;• occurrence of serious adverse events in clinical trials of the same class of agents conducted by other sponsors;and • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;ReNu is in Phase 3 clinical development for the management of symptoms associated with knee OA.Our anticipated timeline for these and other trials and studies on our clinical trial candidates may be subject to delays **due to** factors ~~• insufficient or inadequate supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates;• delays in having patients complete participation in a clinical trial or return for post- treatment follow- up;• clinical trial sites or patients dropping out of a clinical trial at a rate higher than we anticipate;• selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;• receipt of negative or inconclusive clinical trial results;• occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;• occurrence of serious adverse events in clinical trials of the same class of agents conducted by other sponsors;and • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;ReNu is in Phase 3 clinical development for the management of symptoms associated with knee OA.Our anticipated timeline for these and other trials and studies on our clinical trial candidates may be subject to delays due to factors~~ such as those discussed above.Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales,regulatory,development and commercialization milestones and royalties.In addition,if we make manufacturing or formulation changes to our product candidates,we may need to conduct additional studies to bridge our modified product candidates to earlier versions.Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do,which could impair our ability to successfully commercialize our product candidates and may harm our business,financial condition,results of operations and prospects.Success in research and preclinical studies or early clinical trial results may not be indicative of results obtained in later trials.Likewise,preliminary,initial or interim data from clinical trials should be considered carefully and with caution since the final data may be materially different from the preliminary,initial or interim data,particularly as more patient data become available.Results from preclinical studies or early clinical trials,including feasibility studies,or earlier conducted clinical trials are not necessarily predictive of future clinical trial results,and interim results of a clinical trial are not necessarily indicative of final results.Our clinical trial candidates,including ReNu,may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial or earlier clinical trials or preliminary stages of clinical trials.From time to time,we have and may in the future publish or report preliminary,initial or interim data.Preliminary,initial or interim data from our clinical trials and those of our partners may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and / or more patient data become available.In this regard,such data may show initial evidence of clinical benefit,but as patients continue to be followed and more patient data becomes available,there is a risk that any therapeutic effects will not be durable in patients and / or will decrease over time,or cease entirely.Preliminary,initial or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from such preliminary,initial or interim data.As a result,preliminary,initial or interim data should be considered carefully and with caution until the final data are available.There is no guarantee that any of our clinical trials will be successful.In addition,there is a high failure rate for drugs,biologic products

and cell therapies proceeding through clinical trials.Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials.Data obtained from preclinical and clinical activities are subject to varying interpretations,which may delay,limit or prevent regulatory approval.Any such setbacks could adversely affect our business,financial condition,results of operations and prospects.Obtaining the necessary regulatory approvals or clearances for certain of our products will be expensive and time- consuming and may impede our ability to fully exploit our technologies or otherwise limit our ability to meet other business objectives.As biological products and medical devices,many of the products that we market require regulatory approvals or clearances from the FDA,or from similar regulatory authorities outside of the United States,before they may legally be distributed in commerce.In particular,such products may require FDA approval of Biologics License Applications,or BLAs,under Section 351 of the ~~Public Health Service Act (the "~~ PHSA ~~")~~ ,Premarket Approval,or PMA,submissions under Section 515 of the Federal Food,Drug,and Cosmetic Act,or FDCA,or may require clearance under Section 510 (k) of the FDCA.Although we believe that we have all necessary regulatory approvals or clearances legally required for the products that we currently market,the introduction of new or modified products **,or new or modified FDA regulatory rules,** may require us to secure new approvals or clearances.Additionally,the FDA may take the position that some of the products that we currently market without premarket approval or clearance in fact require such approval or clearance.The process of obtaining an approved BLA or PMA requires the expenditure of substantial time,effort and financial resources and may take years to complete.Although obtaining clearance under section 510 (k) is somewhat less burdensome,it is also associated with significant costs and resource commitments.The fee for filing a BLA,PMA or 510 (k) notification,and the annual user fees for any establishment that manufactures biologics or medical devices,as well as product fees applicable to each approved product are substantial.In January 2021,we announced that the first patient was enrolled in the pivotal Phase 3 clinical trial evaluating the safety and efficacy of ReNu for the management of symptoms associated with knee OA.There are significant costs associated with conducting clinical trials to support approvals that cannot necessarily be estimated with any accuracy until investigational plans have been developed.Moreover,data obtained from clinical activities may show a lack of safety or efficacy or may be inconclusive or susceptible to varying interpretations,any of which could delay,limit or prevent regulatory approval.Failure or delay can occur at any time during the clinical trial process.Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful.Even product candidates in later stages of clinical trials may fail to show the required safety profile or meet the efficacy endpoints despite having progressed through preclinical studies and initial clinical trials.A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles,notwithstanding promising results in earlier trials.We cannot be certain that we will not face similar setbacks.Even with positive clinical trial results,there may be other barriers to approval or clearance,and the FDA may not grant approval or clearance on a timely basis,or at all.Even if the FDA clears or approves our products,the clinical data submitted to the FDA may not be sufficient for payers to cover and / or adequately reimburse our customers for use of our products.Additionally,the FDA may limit the indications for use in an approval or clearance,or place other conditions on an approval,that could restrict the commercial application of the products.Regenerative medicine advanced therapy,or RMAT,designation for our product candidates may not lead to faster development or regulatory processes nor does it increase the likelihood that such product candidates will receive marketing approval.RMAT was introduced as a new designation under the 21st Century Cures Act for the development and review of certain regenerative medicine therapies.To receive RMAT designation,a regenerative medicine product candidate must be intended to treat,modify,reverse,or cure a serious or life- threatening disease or condition with preliminary clinical evidence indicating that the drug has the potential to address the unmet medical needs.RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies,as breakthrough designation requires.An RMAT product candidate receives intensive guidance on an efficient product development program;involvement of senior managers and experienced staff on a proactive,collaborative and cross- disciplinary review;and a rolling review.Regenerative medicine therapies that qualify for RMAT designation may also qualify for other FDA expedited programs,including fast track designation,breakthrough therapy designation,accelerated approval and priority review designation,if they meet the criteria for such programs.However,RMAT designation does not assure that marketing approval will be granted and,if granted,that the approval process would be any faster than it would have otherwise been.In January 2021,we announced RMAT designation for ReNu for the management of symptoms associated with knee OA.However,there is no guarantee that the receipt of RMAT designation will result in a faster development process,review or approval for ReNu for the management of symptoms associated with knee OA or increase the likelihood that ReNu will be granted marketing approval for the management of symptoms associated with knee OA.Likewise,any future RMAT designation or other expedited review status such as breakthrough therapy designation for any of our other product candidates neither guarantees a faster development process,review or approval nor improves the likelihood of the grant of marketing approval by FDA for any such product candidate compared to drugs considered for approval under conventional FDA procedures.In addition,the FDA may withdraw any RMAT or other expedited review status at any time.We may seek RMAT or breakthrough therapy designation for our other product candidates,but the FDA may not grant this status to any such product candidates.We may seek fast track designation by the FDA for one or more of our product candidates,but we might not receive such designation,and even if we do,such designation may not actually lead to a faster development or regulatory review or approval process.If a product is intended for the treatment of a serious or life- threatening condition and the product demonstrates the potential to address unmet needs for this condition,the treatment sponsor may apply for FDA fast track designation.Even if we receive fast track designation,fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame.We may not experience a faster development,regulatory review or approval process with fast track designation compared to conventional FDA procedures.Additionally,the FDA may withdraw fast track designation if it believes that the

designation is no longer supported by data from our clinical development program.Fast track designation alone does not guarantee qualification for the FDA' s priority review procedures.A breakthrough therapy designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process,and it would not increase the likelihood that the product candidate will receive marketing approval.We may seek a breakthrough therapy designation for one or more product candidates.A breakthrough therapy is defined as a product candidate that is intended,alone or in combination with one or more other drugs,to treat a serious or life- threatening disease or condition,and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints,such as substantial treatment effects observed early in clinical development.For product candidates that have been designated as breakthrough therapies,interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the new drug application.Designation as a breakthrough therapy is within the discretion of the FDA.Accordingly,even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy,the FDA may disagree and instead determine not to make such designation.In any event,the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process,review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA.In addition,even if one or more of our product candidates qualify as breakthrough therapies,the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.We must comply with applicable post- marketing regulatory obligations,which could include obtaining new regulatory approvals or clearances.Following approval or clearance,some types of changes to the approved or cleared product,such as adding new indications or additional labeling claims or introducing manufacturing changes,are subject to FDA review and approval,which may require further nonclinical or clinical testing.The costs and other resource burdens associated with obtaining new regulatory approvals or clearances for existing or future products may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities.Depending on the nature of the change,we may determine that the change may be carried out without obtaining premarket approval or clearance.The FDA or another regulatory body could disagree with our conclusion and require such premarket approval or clearance,which would disrupt the marketing of these products,potentially expose us to regulatory sanctions,and have a material adverse effect on our business,financial condition and results of operations.The FDA may determine that certain of our products that are,or are derived from,human cells or tissues,such as Affinity,Novachor,and NuShield,do not qualify for regulation solely under Section 361 of the Public Health Services Act,or PHSA,and may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA approval is obtained,which could adversely affect our business,results of operations,and financial condition.Certain of the products that we manufacture,process and distribute are,or are derived from,human cells or tissues,including amniotic tissue.The FDA has specific regulations governing human cells,tissues and cellular and tissue- based products,or HCT / Ps.In particular,HCT / Ps that meet certain criteria set forth in the FDA' s regulations at 21 C.F.R.§ 1271.10 are regulated solely under Section 361 of the PHSA,so- called ~~"~~ " Section 361 HCT / Ps ~~"~~ ",and are not subject to any premarket clearance or approval requirements.They are also subject to less stringent post- market regulatory requirements than products regulated under Section 351 of the PHSA and / or under Sections 505,510 or 515 of the FDCA.The Company has believed that certain of our HCT / Ps,including our products derived from amniotic membrane,qualify for regulation as Section 361 HCT / Ps.However,the regulatory classification of an HCT / P as a Section 361 HCT / P depends in part on the purposes for which the product is intended and in part on the processing to which an HCT / P is subject.On November 16,2017,the FDA issued a final guidance document entitled, ~~"~~ " Regulatory Considerations for Human Cells,Tissues,and Cellular and Tissue- Based Products:Minimal Manipulation and Homologous Use ~~"~~ ",or 361 HCT / P Guidance,which provides FDA' s current thinking on how to apply the existing regulatory criteria for regulation as a Section 361 HCT / P.These include,in addition to other requirements,requirements that an HCT / P be both minimally manipulated and intended for homologous use.In general, ~~"~~ " minimal manipulation ~~"~~ " is a standard referring to the degree to which the original characteristics of an HCT / P have been altered by processing and ~~"~~ " homologous use ~~"~~ " refers to the requirement that an HCT / P perform the same basic function in the donor as in the recipient.Any action by the FDA to apply the principles set forth in the 361 HCT / P Guidance to the HCT / Ps that we distribute could have adverse consequences for us and make it more difficult or expensive for us to conduct our business.In light of the 361 HCT / P Guidance,our labeling and marketing claims for our placental- based membrane products,including our Affinity,NuShield,and **Novachor products,clarify that they are intended as protective barriers,and thus meet the homologous use requirement to qualify as Section 361 HCT / Ps.However,the FDA could disagree with our conclusion and require premarket approval or clearance for Affinity,NuShield,or any placental- based sheet product we market,which would disrupt the marketing of these products,potentially expose us to regulatory sanctions,and have a material adverse effect on our business,financial condition and results of operations.Further,we believe it is necessary to obtain FDA approval of a BLA for NuCel and ReNu because those products may be deemed to be more than minimally manipulated,not for homologous use,or otherwise not regulated as Section 361 HCT / Ps.We continue to conduct clinical studies of ReNu to support FDA approval of a BLA for the management of symptoms associated with knee OA and,based on favorable feasibility studies that are subject to further evaluation,we believe ReNu has potential as a treatment for additional OA and tissue regeneration applications** . We have ~~funded~~ **discontinued clinical development of NuCel. If we obtain BLA approval for ReNu** ~~our~~ **or** NuCel,compliance with applicable post- market regulatory requirements will involve significant time and substantial costs.Even for those products that remain regulated as Section 361 HCT / Ps,increasing regulatory scrutiny within the industry in which we operate could lead to heightened requirements,compliance with which could be costly.The costs and

