Risk Factors Comparison 2024-03-05 to 2023-03-14 Form: 10-K

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Our business involves a number of risks, some of which are beyond our control. The risk and uncertainties described below are not the only ones we face. Set forth below is a discussion of the risks and uncertainties that management believes to be material to us and could adversely affect our business, financial condition, results of operations, cash flows, growth prospects and the trading price of our common stock. Risks Related to Our Business and Strategy Our revenue growth depends on our ability to increase distribution and sales to existing customers and develop new customers, domestically and abroad, and there can be no assurance that these efforts will result in significant increases in sales. Beginning in 2020, we adjusted our commercial strategy to focus on deeper penetration of our existing surgeon customers through the development of long- term users of our algorithm of nerve repair in our largest market opportunity of extremity trauma. We believe that near- term growth can be supported first through expanded productivity of our existing sales force with existing accounts and second by adding additional customers. We expect the number of direct sales professionals to increase ~~over~~ **P36over** time. Additionally, we believe that we have successfully utilized a hybrid commercial approach that includes the use of independent agencies in more remote geographies to provide appropriate local support for customers, without the travel time required of a direct sales representative. We anticipate that we will continue to add to the number of independent sales agencies as it continues to drive higher productivity and efficiency with our direct sales force. We may also need to establish a regional distribution center or centers at some point in the future to account for growth. The incurrence of these expenses may impact our operating results, and there can be no assurance of their effectiveness. If we are unable to increase sales to existing customers and attract new customers, and develop our sales force, there could be a material adverse impact on our business, results of operations, financial condition, and prospects. **Additionally, our growth margin is dependent on maintaining a diversified demand mix. If demand only grows in one use application it could negatively impact gross margin. We are focusing on creating balanced revenue growth and yield improvements in product processing, but we may be unable to do so.** Our revenue depends primarily on ~~four~~ **five** products. Substantially all of our revenue is currently derived from ~~four~~ **five** products, Avance Nerve Graft, Axoguard Nerve Protector, Axoguard Nerve Connector **, Axoguard HA Nerve Protector** , and Axoguard Nerve Cap for the treatment of peripheral nerve damage. Of these ~~four~~ **five** products, Avance Nerve Graft represents approximately 60 % of our total revenue. Any disruption in our ability to generate revenue from the processing, distribution, and sale of products **, especially Avance Nerve Graft,** will have a material adverse impact on our business, results of operations, financial condition, and prospects. Axoguard Nerve Connector and Axoguard Nerve Protector are only available through the Cook Biotech Distribution Agreement. The Distribution Agreement was amended February 26, 2018 **,** to extend the termination date to June 30, 2027 **and on August 4, 2023, to extend the termination date to December 31, 2030** . However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement. Through mutual agreement, the parties have not established such minimums and to date have not enforced such minimum purchase provision. Additionally, in the event that Cook Biotech were to enforce minimum purchase quantities and we fail to reach an agreement as to such minimums, Cook Biotech could terminate the agreement if we fail to generate commercially reasonable sales of Axoguard as measured by sales similar to a competitive product at the same stage in its commercial launch as verified by a mutually acceptable third party. We distribute the Axoguard Nerve Connector and Axoguard Nerve Protector for Cook Biotech, and Cook Biotech is the contract manufacturer for our Axoguard **HA Nerve Protector and Axoguard** Nerve Cap. Although we believe we could develop or obtain products that would replace the Axoguard products obtained through the Cook Biotech agreements, the loss of the ability to sell the Axoguard products could have a material adverse effect on our business, results of operations, financial condition, and prospects **. Further, on January 31, 2024, RTI Surgical, Inc. announced the acquisition of Cook Biotech. While do not expect the acquisition of Cook Biotech to have a material impact on our relationship with Cook Biotech or our operations, it is possible that due to the change in control Cook Biotech elects to enforce the minimum purchase requirements and / or elect not to renew the Distribution Agreement further** . Approximately 60 % of our total revenues are from sales of Avance Nerve Graft. Approximately 60 % of our total revenues are from sales of Avance Nerve Graft, which the FDA