other resource burdens associated with any of these regulatory outcomes may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities.The 361 HCT / P Guidance originally indicated that the FDA was providing a 36- month enforcement grace period to allow time for distributors of HCT / Ps to make any regulatory submissions and obtain any premarket approvals necessary to comply with the guidance.In July 2020,the FDA announced that the enforcement grace period would be extended until May 31,2021 as a result of the challenges presented by the COVID- 19 public health emergency.On April 21,2021,the FDA reaffirmed that the enforcement grace period would end on May 31,2021,at which time we ceased commercial distribution of ReNu and NuCel.Although we believe our suspension of ReNu and NuCel commercialization was timely and proper,the FDA and other regulators may disagree with how or when such commercialization practices were conducted,which could expose us to regulatory sanctions,and have a material adverse effect on our business,financial condition and results of ~~operations~~ operations ~~of operations~~ .To the extent that the FDA may determine that certain of our products that are,or are derived from,human cells or tissues do not qualify for regulation solely under Section 361 of the PHSA,the introduction of new tissue products would become more expensive,expansion of our tissue product offerings could be significantly delayed,and we could be subject to additional post- market regulatory requirements or suspension of product sales until FDA approval is obtained.As stated above,in light of the 361 HCT / P Guidance,the FDA may determine that the types of cell- and tissue- based products that we distribute — and in particular,products derived from allografts consisting of human skin or amniotic tissue — are subject to premarket clearance or approval requirements.Should the FDA make such a determination,products of this type,including future products that we seek to introduce,will be much more costly to commercialize,as we will likely have to carry out preclinical work in animals and / or clinical trials in humans to support approval.Such preclinical work and clinical trials are expensive and time- consuming with no guarantee of success.In addition,these products will be subject to more stringent post- market regulatory requirements than those that currently apply,including but not limited to more stringent restrictions on advertising and promotion of these products,as well as more extensive adverse event reporting.In the future,we may also wish to market our existing HCT / P products for new intended uses that may render them ineligible for regulation as Section 361 HCT / Ps and cause them to require premarket clearance or approval and comply with post- market regulations under the medical device or biological product provisions of the FDCA and / or PHSA instead.Compliance with these requirements will involve significant time and substantial costs and could limit the resources available to us to fully exploit our technologies,including limiting our ability to introduce new allograft- derived products.We conduct a range of nonclinical,as well as clinical trials,comparative effectiveness,economic and other studies of our products.Unfavorable results from these trials or studies or from similar trials or studies conducted by others may negatively affect the use or adoption of our products by physicians,hospitals,and payers,which could have a negative impact on the market acceptance of these products and their profitability.We conduct a variety of nonclinical and clinical trials,comparative effectiveness studies and economic and other studies of our products,including our ongoing clinical trial for ReNu **,in** ~~and~~ ~~capital~~ **an effort to generate comprehensive clinical and real- world outcomes data and cost- effectiveness data in order to obtain product approval and drive further penetration in the markets we serve.In the event that these trials and studies,or similar trials and studies conducted by others,yield unfavorable results,those results could negatively affect the use or adoption of our products by physicians,hospitals,and payers,thereby compromising market acceptance and profitability.Our business is subject to continuing and evolving significant regulatory obligations by the FDA and other authorities,compliance with which is expensive and time- consuming and may impede our ability to fully exploit our technologies or otherwise limit our ability to meet other business objectives.Aside from the obligation to obtain regulatory approvals or clearances,companies such as ours** have ongoing regulatory obligations that are expensive and time- consuming to meet.In particular,the production and marketing of our products are subject to extensive regulation and review by the FDA and numerous other governmental authorities both in the United States and abroad.As noted above,some of the products that we distribute are considered Section 361 HCT / Ps.The FDA' s regulation of HCT / Ps includes requirements for registration and listing of products;donor screening and testing;processing and distribution,known as ~~" "~~ **"** Current Good Tissue Practices, ~~" "~~ **"** or cGTP;labeling;record keeping and adverse- reaction reporting;and inspection and enforcement.Moreover,it is likely that the FDA' s regulation of HCT / Ps will continue to evolve in the future.Complying with any such new regulatory requirements may entail significant time delays and expense,which could have a material adverse effect on our business,results of operations,and financial condition.Our other products are regulated as biologics and medical devices,which are subject to even more stringent regulation by the FDA.As noted above,these products are subject to rigorous premarket review processes,and an approval or clearance may place substantial restrictions on the indications for which the product may be marketed or the population for whom it may be marketed,may require warnings to accompany the product or may impose other restrictions on the sale and / or use of the product.In addition, ~~approved and cleared~~ **most of our** products are subject to continuing obligations to comply with other substantial regulatory requirements,including the FDA' s cGTP regulations, ~~the FDA' s QSR and / or~~ the FDA' s Current Good Manufacturing Practices **(** ~~,or~~ cGMP **)** regulations,adverse event reporting, ~~and~~ FDA inspections **,** ~~.The costs~~ and ~~other~~ -- **the** ~~resource burdens associated with maintaining~~ **FDA' s QSR,and the** regulatory **expectations** ~~approvals or clearances~~ for **these types of** ~~our products and otherwise meeting our~~ regulatory obligations may **evolve over time.** ~~limit the resources available to us to fully exploit our technologies or~~ **For** ~~may otherwise limit our ability to carry out~~ **example,on January 31,2024,** ~~other~~ -- **the FDA issued** ~~business activities.In some states,the manufacture,storage,or distribution of HCT / Ps requires~~ a **final rule** ~~license or permit to operate as a tissue bank or tissue distributor.We believe that we have all required state licenses or permits applicable to the distribution of HCT / Ps,but there is a risk that there may be state or local license or permit requirements of which we are unaware or with which we have not complied.In the event that such noncompliance exists in a given jurisdiction,we could be precluded from distributing HCT / Ps in that jurisdiction and also could be subject to fines or other penalties.If any such actions were to be instituted against us, spending~~ **amending the QSR for medical devices. This final rule is intended to more closely align the FDA QSR with the international consensus standard**

for device quality management and will become effective on February 2 , ~~in part~~ **2026. We may need to dedicate considerable resources to come into compliance with the new QSR by the final rule' s effective date. The costs and other resource burdens associated with maintaining regulatory approvals or clearances for our products and otherwise meeting our regulatory obligations may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities. In some states** , the manufacture,storage,or distribution of HCT / Ps requires a license or permit to operate as a tissue bank or tissue distributor.We believe that we have all required state licenses or permits applicable to the distribution of HCT / Ps,but there is a risk that there may be state or local license or permit requirements of which we are unaware or with which we have not complied.In the event that such noncompliance exists in a given jurisdiction,we could be precluded from distributing HCT / Ps in that jurisdiction and also could be subject to fines or other penalties.If any such actions were to be instituted against us,it could adversely affect our business and / or financial condition.The American Association of Tissue Banks,or AATB,has issued operating standards for tissue banking.Compliance with these standards is a requirement in order to become an accredited tissue bank.In addition,some states have their own tissue banking regulations.In addition,procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act,or NOTA,which prohibits the transfer of certain human organs,including skin and related tissue for valuable consideration,but permits the reasonable payment associated with the removal,transportation,implantation,processing,preservation,quality control and storage of human tissue and skin.We reimburse tissue banks,hospitals,and physicians for their services associated with the recovery,storage,and transportation of donated human tissue. ~~through -~~ **Although we have independent** third- party ~~debt~~ **appraisals that confirm the reasonableness of the service fees we pay, if we were to be found to have violated NOTA' s prohibition on the sale or transfer of human tissue for valuable consideration, we, our officers, or employees, would potentially be subject to criminal enforcement sanctions, which could materially** and **adversely affect our business, results of operations, and financial condition. Many of the products we manufacture and** ~~proceeds --~~ **process are derived** from **human tissue and therefore have the potential for disease transmission. The utilization of human tissue creates the potential for transmission of communicable diseases, including, but not limited to, human immunodeficiency virus, or HIV, viral hepatitis, syphilis and** ~~the~~ **other viral,fungal or bacterial pathogens.We are required to comply with federal and state regulations intended to prevent communicable disease transmission.Although we maintain strict quality controls over the procurement and processing of our tissue,there is no assurance that these quality controls will be adequate.In addition,negative publicity concerning disease transmission from** other companies' improperly processed donated tissue could have a negative impact on the demand for our products.If any of our products are implicated in the transmission of any communicable disease,our officers,employees and we could be subject to government sanctions including but not limited to recalls,and civil and criminal liability,with sanctions that include exclusion from doing business with the federal government.We could also be exposed to product liability claims from those who used or received our products as well as loss of our reputation.Defects,failures,or quality issues associated with our products could lead to product recalls or safety alerts,adverse regulatory actions,litigation,including product liability claims,and negative publicity that could erode our competitive advantage and market share and materially adversely affect our reputation,business,results of operations,and financial condition.Quality is extremely important to us and our customers due to the serious and costly consequences of product failure.Quality and safety issues may occur with respect to any of our products,and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with respect to our quality system.The development,manufacture,and control of our products are subject to extensive and rigorous regulation by numerous government agencies,including the FDA and similar foreign agencies.Compliance with these regulatory requirements,including but not limited to the FDA' s QSR,GMPs,and adverse events / recall reporting requirements in the United States and other applicable regulations worldwide,is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory authorities.The FDA and foreign regulatory authorities may also require post- market testing and surveillance to monitor the performance of approved products.Our manufacturing facilities and those of our suppliers and independent sales agencies are also subject to periodic regulatory inspections.If the FDA or a foreign authority were to conclude that we have failed to comply with any of these requirements,it could institute a wide variety of enforcement actions,ranging from a public warning letter to more severe sanctions,such as product recalls or seizures,withdrawals,monetary penalties,consent decrees,injunctive actions to halt the manufacture or distribution of products,import detentions of products made outside the United States,export restrictions,restrictions on operations or other civil or criminal sanctions.Civil or criminal sanctions could be assessed against our officers,employees,or us.Any adverse regulatory action,depending on its magnitude,may restrict us from effectively manufacturing,marketing,and selling our products.In addition,we cannot predict the results of future legislative activity or future court decisions,any of which could increase regulatory requirements,subject us to government investigations or expose us to unexpected litigation.Any regulatory action or litigation,regardless of the merits,may result in substantial costs,divert management' s attention from other business concerns,and place additional restrictions on our sales or the use of our products.In addition,negative publicity,including regarding a quality or safety issue,could damage our reputation,reduce market acceptance of our products,cause us to lose customers,and decrease demand for our products.Any actual or perceived quality issues may also result in issuances of physician' s advisories against our products or cause us to conduct voluntary recalls.Any product defects or problems,regulatory action,litigation,negative publicity or recalls could disrupt our business and have a material adverse effect on our business,results of operations,and financial condition.We may implement a product recall or voluntary market withdrawal,which could significantly increase our costs,damage our reputation and disrupt our business.The manufacturing,marketing,and processing of our products involve an inherent risk that our products or processes may not meet manufacturing specifications,applicable regulatory requirements or quality standards.In that event,we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.A recall or market withdrawal of

one of our products would be costly and would divert management resources.A recall or withdrawal of one of our products,or a similar product processed by another entity,also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal,or as a result of the damage to our reputation for quality and safety.We are subject to various governmental regulations relating to the labeling,marketing,and ~~sale of our products.Both before and after a product is commercially released,we have ongoing responsibilities under regulations promulgated by the FDA,the Federal Trade Commission,and similar U.S.and foreign regulations governing product labeling and advertising,distribution,sale,and marketing of our products.Manufacturers of medical devices~~ sale of our ~~Class regulatory requirements,subject us to government investigations or expose us to unexpected litigation.Any regulatory action or litigation,regardless of the merits,may result in substantial costs,divert management' s attention from other business concerns,and place additional restrictions on our sales or the use of our products.In addition,negative publicity,including regarding a quality or safety issue,could damage our reputation,reduce market acceptance of our products,cause us to lose customers,and decrease demand for our products.Any actual or perceived quality issues may also result in issuances of physician' s advisories against our products or cause us to conduct voluntary recalls.Any product defects or problems,regulatory action,litigation,negative publicity or recalls could disrupt our business and have a material adverse effect on our business,results of operations,and financial condition.We may implement a product recall or voluntary market withdrawal,which could significantly increase our costs,damage our reputation and disrupt our business.The manufacturing,marketing,and processing of our products involve an inherent risk that our products or processes may not meet manufacturing specifications,applicable regulatory requirements or quality standards.In that event,we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.A recall or market withdrawal of one of our products would be costly and would divert management resources.A recall or withdrawal of one of our products,or a similar product processed by another entity,also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal,or as a result of the damage to our reputation for quality and safety.We are subject to various governmental regulations relating to the labeling,marketing,and sale of our~~ products.Both before and after a product is commercially released,we have ongoing responsibilities under regulations promulgated by the FDA,the Federal Trade Commission,and similar U.S.and foreign regulations governing product labeling and advertising,distribution,sale,and marketing of our products.Manufacturers of medical devices and biological products are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. ~~A~~ **Traditionally,many of our wound dressing products have been marketed and,in some cases,specifically cleared,for use in " wound management;" however,the FDA is currently reconsidering whether wound dressings may continue to use that term in device labeling and promotional materials.On November 30,2023,the FDA issued a proposed rule that would prohibit wound dressings from using the term " wound management," a generally well- understood and accepted term in the healthcare community that describes a context of use.If the rule is finalized,we will be required to update the labeling and promotional material for many of our wound dressings which may make it more difficult to distinguish our wound dressings from competing wound care products.In addition,a** number of enforcement actions have been taken against manufacturers that promote products for ~~"~~ off-label ~~"~~ uses (i.e.,uses that are not described in the approved or cleared labeling),including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for ~~"~~ off- label ~~"~~ uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off- label promotion.The failure to comply with prohibitions on ~~"~~ off- label ~~"~~ promotion can result in significant monetary penalties,revocation or suspension of a company' s business license,suspension of sales of certain products,product recalls,civil or criminal sanctions,exclusion from participating in federal healthcare programs,or other enforcement actions.In the United States,allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S.government that imposes significant administrative obligations and costs.We and our employees and contractors are subject,directly or indirectly,to federal,state and foreign healthcare fraud and abuse laws,including false claims laws.If we are unable to comply,or have not fully complied,with such laws,we could face substantial penalties.Our operations are subject to various federal,state,and foreign fraud and abuse laws.These laws may constrain our operations,including the financial arrangements and relationships through which we market,sell,and distribute our products.U.S.federal and state laws that affect our ability to operate include,but are not limited to:• the federal Anti- Kickback Statute,which prohibits,among other things,persons or entities from knowingly and willfully soliciting,receiving,offering,or paying any remuneration (including any kickback,bribe,or rebate),directly or indirectly,overtly or covertly,in cash or in kind in return for,the purchase,recommendation,leasing or furnishing of an item or service reimbursable under a federal healthcare program,such as the Medicare and Medicaid programs;• the federal physician self- referral law,which prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member) has a financial relationship,for the furnishing of certain designated health services for which payment may be made by Medicare or Medicaid,unless an exception applies;• federal civil and criminal false claims laws and civil monetary penalty laws,which prohibit,among other things,individuals or entities from knowingly presenting,or causing to be presented,claims for payment or approval from Medicare,Medicaid,or other government payers that are false or fraudulent;• 18 U.S.C.§ 1347,which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program (i.e.,public or private);• federal transparency laws,including the Physician Payments Sunshine Act which requires the tracking and disclosure to the federal government by pharmaceutical and medical device manufacturers of payments and other transfers of value to physicians and teaching hospitals as well as ownership and investment interests that are held by physicians and their immediate family members;and • state law equivalents of each of these federal laws,such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payer,including commercial insurers;state laws that require pharmaceutical and medical device companies to comply with their industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict certain payments that may be made to healthcare

providers and other potential referral sources;state laws that require drug and medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures;state laws that prohibit giving gifts to licensed healthcare professionals;and state laws governing the privacy and security of health information in certain circumstances,many of which differ from each other in significant ways and may not have the same effect,thus complicating compliance efforts in certain circumstances,such as specific disease states.Activities and arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud,waste,and other abusive practices.These laws and regulations may restrict or prohibit a wide range of activities or other arrangements related to the development,marketing,or promotion of products,including pricing and discounting of products,provision of customer incentives,provision of reimbursement support,other customer support services,provision of sales commissions or other incentives to employees and independent contractors and other interactions with healthcare practitioners,other healthcare providers and patients.Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available,our business activities could be challenged under one or more of these laws.Relationships between medical product manufacturers and health care providers are an area of heightened scrutiny by the government.We engage in various types of activities,including the conduct of speaker programs to educate physicians,the provision of reimbursement advice and support to customers,and the provision of customer and patient support services,that have been the subject of government scrutiny and enforcement action within the medical device industry.Government expectations and industry best practices for compliance continue to evolve and our past activities may not always be consistent with current industry best practices.Further,there is a lack of government guidance as to whether many varied industry practices comply with these laws,and government interpretations of these laws continue to evolve,all of which create compliance uncertainties.Any non-compliance could result in regulatory sanctions,criminal or civil liability,and serious harm to our reputation.Although we have a comprehensive compliance program designed to ensure that our employees' and commercial partners' activities and interactions with healthcare professionals and patients are appropriate,ethical,and consistent with all applicable laws,regulations,guidelines,policies,and standards,it is not always possible to identify and deter misconduct,and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct,mitigating risks,or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.If a government entity opens an investigation into possible violations of any of these laws (which may include the issuance of subpoenas or civil investigative demands),we would have to expend significant resources to defend ourselves against the allegations.Allegations that we,our officers,or our employees violated any one of these laws can be made by individuals called ~~"~~ whistleblowers ~~"~~ who may be our employees,customers,competitors,or other parties.Government policy is to encourage individuals to become whistleblowers and file a complaint in federal court alleging wrongful conduct.The government is required to investigate all of these complaints and decide whether to intervene.If the government intervenes and we are required to pay money back to the government,the whistleblower,as a reward,is awarded a percentage of the collection.If the government declines to intervene,the whistleblower may proceed on their own and,if they are successful,they will receive a percentage of any judgment or settlement amount the company is required to pay.The government may also initiate an investigation on its own.Such actions could have a significant impact on our business,including the imposition of significant fines,and other sanctions that may materially impair our ability to run a profitable business.In particular,if our operations are found to be in violation of any of the laws described above or if we agree to settle with the government without admitting to any wrongful conduct or if we are found to be in violation of any other governmental regulations that apply to us,we,our officers and employees may be subject to sanctions,including civil and criminal penalties,damages,fines,exclusion from participation in government health care programs,such as Medicare and Medicaid,imprisonment,the curtailment or restructuring of our operations and the imposition of a corporate integrity agreement,any of which could adversely affect our business,results of operations,and financial condition.We could be subject to legal exposure if we do not report the average sales prices,or ASP,to government agencies or if our reporting is not accurate and complete.Our products are reimbursed by Medicare in physician office settings at a rate of ASP plus 6 %.All Medicare payments,including payments based on the ASP methodology,are subject to sequestration.Congress previously suspended sequestration imposed under the BCA,and there was no sequestration through March 31,2022.On April 1,2022,there was a 1 % sequestration and beginning on July 1,2022,the sequestration returned to 2 %.Sequestration applies to the government' s payment portion,which is 80 % of the total payment amount.Additionally,in future years,it is possible that an up- to 4 % Medicare sequestration could be ordered under Statutory PAYGO,which requires deficit neutrality in most laws passed by Congress.Until January 2022,we were not required to report ASP for all our skin substitute products that are paid separately as biologics because they are regulated as medical devices by the FDA,although we chose to report ASP for some of our products.Starting with the reporting deadline for the first quarter of 2022,we were required to report ASP for all our skin substitute products that are paid separately as biologics as a result of provisions included in the Consolidated Appropriations Act of 2020.As of January 1,2022,we began reporting ASP for all our skin substitute products that are paid separately as biologics.The first such ASP report was made on April 30,2022 for Q1 2022.Government price reporting requirements are complex.If we do not report ASP correctly,we may have to restate ASP for prior quarters and we could be subject to civil monetary penalties and / or,if the violation is knowing or reckless,be subject to False Claims Act liability.In the case of very serious or repeated violations,we could be excluded from doing business with the Medicare program and other federal healthcare programs.We face significant uncertainty in the industry due to government healthcare reform and other legislative action.There have been and continue to be laws enacted by the federal government,state governments,regulators,and third- party payers to control healthcare costs,and generally,to reform the healthcare system in the United States.For example,the ~~Patient Protection and Affordable Care Act of 2010 (" PPACA ")~~ and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers.These changes included the creation of demonstration programs and other value- based purchasing initiatives