considers to be a biological product subject to BLA approval requirements. The product is currently distributed pursuant to a transition plan with the FDA. Any change in position by the FDA regarding its use of enforcement discretion regarding the sale of Avance Nerve Graft, or if the BLA we intend to submit is not approved, if our indications are narrowed, or use of Avance Nerve is curtailed in any other way, it will have a material negative impact on our revenues and our operations. For additional information see: " Risk Factors – Our Avance Nerve Graft product is currently distributed pursuant to a transition plan with the FDA; however, we expect to ~~file a~~ **complete the rolling** BLA ~~by~~ **submission for** the ~~end~~ **Avance Nerve Graft in the third quarter of** ~~2023~~ **2024 ,** and if the FDA does not approve our BLA or otherwise limits on use of our Avance Nerve Graft product it would have a significant impact on our revenues and thus would have a material adverse effect on us. " **Macroeconomic trends, such** ~~The failure of Silicon Valley Bank~~ as ~~well as the recent turmoil in the banking industry may negatively impact our business, results of operations and financial condition. On March 10, 2023, the California Department of Financial Protection and Innovation closed Silicon Valley Bank (" SVB ") and appointed Federal Deposit Insurance Corporation (the " FDIC ") receiver. On March 12, 2023, the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their~~ -- **the** ~~funds~~ **inflationary pressure** , **and political instability** ~~even those in excess of the standard FDIC insurance limits, under a systemic risk exception. As of March 14, 2023, we have approximately $ 8. 0~~

~~million of cash with SVB, our sole depositor until recent events, after which we have made arrangements to open new accounts with JP Morgan Chase. We~~ could **continue** ~~experience disruption with customer receivables and vendor payments as we transition~~ to ~~new accounts. The majority of our other cash, cash equivalents and investments, consisting of a variety of short-term and high- credit treasury and corporate bonds and other liquid investments, is held in custodial accounts with U. S. Bank for which SVB Asset Management is the advisor, and we have made arrangements to transfer such cash, cash equivalents and investments to JP Morgan Chase. Despite our proactive measures and the measures taken by the United States federal government, there is great uncertainty in the markets regarding the stability of regional banks and the safety of deposits in excess of the FDIC insured deposit limits. The ultimate outcome of these events, and whether further regulatory actions will be taken, cannot be predicted, but these events may~~ have a material adverse effect on our ~~liquidity and financial condition if our ability to access funds at SVB and our ability to transfer our other cash, cash equivalents and investments to JP Morgan Chase are impaired. Further, these events may make equity or debt financing more difficult to obtain, and additional equity or debt financing might not be available on reasonable terms, if at all; difficulties obtaining equity or debt financing could have a material adverse effect on our financial condition, as well as our ability to continue to grow our operations. Macroeconomic trends, such as the COVID- 19 pandemic, inflationary pressure, recent events associated with SVB and the aftermath thereof, and political instability could continue to have a material adverse effect on our~~ ability to operate, results of operations, financial condition, liquidity, and capital investments. We continue to actively monitor the impact of various macroeconomic trends, **including** ~~such as recent events associated with SVB and the aftermath thereof,~~ high rates of inflation, increasing interest rates, increasing labor costs, supply chain disruptions, labor shortages **and** , geopolitical instability ~~, and the COVID- 19 pandemic~~ on our business. We ~~believe that the COVID- 19 pandemic negatively impacted hospital staffing and surgical procedure volumes which has negatively impacted our revenue. Additionally, we~~ have experienced increased costs consistent with rising interest rates, and inflationary pressures. At this time, we cannot predict the specific extent, duration or full impact **of** ~~that recent events associated with SVB and the aftermath thereof,~~ inflationary conditions, supply chain disruptions, geopolitical instability will have on our ongoing and planned clinical trials, our ability to operate, results of operations, financial condition, liquidity, and capital investments. Economic conditions, such as ~~recent events associated with SVB and the aftermath thereof,~~ rising inflation, higher interest rates, increasing labor costs, supply chain pressures, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can also have a significant effect on the cost of **P37** operations including the cost of materials and labor, as well as the interest on our debt. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. In addition, the geopolitical instability and related sanctions could continue to have significant ramifications ~~on~~ **including volatility in the U. S. and** global financial markets ~~, including volatility in the U~~ . ~~S.