that provide financial incentives for physicians and hospitals to reduce costs,including incentives for furnishing low- cost therapies for chronic wounds even if those therapies are less effective than our products.There were extensive efforts recently to modify or repeal all or part of PPACA.Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so- called ~~“~~ **"** individual mandate ~~”~~ **"**).Such actions or similar actions could have a negative effect on the utilization of our products.We expect such efforts to continue and that there may be additional reform proposals at federal and state levels.On December 18,2019,the United States Court of Appeals for the Fifth Circuit upheld a lower court’ s determination in California v.Texas (orig.Texas v.Azar,4:18- cv- 00167),that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law.The United States Supreme Court agreed to review the case and on June 17,2021,ordered that the Fifth Circuit’ s decision be reversed and that the case be dismissed.Additionally,on August 16,2022,Congress passed legislation to limit the price of drugs and ~~biological~~ **biologicals** under the Medicare program.The ~~Inflation Reduction Act (~~ IRA ~~)~~ establishes a Drug Price Negotiation Program that requires the Secretary of Health and Human Services to negotiate the price of certain high expenditure Medicare drugs that do not have generic or biosimilar competition.The law also establishes Medicare Part B inflationary rebates,effective Q1 2023.Generally,manufacturers of Part B drugs with an ASP 6 % that exceeds the inflation- adjusted payment amount from Q3 2021 will be required to pay a rebate to the Medicare program.These and similar drug pricing reforms could increase pricing pressure on our products.General legislative action may also affect our business.For example,the Budget Control Act of 2011 included provisions to reduce the federal deficit.The Budget Control Act,as amended,resulted in the imposition of reductions of up to 2 % in Medicare payments to providers which began in April 2013 and are scheduled to remain in effect through the first six months of 2032.The Coronavirus Aid,Relief,and Economic Security (CARES) Act and subsequent legislation suspended the payment adjustment from May 1,2020 through March 31,2022.There was 1 % Medicare sequestration from April 1 to June 30,2022,and the 2 % Medicare sequester was reinstated on July 1,2022.Additionally,under Statutory PAYGO,a 4 % Medicare sequester could be ordered at the end of the 2024 Congressional session.These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.Bills currently before the United States Congress may also affect our business,if enacted.For example,during the 117th Congressional session,the Cures 2.0 Act,H.R.6000,117th Cong.(2021) was introduced into the United States House of Representatives.If reintroduced in a similar form,it may contain provisions that could result in legal and regulatory changes that affect our business.These changes may include a new payment pathway for breakthrough medical devices that are FDA approved or cleared on or after a certain date.The enactment of Cures 2.0 (or similar legislation) may also accelerate FDA timelines for designation of breakthrough and RMAT therapies and also result in new requirements for the use of patient experience data and real- world evidence in regulating certain FDA products.If enacted,these changes could make it easier for our competitors to bring comparable or more advanced products to market quickly,resulting in reduced demand for our products.Our sales into foreign markets expose us to risks associated with international sales and operations.We are currently selling into foreign markets and plan to expand such sales.Managing a global organization is difficult,time- consuming,and expensive.Conducting international operations subjects us to risks that could be different from those faced by us in the United States.The sale and shipment of our products across international borders,as well as the purchase of components and products from international sources,subject us to extensive U.S.and foreign governmental trade,import and export and customs regulations and laws,including but not limited to,the Export Administration Regulations and trade sanctions against embargoed countries,which are administered by the Office of Foreign Assets Control within the Department of the Treasury,as well as the laws and regulations administered by the Department of Commerce.These regulations limit our ability to market,sell,distribute,or otherwise transfer our products or technology to prohibited countries or persons.Compliance with these regulations and laws is costly,and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include,but are not limited to,significant criminal,civil,and administrative penalties,including imprisonment of individuals,fines and penalties,denial of export privileges,seizure of shipments and restrictions on certain business activities.Also,the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.These risks may limit or disrupt our expansion,restrict the movement of funds,or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation.Operating in international markets also requires significant management attention and financial resources.We could be adversely affected by violations of the U.S.Foreign Corrupt Practices Act and similar worldwide anti- bribery laws.The U.S.Foreign Corrupt Practices Act,or FCPA,the U.K.Bribery Act of 2010,and similar anti- bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business.Our policies mandate compliance with these anti- bribery laws,including the requirements to maintain accurate information and internal controls.We operate in many parts of the world that have experienced governmental corruption to some degree and in certain circumstances,strict compliance with anti- bribery laws may conflict with local customs and practices.There is no assurance that our internal control policies and procedures will protect us from acts committed by our employees or agents.If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence,or due to the acts or inadvertence of others),we could suffer from civil and criminal penalties or other sanctions,including contract cancellations or debarment,and loss of reputation,any of which could have a material adverse impact on our business,financial condition,and results of operations.Risks Related to Reimbursement for our Products The rate of reimbursement and coverage for the purchase of our products by government and private insurance is subject to change.Sales of almost all of our products depend partly on the ability of our customers to obtain reimbursement for the cost of our products under government healthcare programs such as Medicare and Medicaid and from other global government authorities.Government healthcare programs and private health plans continuously seek to reduce healthcare costs.For example,in 2014,Medicare established a policy to stop

making separate payment for our products in certain clinical settings.This policy required us to reduce prices for our products which caused significant reduction in our revenue.Our success will depend in part on the extent to which coverage and adequate reimbursement for the costs of such products and related treatments will be available from government health administration authorities,private health insurers,and other third- party payers and we do not know whether such reimbursement will be available.For example,currently most private payers provide limited coverage for our PuraPly AM,PuraPly,Novachor,and NuShield products and as a result,there is limited use of these products for patients covered by private payers.The continuing efforts of government agencies,private health plans,and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:• the availability of our products due to restricted coverage;• the ability of our customers to pay for our products;• our ability to maintain pricing so as to generate revenues or achieve or maintain profitability;and • our ability to access capital.The proposed updates to the MPFS for calendar year 2023 included a proposal to stop making separate payments for all skin substitutes,including all of our products,in 2024 or 2025.Instead of making separate payment for skin substitutes,Medicare would bundle the payment for skin substitutes into the payment made for the application procedure.As part of this proposal,Medicare would consider all skin substitutes to be supplies instead of biologicals and would require manufacturers of skin substitutes,including us,to apply for new HCPCS codes that would be effective starting in 2024.In the 2023 MPFS final rule,published on November 1,2022,CMS did not finalize this bundling proposal and will consider more public input in the future;however,they may propose the same policy again or make other proposals in the future that could affect our business and our revenue.If Medicare reproposes and finalizes a policy to stop making separate payment for skin substitutes in calendar year 2024 or calendar year 2025,reimbursement for our products may not be adequate and our business,results of operations,and financial condition may be negatively affected.Payers are increasingly attempting to contain healthcare costs by limiting both the breadth of coverage and the level of reimbursement,particularly for new therapeutic products generally or specifically for new therapeutic products that target an indication that is perceived to be well served by existing treatments.Specifically,the Patient Protection and Affordable Care Act,or PPACA,enacted in 2010,contains provisions for Medicare demonstration programs that create financial incentives to treat patients with chronic wounds conservatively and not use our products.Furthermore,all our products are not paid separately in the outpatient hospital setting which is our largest customer base.This payment policy has created incentives to use our competitors' products.Accordingly,even if coverage and reimbursement are provided,market acceptance of our products has been and will be adversely affected if access to coverage is administratively burdensome to obtain and / or use of our products is administratively burdensome or unprofitable for healthcare providers or less profitable than alternative treatments.In addition,Medicare,which is the major source of revenue for most of our customers,reimburses the same amounts for most of our products and the products of our competitors targeting the same indications in the hospital outpatient setting.Because in some sites of care,the reimbursement amount is not based on the cost we charge our customers for our products or the cost our competitors charge for products targeting the same indication,our customers may elect to use products cheaper than ours in order to increase their margins,which could have a material adverse effect on our business,results of operations,and financial condition.Reimbursement from Medicare,Medicaid,and other third-party payers is usually adjusted yearly as a result of legislative,regulatory,and policy changes as well as budgetary pressures.In fact,Medicare has signaled that it may discontinue its two- tier bundling policy when it solicited comments on alternatives in its calendar year 2019 rulemaking.Changes in the policy could occur as early as calendar year ~~2023~~ **2024** and could include the establishment of a single bundle for all products which could place our products at a significant competitive disadvantage.Possible reductions in,or eliminations of,coverage or reimbursement by third- party payers,or the denial of,or provision of uneconomical reimbursement for new products,as a result of these changes may affect our customers' revenue and ability to purchase our products.Any changes in the healthcare regulatory,payment,or enforcement landscape relative to our customers' healthcare services also have the potential to significantly affect our operations and revenue.In addition,Medicare uses regional contractors called Medicare Administrative Contractors,or MACs,to process claims,develop coverage policies and make payments within designated geographic jurisdictions.While our products are currently covered by most MACs,we cannot be certain they will be in the future.Wound care supplies,such as our product line acquired from CPN Biosciences,are subject to coding verification from CMS' s Pricing,Data Analysis and Coding contractor (the ~~"~~ PDAC ~~"~~).The PDAC is responsible for verifying the HCPCS Level II DMEPOS Codes for all wound care supplies.Our current wound care supplies sold through CPN have received coding verification from the PDAC and all products have HCPCS Level II codes.Additional wound care supplies that we develop or acquire will also be subject to the PDAC coding verification process.We cannot guarantee the outcome of the PDAC coding verification process.If we are unsuccessful in receiving verification of the applicable HCPCS codes for our products,our wound care supplies could be ineligible for reimbursement or reimbursed at a lower rate than appropriate for our supplies.While we cannot predict the outcome of current or future legislation,we anticipate,particularly given the recent focus on healthcare reform legislation,that governmental authorities will continue to introduce initiatives directed at lowering the total cost of healthcare and restricting coverage and reimbursement for our products.If we are not successful in obtaining adequate reimbursement for our products from third- party payers,the market' s acceptance of our products could be adversely affected.Inadequate reimbursement levels also likely would create downward price pressure on our products.Even if we do succeed in obtaining widespread reimbursement for our products,future changes in reimbursement policies could have a negative impact on our business,financial condition and results of operations.The rate of reimbursement and coverage for the purchase of our products by government and private insurance (including by Medicare Administrative Contractors) is subject to uncertainty.Our products are subject to varying forms of governmental and private payor reimbursement,and fluctuations in these forms of payment may adversely affect our business.For example,in sites of service where payment for skin substitutes is based on the ASP methodology,Medicare pays for skin substitutes separately from the application procedure.In this case,the Medicare payment rate for all skin substitutes (including ours) is calculated on a per square centimeter basis.These rates are adjusted quarterly based on manufacturer ASP reporting,and the payment amount is ASP plus 6 % **when Medicare includes**

our ASP in its quarterly ASP file;when ASP data is not available in the quarterly ASP file , MACs may ask CMS what the ASP is or they may reimburse at WAC plus 3 %,or invoice pricing.All Medicare payment amounts,including **separate payments under the ASP methodology,are subject to sequestration.The Medicare sequestration of 2 %,under the BCA,was temporarily suspended and that suspension continued through March 31,2022.On April 1,2022,the sequestration became 1 % and it returned to 2 % as of July 1,2022.Additionally,under Statutory PAYGO,a 4 % Medicare sequester could be ordered at the end of the 2024 Congressional session.Before January 2022,the Medicare statute did not require us to report ASP for our products because they are regulated by the FDA as medical devices.However,starting with the reporting deadline for the first quarter of 2022,we were required to report ASP for our products based on a provision within the Consolidated Appropriations Act of 2020,signed into law on December 27,2020.When ASP data are not available in the quarterly ASP file published by CMS (for instance our Affinity product in the fourth quarter of 2021),the Part** A ~~common stock setting.Because in some sites of care,the reimbursement amount is not based on the cost we charge our customers for our products or the cost our competitors charge for products targeting the same indication,our customers may elect to use products cheaper than ours in order to increase their margins,which could have a material adverse effect on our business,results of operations,and financial condition.Reimbursement from Medicare,Medicaid,and other third- party payers is usually adjusted yearly as a result of legislative,regulatory,and policy changes as well as budgetary pressures.In fact,Medicare has signaled that it may discontinue its two- tier bundling policy when it solicited comments on alternatives in its calendar year 2019 rulemaking.Changes in the policy could occur as early as calendar year 2023 and could include the establishment of a single bundle for all products which could place our products at a significant competitive disadvantage.Possible reductions in,or eliminations of,coverage or reimbursement by third- party payers,or the denial of,or provision of uneconomical reimbursement for new products,as a result of these changes may affect our customers' revenue and ability to purchase our products.Any changes in the healthcare regulatory,payment,or enforcement landscape relative to our customers' healthcare services also have the potential to significantly affect our operations and revenue.In addition,Medicare uses regional contractors called Medicare Administrative Contractors,or MACs,to process claims,develop coverage policies and make payments within designated geographic jurisdictions.While our products are currently covered by most MACs,we cannot be certain they will be in the future.Wound care supplies,such as our product line acquired from CPN Biosciences,are subject to coding verification from CMS' s Pricing,Data Analysis and Coding contractor (the " PDAC ").The PDAC is responsible for verifying the HCPCS Level II DMEPOS Codes for all wound care supplies.Our current wound care supplies sold through CPN have received coding verification from the PDAC and all products have HCPCS Level II codes.Additional wound care supplies that we develop or acquire will also be subject to the PDAC coding verification process.We cannot guarantee the outcome of the PDAC coding verification process.If we are unsuccessful in receiving verification of the applicable HCPCS codes for our products,our wound care supplies could be ineligible for reimbursement or reimbursed at a lower rate than appropriate for our supplies.While we cannot predict the outcome of current or future legislation,we anticipate,particularly given the recent focus on healthcare reform legislation,that governmental authorities will continue to introduce initiatives directed at lowering the total cost of healthcare and restricting coverage and reimbursement for our products.If we are not successful in obtaining adequate reimbursement for our products from third- party payers,the market' s acceptance of our products could be adversely affected.Inadequate reimbursement levels also likely would create downward price pressure on our products.Even if we do succeed in obtaining widespread reimbursement for our products,future changes in reimbursement policies could have a negative impact on our business,financial condition and results of operations.The rate of reimbursement and coverage for the purchase of our products by government and private insurance (including by Medicare Administrative Contractors) is subject to uncertainty.Our products are subject to varying forms of governmental and private payor reimbursement,and fluctuations in these forms of payment may adversely affect our business.For example,in sites of service where payment for skin substitutes is based on the ASP methodology,Medicare pays for skin substitutes separately from the application procedure.In this case,the Medicare payment rate for all skin substitutes (including ours) is calculated on a per square centimeter basis.These rates are adjusted quarterly based on manufacturer ASP reporting,and the payment amount is ASP plus 6 %,WAC plus 3 %,or invoice pricing.All Medicare payment amounts,including separate payments under the ASP methodology,are subject to sequestration.The Medicare sequestration of 2 %,under the BCA,was temporarily suspended and that suspension continued through March 31,2022.On April 1,2022,the sequestration became 1 % and it returned to 2 % as of July 1,2022.Additionally,under Statutory PAYGO,a 4 % Medicare sequester could be ordered at the end of the 2024 Congressional session.Before January 2022,the Medicare statute did not require us to report ASP for our products because they are regulated by the FDA as medical devices.However,starting with the reporting deadline for the first quarter of 2022,we were required to report ASP for our products based on a provision within the Consolidated Appropriations Act of 2020,signed into law on December 27,2020.When ASP data are not available in the quarterly ASP file published by CMS (for instance our Affinity product in the fourth quarter of 2021),the Part A~~ / B MACs establish payment for drugs and biologics in their jurisdiction (s).In these situations,MACs can update their reimbursement methodology as frequently as quarterly,without notice.MACs also have the discretion to establish coverage policies for all skin substitute products (including ours).Accordingly,even if coverage and reimbursement are provided,market acceptance of our products has been and will be adversely affected if access to coverage is administratively burdensome to obtain,use of our products is administratively burdensome,or is unprofitable for healthcare providers or less profitable than alternative treatments.Furthermore,Medicare has signaled that it may revise its two- tiered bundled payment policy for skin substitutes.Medicare solicited comments in rulemaking for calendar year 2019 related to proposed updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center ~~(ASC)~~ Payment System.Medicare specifically solicited comments on whether it should eliminate the two- tiered bundle policy and establish a single bundle for all products.However,Medicare did not make any changes to its two- tiered payment policy in response to those comments.If CMS proposes and finalizes any revisions to its two- tiered

payment policy,those changes could result in decreased reimbursement for our products which could decrease utilization and reduce our revenues.Moreover,any new policy could result in a financial incentive for hospitals and ASCs to use our competitor' s products,thereby reducing our market share and **revenue.Three MACs recently withdrew LCDs for skin substitutes and / or CTPs for the treatment of DFUs and VLUs in the Medicare population that would have eliminated coverage for certain of our products as of October 1,2023.Had these LCDs taken effect or if new LCDs are adopted and take effect in the future that eliminate or reduce coverage for our products,it could have a material adverse effect on utilization of our products,our business and our revenue.On August 3,2023,three MACs (Novitas,First Coast Services,and CGS) published final LCDs for skin substitutes and CTPs for the treatment of DFUs and VLUs in the Medicare population that would have eliminated coverage for our PuraPly,Novachor,TransCyte,Affinity and NuShield products as of October 1,2023.These LCDs were withdrawn by the MACs on September 28,2023 and our products remain covered.Had coverage for these products been eliminated,it would have presented a significant amount of uncertainty regarding (i) future revenue for the affected products in the applicable regions and (ii) the potential impact on demand for our products when used for treatment of non- DFU / VLU wounds.While in this case the LCDs were ultimately withdrawn before they took effect,there is no guarantee that the MACs will not adopt new LCDs in the future that could eliminate or reduce coverage for our products.If new LCDs are adopted in the future that eliminate or reduce coverage for our products and we are unable to convince the MACs to withdraw them,it could materially and adversely impact utilization of our products,our business,and our** revenue.Cost- containment efforts of our customers,purchasing groups,third- party payers,and governmental organizations could adversely affect our business,results of operations,and financial condition.Many existing and potential customers for our products within the United States are members of GPOs and / or IDNs,including accountable care organizations or public- based purchasing organizations,and our business is partly dependent on major contracts with these organizations.Our products can be contracted under national tenders or with larger hospital GPOs.GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members.GPOs and IDNs typically award contracts on a category- by-category basis through a competitive bidding process.At any given time,we are typically at various stages of responding to bids and negotiating and renewing GPO and IDN agreements,including agreements that would otherwise expire.Bids are generally solicited from multiple manufacturers or service providers with the intention of obtaining lower pricing.Due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the United States,we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our product portfolio.Failure to be included in certain of these agreements could have a material adverse effect on our business,financial condition and results of operations.In addition,while having a contract with a major purchaser,such as a GPO or IDN,for a given product category can facilitate sales,sales volumes of those products may not be maintained.For example,GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category.Even when we are the sole contracted supplier of a GPO or IDN for a certain product category,members of the GPO or IDN generally are free to purchase from other suppliers.Furthermore,GPO and IDN contracts typically are terminable without cause upon 60 to 90 days' notice.The healthcare industry has been consolidating,and the consolidation among third- party payers into larger purchasing groups will increase their negotiating and purchasing power.Such consolidation may result in greater pricing pressure on us due to pricing concessions and may further exacerbate the risks described above.Risks Related to Our Intellectual Property Our ability to compete effectively will depend,in part,on our ability to maintain the proprietary nature of our technology and manufacturing processes.We rely on manufacturing and other know- how,patents,trade secrets,trademarks,license agreements,and contractual provisions to establish our intellectual property rights and protect our products.These legal means,however,afford only limited protection and may not adequately protect our rights.The failure to obtain,maintain,enforce,or defend such intellectual property rights,for any reason,could allow third parties to make competing products or impact our ability to develop,manufacture and market our own products on a commercially viable basis,or at all,which could have a material adverse effect on our revenues,financial condition or results of operations.In particular,we rely primarily on trade secrets,know- how,and other unpatented technology,which are difficult to protect.Although we seek such protection in part by entering into confidentiality agreements with our vendors,employees,consultants,and others who may have access to proprietary information,we cannot be certain that these agreements will not be breached,adequate remedies for any breach would be available or our trade secrets,know- how,and other unpatented proprietary technology will not otherwise become known to or be independently developed by our competitors.If we are unsuccessful in protecting our intellectual property rights,sales of our products may suffer and our ability to generate revenue could be severely impacted.We have filed applications to register various trademarks for use in connection with our products in various countries and also,with respect to certain products,rely on the trademarks of third parties.These trademarks may not afford adequate protection.We or these third parties also may not have the financial resources to enforce the rights under these trademarks which may enable others to use the trademarks and dilute their value.Additionally,our marks may be found to conflict with the trademarks of third parties.In such a case,we may not be able to derive any value from such trademarks or,even,may be required to cease using the conflicting mark.The value of our trademarks may also be diminished by our own actions,such as failing to impose appropriate quality control when licensing our trademarks.Any of the foregoing could impair the value of,or ability to use,our trademarks and have an adverse effect on our business.Most of the key patents related to our marketed products are expired.We have no patent protection covering,for example,our Apligraf,Dermagraft,or NuShield products.However,in addition to trade secrets,trademarks,know- how,and other unpatented technology,we have pursued and plan to continue to pursue patent protection where we believe that doing so offers potential commercial benefits.However,we may be incorrect in our assessments of whether or when to pursue patent protection.Moreover,patents may not issue from any of our pending patent applications.Even if we obtain or in- license issued patents,such patent rights may not provide valid patent protection sufficiently broad to prevent any third party from developing,using,or commercializing products that are similar or

functionally equivalent to our products or technologies,or otherwise provide any competitive advantage.In addition,these patent rights may be challenged,revoked,invalidated,infringed,or circumvented by third parties.Laws relating to such rights may in the future be changed or withdrawn in a manner adverse to us.Additionally,our products or the technologies or processes used to formulate or manufacture our products may now,or in the future,infringe the patent rights of third parties.It is also possible that third parties will obtain patent or other proprietary rights that might be necessary or useful for the development,manufacture,or sale of our products.In such cases,we may need or choose to obtain licenses for intellectual property rights from others and it is possible that we may not be able to obtain these licenses on commercially reasonable terms,if at all.Pending and future intellectual property litigation could be costly and disruptive and may have an adverse effect on our business,results of operations,and financial condition.We operate in an industry characterized by extensive intellectual property litigation.Defending intellectual property litigation is expensive and complex,takes significant time and diverts management' s attention from other business concerns,and the outcomes are difficult to predict.We have in the past been subject to claims that our products or technology violate a third party' s intellectual property rights,and we may be subject to such assertions in the future.Any pending or future intellectual property litigation may result in significant damage awards,including treble damages under certain circumstances,and injunctions that could prevent the manufacture and sale of affected products or could force us to seek a license and / or make significant royalty or other payments in order to continue selling the affected products.Such licenses may not be available on commercially reasonable terms,if at all.We have in the past and may in the future choose to settle disputes involving third- party intellectual property by taking a license.Such licenses or other settlements may involve,for example,upfront payments,yearly maintenance fees and royalties.At any given time,we may be involved as either a plaintiff or a defendant in a number of intellectual property actions,the outcomes of which may not be known for prolonged periods of time.A successful claim of patent or other intellectual property infringement or misappropriation against us could materially adversely affect our business,results of operations,and financial condition.We may be subject to damages resulting from claims that we,our employees,or our independent contractors have wrongfully used or disclosed alleged trade secrets,proprietary or confidential information of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors.Some of our employees were previously employed at other medical device,pharmaceutical,or biotechnology companies.We may also hire additional employees who are currently employed at other medical device,pharmaceutical,or biotechnology companies,including our competitors.Additionally,consultants or other independent agents with whom we may contract may be or have been in a contractual arrangement with one or more of our competitors.Although no claims are currently pending,we may be subject to claims that we,our employees,or our independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors.In addition,we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement.Litigation may be necessary to defend against these claims.Even if we are successful in defending against these claims,litigation could result in substantial costs and be a distraction to management.If we fail to defend such claims,in addition to paying monetary damages,we may lose valuable intellectual property rights or personnel.There can be no assurance that this type of litigation will not occur,and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives,or other personnel.A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products,which could severely harm our business.We may become involved in lawsuits to protect or enforce our patents or other intellectual property,which could be expensive,time- consuming,and ultimately unsuccessful.Competitors may infringe or misappropriate the patents or other intellectual property that we own or license.In response,we may be required to file infringement claims,which can be expensive and time- consuming.Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us,such as alleging that we infringe their patents.In addition,in a patent infringement proceeding,a court may decide that a patent that we own or license is invalid or unenforceable,in whole or in part,construe the patent' s claims narrowly or conclude that there is no infringement.An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to the patents or patent applications that we own or license.An unfavorable outcome could require us to cease using the invention or attempt to license rights to it from the prevailing party.Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms.Our defense of litigation or interference proceedings may fail and,even if successful,may result in substantial costs and distract our management and other employees.We may not be able to prevent,alone or with our licensors,misappropriation of our intellectual property rights,particularly in countries where the laws may not protect those rights as fully as in the United States.If we are unable to protect the confidentiality of our trade secrets and know- how,our business and competitive position would be harmed.We seek to protect our proprietary technology and processes,in part,by entering into confidentiality and assignment of inventions agreements with our employees,consultants,scientific advisors,and contractors.We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.Despite our efforts,agreements may be breached and security measures may fail,and we may not have adequate remedies for any breach or failure.In addition,our trade secrets and know- how may otherwise become known or be independently discovered by competitors.Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult,expensive,and time- consuming,and the outcome is unpredictable.In addition,some courts inside and outside the United States are less willing or unwilling to protect trade secrets.Moreover,if any of our trade secrets were to be lawfully obtained or independently developed by a competitor,we would have no right to prevent them,or those to whom they communicate it,from using that technology or information to compete with us.If any of our trade secrets were to be disclosed to or independently developed by a competitor,our competitive position would be harmed.We may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or

license.We may be subject to claims that former employees,collaborators,or other third parties have an ownership interest in the patents and intellectual property that we own or license.While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements obligating them to assign such intellectual property to us,we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own;our licensors may face similar obstacles.We could be subject to ownership disputes arising,for example,from conflicting obligations of consultants or others who are involved in developing our product candidates.Litigation may be necessary to defend against any claims challenging inventorship or ownership.If we fail in defending any such claims,we may have to pay monetary damages and may lose valuable intellectual property rights,such as exclusive ownership of,or right to use,intellectual property,which could adversely impact our business,results of operations,and financial condition.Obtaining and maintaining patent protection depends on compliance with various procedural,document submission,fee payment and other requirements imposed by governmental agencies,and our patent protection could be reduced or eliminated for non- compliance with these requirements.Periodic maintenance fees,renewal fees,annuity fees,and other fees on patents and patent applications will be **due to be paid to the U.S.Patent and Trademark Office and similar foreign agencies in several stages over the lifetime of the patents and patent applications.We rely on our outside counsel to pay these fees due to foreign patent agencies.The U.S.Patent and Trademark Office and various foreign patent agencies require compliance with a number of procedural,documentary,fee payment,and other provisions during the patent application process.We employ law firms and other professionals to help us comply,and in many cases,an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules.However,there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application,resulting in partial or complete loss of patent rights in the relevant jurisdiction.In such an event,potential competitors might be able to enter the market,which could have a material adverse effect on our business,results of operations,and financial condition.Changes in U.S.patent law could diminish the value of patents in general,thereby impairing our ability to protect our products.Success in the biopharmaceutical industry is heavily dependent on intellectual property,particularly patents.Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity,and therefore obtaining and enforcing pharmaceutical patents is costly,time- consuming,and inherently uncertain.Recent patent reform legislation could increase the uncertainties and costs of prosecuting patent applications and enforcing and defending patents.Enacted in 2011,the Leahy- Smith America Invents Act,or the Leahy-Smith Act,made significant changes to U.S.patent law,including provisions that affect the prosecution of patent applications and also affect patent litigation.The U.S.Patent and Trademark Office developed new regulations and procedures to govern administration of the Leahy- Smith Act,and many of the substantive changes to patent law associated with the Leahy- Smith Act,including the first to file provisions,only became effective in March 2013.The full impact of the Leahy- Smith Act on our business is not yet clear,but it could result in increased costs and more limited patent protection,either of which could adversely affect our business,results of operations,and financial condition.Moreover,recent U.S.Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations.In addition to increasing uncertainty regarding our ability to obtain patents in the future,this combination of events has created uncertainty regarding the value of any patents we do obtain.Depending on decisions by the U.S.Congress,the federal courts,and the U.S.Patent and Trademark Office,the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any current or future patents that we may own or license.Risks Related to Our Indebtedness Our indebtedness could have a material adverse effect on our business,results of operations,and financial condition.As of December 31,2023,we had approximately $ 66.6 million of aggregate principal amount of indebtedness outstanding under our 2021 Credit Agreement** . Our 2021 Credit Agreement requires that we comply with certain financial covenants that include Consolidated Fixed Charge Coverage Ratio and Consolidated Total Net Leverage Ratio, tested quarterly. If we are unable to meet these financial covenants ~~due to the economic impact of COVID- 19 or otherwise~~ , the borrowings under the 2021 Credit Agreement may become due and payable immediately unless we obtain an amendment from our lenders and we would be prohibited from making any borrowings under the Revolving Facility **(see" Indebtedness- 2021 Credit Agreement")** . There can be no assurance that our lenders would agree to any such amendment on acceptable terms, or at all. In addition, any sustained disruption in the capital markets..... or clearances, companies such as ours - **our** have ongoing regulatory obligations that are expensive..... under our 2021 Credit Agreement. Our indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness and could have other important consequences to our debt holders and significant effects on our business. For example, it could: • increase our vulnerability to adverse changes in general economic, industry, and competitive conditions; • require us to dedicate a substantial portion of our cash flow from operations to making payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures, and other general corporate purposes; • limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; • expose us to the risk of increased interest rates as certain of our borrowings are at variable rates, and we may not be able to enter into interest rate swaps and any swaps we enter into may not fully mitigate our interest rate risk; • restrict us from capitalizing on business opportunities; • make it more difficult to satisfy our financial obligations, including payments on our indebtedness; • place us at a competitive disadvantage compared to our competitors that have less debt; and limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy, or other general corporate purposes. In addition, the credit agreements governing our senior secured credit facilities collateralize substantially all of our personal property and assets, including our intellectual property, and contain restrictive covenants that limit our ability to engage in activities that may be in our long- term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or

waived, could result in the acceleration of all of our indebtedness. Despite our current level of indebtedness, we may incur substantially more debt. This could further exacerbate the risks associated with our substantial leverage. We may incur significant additional indebtedness in the future. Although the credit agreements governing our senior secured and subordinated credit facilities limit our ability and the ability of our present and future subsidiaries to incur additional indebtedness, the terms of the senior secured and subordinated credit facilities permit us to incur significant additional indebtedness under certain circumstances. In addition, the credit agreements governing our senior secured and subordinated credit facilities do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risk associated with our substantial indebtedness described above, including our potential inability to service our debt, will increase. We will require a significant amount of cash to service our debt, and our ability to generate cash depends on many factors beyond our control, and any failure to meet our debt service obligations could materially adversely affect our business, results of operations, and financial condition. Our ability to make payments on and to refinance our indebtedness and to fund working capital needs and planned capital expenditures will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, business, legislative, regulatory, and other factors that are beyond our control. If our business does not generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to enable us to pay our indebtedness or to fund our other liquidity needs, we may need to refinance all or a portion of our indebtedness on or before the maturity thereof, sell assets, reduce or delay capital investments or seek to raise additional capital, any of which could have a material adverse effect on our business, results of operations, and financial condition. In addition, we may not be able to effect any of these actions, if necessary, on commercially reasonable terms or at all. Our ability to restructure or refinance our indebtedness will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. The terms of existing or future debt instruments, including the credit agreements governing our senior and subordinated secured credit facilities, may limit or prevent us from taking any of these actions. In addition, any failure to make scheduled payments of interest and principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could harm our ability to incur additional indebtedness on commercially reasonable terms or at all. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would have an adverse effect, which could be material, on our business, results of operations, and financial condition, as well as on our ability to satisfy our obligations in respect of the senior and subordinated secured credit facilities and our other indebtedness. Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in an event of default that could materially adversely affect our business, results of operations, and financial condition. If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately. We cannot guarantee that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our indebtedness under our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. In addition, any event of default or declaration of acceleration under one debt instrument could also result in an event of default under one or more of our other debt instruments. As a result, any default by us on our indebtedness could have a material adverse effect on our business, results of operations, and financial condition. The credit agreements governing our senior secured credit facility and our subordinated credit facility restrict our current and future operations, particularly our ability to respond to changes or to take certain actions. The credit agreements governing our senior secured credit facility and our subordinated credit facility are collateralized by substantially all of our assets, including our intellectual property, and impose significant operating and financial restrictions and limit our ability and our other restricted subsidiaries' ability to, among other things: • incur additional indebtedness for borrowed money and guarantee indebtedness; • pay dividends or make other distributions in respect of, or repurchase or redeem, capital stock; • enter into any new line of business not reasonably related to our existing business; • prepay, redeem or repurchase certain debt; • make loans and investments; • sell or otherwise dispose of assets; • incur liens; • enter into transactions with affiliates; and • enter into agreements restricting our subsidiaries' ability to pay dividends; and consolidate, merge or sell all or substantially all of our assets. As a result of these covenants and restrictions, we are and will be limited in how we conduct our business, and we may be unable to raise additional debt or equity financing to compete effectively or to take advantage of new business opportunities. In addition, our senior secured credit facility requires us to comply with a minimum consolidated revenue covenant (measured on a trailing twelve- month basis) and a minimum monthly liquidity ratio (measured as of the last day of each month). The operating and financial restrictions and covenants in the senior secured credit facility, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. For example, in the past, we have not been in compliance with certain financial covenants in our debt agreements, which may occur again in the future. We cannot guarantee that we will be able to maintain compliance with these covenants in the future and, if we fail to do so, that we will be able to obtain waivers from the lenders and / or amend the covenants. Our failure to comply with the restrictive covenants described above as well as others contained in our future debt instruments from time to time could result in an event of default, which, if not cured or waived, could result in our being required to repay these borrowings before their due date. If we are forced to refinance these borrowings on less favorable terms, our business, results of operations, and financial condition could be adversely affected. Risks Related to Our Class A Common Stock The Significant Stockholder Group exercises significant control over us, and their interests may conflict with yours in the future. Alan A. Ades, Albert Erani, Glenn H. Nussdorf, Dennis Erani, Starr Wisdom, and certain of their respective affiliates, including Organo PFG LLC, Organo

Investors LLC, Dennis Erani 2012 Issue Trust, Alan Ades as Trustee of the Alan Ades 2014 GRAT, Albert Erani Family Trust dated 12 / 29 / 2012, GN 2016 Family Trust u / a / d August 12, 2016, GN 2016 Organo 10- Year GRAT u / a / d September 30, 2016 and RED Holdings, LLC, who we refer to collectively as the Significant Stockholder Group, control a significant amount of the voting power of the outstanding Class A common stock. As of February ~~15~~ **26**, ~~2023~~ **2024**, the Significant Stockholder Group collectively beneficially owns approximately ~~45~~ **46** % of the Company' s Class A common stock. As a result of this voting control, the Significant Stockholder Group collectively can effectively determine the outcome of all matters requiring stockholder approval, including, but not limited to, the election and removal of the Company' s directors (including the right to designate four of our directors pursuant to the terms of an agreement between the Company and the Significant Stockholder Group), as well as other matters of corporate or management policy (such as potential mergers or acquisitions, payment of dividends, asset sales, and amendments to the Company' s certificate of incorporation and bylaws). This concentration of ownership may delay or deter possible changes in control and limit the liquidity of the trading market for the Company' s Class A common stock, which may reduce the value of an investment in its Class A common stock. This voting control could also deprive stockholders of an opportunity to receive a premium for their shares of Class A common stock as part of a potential sale of the Company. So long as the Significant Stockholder Group and their affiliates continue to own a significant amount of the Company' s combined voting power, they may continue to be able to strongly influence or effectively control its decisions. The interests of the Significant Stockholder Group and their affiliates may not coincide with the interests of other holders of the Company Class A common stock. In the ordinary course of their business activities, the Significant Stockholder Group and their affiliates may engage in activities where their interests conflict with our interests or those of our other stockholders. In addition, the Significant Stockholder Group may have an interest in pursuing acquisitions, divestitures, and other transactions that, in their judgment, could enhance their investment, even though such transactions might involve risks to you. Our stock price has been, and is likely to continue to be, volatile. Fluctuations in revenue or results of operations could cause additional volatility in our stock price and thus our stockholders could incur substantial losses. Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies ~~, which in some cases has been exacerbated by the COVID- 19 pandemic~~. Any unanticipated shortfall in our revenue in any fiscal quarter could have an adverse effect on our results of operations in that quarter. The effect on our net income of such a shortfall could be exacerbated by the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future. Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation, as we are and as disclosed in Item 3, ~~“~~ **"** Legal Proceedings ~~”~~ **"**. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time- consuming, and could divert our management' s attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our Class A common stock. The Company bylaws designate the Court of Chancery of the State of Delaware, to the fullest extent permitted by law, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by the Company stockholders, which could limit the ability of the Company stockholders to obtain a favorable judicial forum for disputes with the Company or with directors, officers or employees of the Company and may discourage stockholders from bringing such claims. Under the Company bylaws, unless the Company consents in writing to the selection of an alternative forum, the sole and exclusive forum will be the Court of Chancery of the State of Delaware for: • any derivative action or proceeding brought on behalf of the Company; • any action asserting a claim of breach of a fiduciary duty owed by, or any wrongdoing by, any director, officer or employee of the Company to the Company or the Company' s stockholders; • any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation (including as it may be amended from time to time), or the bylaws; • any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or • any action asserting a claim governed by the internal affairs doctrine, in each case, except for, (1) any action as to which the Court of Chancery determines that there is an indispensable party not subject to the personal jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination) and (2) any action asserted under the Securities Exchange Act of 1934, as amended, or the rules and regulations promulgated thereunder, for which federal courts have exclusive jurisdiction. These provisions of the Company' s certificate of incorporation and bylaws could limit the ability of the Company stockholders to obtain a favorable judicial forum for certain disputes with the Company or with its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers, and employees. Alternatively, if a court were to find these provisions of the Company' s certificate of incorporation or bylaws inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings listed above including, without limitation, any actions asserted under the Securities Act of 1933, as amended, the Company may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect its business, financial condition and results of operations. In addition, there is uncertainty as to whether a court would enforce the Company' s forum selection provision with respect to any actions asserted under the Securities Act of 1933, as amended, as investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Provisions in the Company' s charter may inhibit a takeover of the Company, which could limit the price investors might be willing to pay in the future for the Company' s Class A common stock and could entrench management. The Company' s certificate of incorporation contains provisions that may discourage unsolicited takeover

proposals that shareholders may consider to be in their best interests. These provisions include the ability of the Board of Directors to designate the terms of and issue new series of preferred shares, which may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for the Company' s securities. General Risk Factors We are currently and in the future may be, subject to securities class action litigation or other litigation that could cause us to incur significant legal expenses, divert management' s attention, and result in harm to our business. We are exposed to potential liabilities and reputational risk associated with securities class action litigation. We are party to a securities class action lawsuit as disclosed in Item 3, " Legal Proceedings ". We may be subject to additional lawsuits, including class action or securities derivative lawsuits as well as incur additional legal fees and may face negative impacts to our stock price and reputation. In addition, we are obligated to indemnify and advance expenses to certain individuals involved in certain of these proceedings. Any adverse judgment in or settlement of any pending or any future litigation could result in significant payments, fines and penalties that could have a material adverse effect on our business, results of operations, financial condition and reputation. Such payments, damages or settlement costs, if any, related to these matters could be in excess of our insurance coverage. The amount of time that is required to resolve these lawsuits is unpredictable and any litigation or claims against us, even those without merit, may cause us to incur substantial costs, divert management' s attention from the day- to- day operation of our business, and materially harm our reputation. We face significant and continuing competition in our business, which is characterized by rapid technological change and significant price competition. Market share can shift as a result of technological innovation and other business factors. Our customers consider many factors when selecting a product, including product reliability, clinical outcomes, economic outcomes, price, and services provided by the manufacturer. Our ability to compete depends in large part on our ability to provide compelling clinical and economic benefits to our customers and payers, develop and commercialize new products and technologies and anticipate technological advances. Product introductions or enhancements by competitors which may have advanced technology, better features, or lower pricing may make our products obsolete or less competitive. In addition, consolidation in the healthcare industry continues to lead the demand for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations or financial condition. The presence of this competition in our market may lead to pricing pressure, which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. As a result, we will be required to devote continued efforts and financial resources to bring our products under development to market, deliver cost- effective clinical outcomes, expand our geographic reach, enhance our existing products, and develop new products for the advanced wound care and soft tissue repair markets. Even if we develop cost effective and / or new products, they may not be covered or reimbursed due to cost- containment and other financial pressures from payers. Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all. Continued expansion of our business will be expensive and we may seek funds from stock offerings, borrowings under our existing or future credit facilities or other sources. Our capital requirements will depend on many factors, including: • the revenues generated by sales of our products; • the costs associated with expanding our sales and marketing efforts; • the expenses we incur in manufacturing and selling our products; • the costs of developing and commercializing new products or technologies; • the cost of obtaining and maintaining regulatory approval or clearance of certain products and products in development; • the number and timing of acquisitions and other strategic transactions such as our acquisitions of NuTech Medical and CPN Biosciences, and integration costs associated with such acquisitions; • the costs associated with capital expenditures; and • unanticipated general, legal, and administrative expenses. Our operating plan may change as a result of many factors currently unknown to us and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Furthermore, if we issue equity or convertible debt securities to raise capital, you may experience dilution, and the new equity or convertible debt securities may have rights, preferences, and privileges that are senior to or otherwise adversely affect your rights as a stockholder. In addition, if we raise capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop our product candidates, enhance our existing products, execute our business plan, take advantage of future opportunities, or respond to competitive pressure, changes in our supplier relationships, or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material adverse effect on our business, results of operations, and financial condition. Our future success depends on our ability to retain key employees, consultants and advisors, and to attract, retain and motivate qualified personnel. We are highly dependent on our executive officers, the loss of whose services may adversely impact the achievement of our objectives. In particular, we depend on Gary Gillheeney, our President and Chief Executive Officer. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and scientific personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous medical device companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development, and sales growth objectives. Our ability to recruit, retain and motivate our employees and consultants will depend in part on our ability to offer attractive compensation. We may also need to increase the level of cash compensation that we pay to them, which may reduce funds available for research and development and support of our sales growth objectives. There can be no assurance that we will have sufficient cash available to offer our employees and consultants attractive compensation. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us. The loss of the services of any of our executive officers or other key employees and our inability to

find suitable replacements could potentially harm our business, prospects, financial condition or results of operations. We do not maintain ~~“~~ **"** key person ~~”~~ **"** insurance policies on the lives of these individuals or any of our other employees. Many of the companies that we compete against for qualified personnel have substantially greater financial and other resources and different risk profiles than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we can offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited. **Our results of operations** ~~Business or economic disruptions or global health concerns~~ could **be** ~~seriously harm our business. Broad- based business or economic disruptions could adversely affect our business and the sale of our products. For example, in December 2019 an outbreak of a novel strain of coronavirus (COVID- 19) originated in Wuhan, China, and spread to a number of other countries, including the United States. This outbreak resulted in extended shutdowns of certain businesses throughout the world. While the COVID- 19 pandemic has not materially~~ adversely affected ~~our~~ **by general conditions in the global economy and in the global** financial **markets** ~~results and business operations through December 31, 2022, COVID- 19 continues to present risks to the Company and we continue to closely monitor the impact of the pandemic on all aspects of our business. Global health concerns, such as the COVID- 19 pandemic, often disproportionately impact the hospitals, clinics, and healthcare providers to whom we sell our products, which could have a material adverse effect on our business and our results of operation and financial condition. Uncertainty and adverse changes in the general economic conditions may negatively affect our business~~ . If general economic conditions in the United States decline, or if consumers fear that economic conditions will decline, sales of our products may decline. Adverse changes may occur as a result of adverse economic conditions, fluctuating oil prices, supply chain problems, inflation, political instability, declining consumer confidence, a continuation or worsening of the COVID- 19 pandemic or another pandemic, unemployment, fluctuations in stock markets, contraction of credit availability, or other factors affecting economic conditions generally. These changes may negatively affect the sales of our existing or development of future products, increase the cost, and decrease the availability of financing, or increase costs associated with producing and distributing our products and potential product candidates. **Moreover, there has been recent turmoil in the global banking system. On March 10, 2023, Silicon Valley Bank (" SVB"), was closed, followed on March 11, 2023 and May 1, 2023, by Signature Bank and First Republic Bank, respectively, and the FDIC was appointed as receiver for those banks. SVB is one of our lenders at which we maintained deposit and money market accounts prior to its closure and have since transferred all of our deposits previously held with the bank to other banking institutions, with the exception of $ 2. 3 million which we maintain in one operating account at SVB. There have been reports of instability at other banks across the globe including Credit Suisse, which was acquired by UBS. Despite the steps taken to date by U. S. agencies to protect depositors and our current belief that we do not have exposure to loss as a result of SVB' s receivership, the follow- on effects of the events surrounding the SVB, Signature Bank and First Republic Bank failures and pressure on other banks are unknown and could include failures of other financial institutions or significant disruptions to our operations, financial position, and reputation. A severe or prolonged economic downturn, such as the global financial crisis of 2007- 2008, could result in a variety of risks to our business, including a decrease in the demand for our products and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. We cannot anticipate all the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.** Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our business, results of operations, and financial condition. ~~United States generally accepted accounting principles (“~~ GAAP ~~”)~~ and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business are highly complex. These matters include, but are not limited to, revenue recognition, leases, income taxes, impairment of goodwill and long- lived assets and equity- based compensation. Changes in these rules, guidelines or interpretations could significantly change our reported or expected financial performance or financial condition. In addition, the preparation of financial statements in conformity with GAAP requires management to make assumptions, estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of net revenues and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. The failure by us or one of our suppliers to comply with applicable regulatory requirements could result in, among other things, the FDA or other governmental authorities: • imposing fines and penalties on us; • preventing us from manufacturing or selling our products; • delaying or denying pending applications for approval or clearance of our products or of new uses or modifications to our existing products, or withdrawing or suspending current approvals or clearances; • ordering or requesting a recall of our products; • issuing warning letters or untitled letters; • imposing operating restrictions, including a partial or total shutdown of production or investigation of any or all of our products; • refusing to permit to import or export of our products; • detaining or seizing our products; • obtaining injunctions preventing us from manufacturing or distributing any or all of our products; • commencing criminal prosecutions or seeking civil penalties; and • requiring changes in our advertising and promotion practices. Failure to comply with applicable regulatory requirements could also result in civil actions against us by private parties (e. g., under the federal Lanham Act and / or state unfair competition laws), and other unanticipated negative consequences. If any of these

actions were to occur it could harm our reputation and cause our product sales to suffer and may prevent us from generating revenue. Our officers, employees, independent contractors, principal investigators, consultants and commercial partners may engage in misconduct or activities that are improper under other laws and regulations, which would create liability for us. We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations, or CROs), principal investigators, consultants and commercial partners may engage in fraudulent conduct or other illegal activity and / or may fail to disclose unauthorized activities to us. Misconduct by these parties could include, but is not limited to, intentional, reckless and / or negligent failures to comply with: • the laws and regulations of the FDA and its foreign counterparts requiring the reporting of true, complete and accurate information to such regulatory bodies, including but not limited to safety problems associated with the use of our products; • laws and regulations of the FDA and its foreign counterparts concerning the conduct of clinical trials and the protection of human research subjects; • other laws and regulations of the FDA and its foreign counterparts relating to the manufacture, processing, packing, holding, investigating or distributing in commerce of medical devices, biological products and / or HCT / Ps; or • manufacturing standards we have established. In particular, companies involved in the manufacture of medical products are subject to laws and regulations intended to ensure that medical products that will be used in patients are safe and effective, and specifically that they are not adulterated or contaminated, that they are properly labeled, and have the identity, strength, quality and purity that which they are represented to possess. Further, companies involved in the research and development of medical products are subject to extensive laws and regulations intended to protect research subjects and ensure the integrity of data generated from clinical trials and of the regulatory review process. Any misconduct in any of these areas — whether by our own employees or by contractors, vendors, business associates, consultants, or other entities acting as our agents — could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. Although we have a comprehensive compliance program designed to ensure that our employees', CRO partners', principal investigators', consultants', and commercial partners' activities and interactions with healthcare professionals and patients are appropriate, ethical, and consistent with all applicable laws, regulations, guidelines, policies and standards, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, results of operations, and financial condition. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, manufacture and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of the Company' s income or other tax returns could adversely affect the Company' s financial condition and results of operations. The Company is subject to income tax in the United States and Switzerland, and the Company' s domestic tax liabilities will be subject to the allocation of expenses in differing jurisdictions. The Company' s future effective tax rates could be subject to volatility or adversely affected by a number of factors, including: • changes in the valuation of the Company' s deferred tax assets and liabilities; • expected timing and amount of the release of any tax valuation allowances; • tax effects of stock- based compensation; • costs related to intercompany restructurings; • changes in tax laws, regulations or interpretations thereof; and • lower than anticipated future earnings in jurisdictions where the Company has lower statutory tax rates and higher than anticipated future earnings in jurisdictions where the Company has higher statutory tax rates. In addition, the Company may be subject to audits of the Company' s income, sales and other taxes by U. S. federal, state, local and non- U. S. taxing authorities. Outcomes from these audits could have an adverse effect on the Company' s financial condition and results of operations. A market for the Company' s securities may not continue, which would adversely affect the liquidity and price of the Company' s securities. The price of the Company' s securities may fluctuate significantly due to general market and economic conditions. An active trading market for the Company' s securities may never develop or, if developed, it may not be sustained. In addition, the price of the Company' s securities can vary due to general economic conditions and forecasts, the Company' s general business condition and the release of the Company' s financial reports. Additionally, if the Company' s securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter- dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of the Company' s securities may be more limited than if the Company was quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained. The Company' s quarterly operating results may fluctuate significantly and could fall below the expectations of securities analysts and investors due to seasonality and other factors, some of which are beyond the Company' s control, resulting in a decline in the Company' s stock price. The Company' s quarterly operating results may fluctuate

significantly because of several factors, including: • labor availability and costs for hourly and management personnel; • profitability of the Company' s products, especially in new markets and due to seasonal fluctuations; • changes in interest or exchange rates; • impairment of long- lived assets; • macroeconomic conditions, both nationally and locally; • negative publicity relating to our products; • changes in consumer preferences and competitive conditions; and • expansion to new markets. If securities or industry analysts do not publish or cease publishing research or reports about the Company, its business, or its market, or if they change their recommendations regarding the Company Class A common stock adversely, then the price and trading volume of the Company Class A common stock could decline. The trading market for the Company Class A common stock will be influenced by the research and reports that industry or securities analysts may publish about us, the Company' s business, the Company' s market, or the Company' s competitors. Securities and industry analysts may stop publishing research on the Company. If any analyst who covers the Company were to cease coverage of the Company or fail to regularly publish reports on it, we could lose visibility in the financial markets, which could cause the Company' s stock price or trading volume to decline. If any of the analysts who cover the Company change their recommendation regarding the Company' s stock adversely, or provide more favorable relative recommendations about the Company' s competitors, the price of the Company Class A common stock would likely decline. Changes in laws, regulations or rules, or a failure to comply with any laws, regulations or rules, may adversely affect the Company' s business, investments and results of operations. The Company is subject to laws, regulations and rules enacted by national, regional and local governments and Nasdaq. In particular, the Company is required to comply with certain SEC, Nasdaq and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules is difficult, time- consuming and costly. Those laws, regulations or rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on the Company' s business, investments and results of operations. In addition, a failure to comply with applicable laws, regulations or rules, as interpreted and applied, could have a material adverse effect on the Company' s business and results of operations. Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities. If we fail to satisfy the continued listing requirements of Nasdaq such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, trading our common stock could be conducted only in the over- the- counter (~~"~~OTC ~~"~~) market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board, an inter- dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.