~~ **Our operating results could be adversely impacted if we are unable to effectively manage** and ~~global financial markets~~ **sustain our future growth or scale our operations** . ~~COVID- 19 caused~~ **There can be no assurance that we will be able to manage our future growth efficiently or profitably. Our business is unproven on a large scale,** and **actual revenue and operating margins, or revenue and margin growth,** may **be less than expected** ~~continue to cause decreased access to customer channels, slowing or stopping of the development of clinical products or clinical data, decreased employee availability, hospital staffing shortages, adverse economic conditions, border closures and other disruptions to our business, as well as the businesses of our business partners and others. Furthermore, COVID- 19 may have the effect of heightening many of the other risks described in this Annual Report on Form 10- K. COVID- 19 has also imposed significant burden on the FDA and forced the agency to divert resources from product review and its approval process. The extent of the impact of the COVID- 19 pandemic on our business and operations remains uncertain and will depend on certain developments, including the duration and spread of the pandemic and its future impact on elective procedures, third- party manufacturers, and other third parties with which we do business, as well as its impact on regulatory resources, inspections, and review timelines~~ . If we **are unable to scale** ~~or~~ **our** ~~any of the third parties with whom~~ **production capabilities efficiently or maintain pricing without significant discounting,** we ~~engage were~~ **may fail** to ~~experience additional shutdowns~~ **achieve expected operating margins, which would have a material and adverse effect on** ~~or~~ **our operating results. Growth may also stress** ~~other prolonged business disruptions due to the COVID- 19 pandemic,~~ our ability to ~~conduct~~ **adequately manage our operations, quality of products, safety, and regulatory compliance. Failure to implement necessary procedures, equipment,** ~~our~~ **or** ~~business~~ **processes or to hire the necessary personnel in a timely and effective manner could result in higher costs or an inability to meet market demand and** could have a material adverse impact on our business, results of ~~operation~~ **operations** ~~and~~ **,** financial condition **, and prospects** . ~~Our success~~ **Additionally, our future growth will increase the demands placed on our third- party suppliers, and there is no guarantee that our suppliers** will be **able to support** ~~dependent on continued acceptance of~~ our **anticipated growth** ~~products by the medical community~~ . **If growth significantly decreases** ~~Our success is dependent on continued acceptance of our products by the medical community~~ , ~~which~~ **it** will **negatively impact** ~~depend on our ability to demonstrate that our products are an attractive alternative to existing or~~ **our cash reserves** ~~new nerve reconstruction treatment options~~ , ~~including both surgical techniques~~ and ~~products. Our ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost- effectiveness, including insurance reimbursement, of our nerve repair products. For example, although our Avance Nerve Graft follows stringent safety standards, including sterilization by gamma irradiation,~~ we ~~believe that a small portion of the medical community has lingering concerns over the risk of disease transmission through the use of allografts in general. If the medical community and patients do not ultimately accept our products as safe and effective or we are unable to raise awareness of our products and processes, our ability to sell the products~~ may be **required to obtain additional** ~~materially and adversely affected, and our business, results of operations, financial~~ **financing** ~~condition~~ , **which** ~~and prospects~~ may **increase indebtedness or result in dilution to shareholders. Further, there can** be ~~adversely affected~~ **no assurance that we would be able to obtain additional financing on acceptable terms, if at all** . We **have a history of net losses and** have not consistently experienced positive cash flow from ~~our~~ operations, ~~and have a~~

~~history of net losses~~ and our ability to achieve consistent ~~,~~ positive cash flow ~~from operations~~ will depend on increasing revenue from distribution of our products, which may not be achievable. We have historically incurred net losses and operated with negative cash flow from our operations and may continue to incur losses and operate with negative cash flow from operations for the foreseeable future. We have incurred net losses of $ **21. 7 million, $** 28. 9 million ~~,~~ **and** $ 27. 0 ~~million and $ 23. 8~~ million for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of approximately $ ~~259~~ **281** . ~~6~~ **3** million. If revenue does not increase as anticipated, then we will continue to incur net losses and experience negative cash flows and adverse operating conditions. In June 2020, we entered into a seven- year $ ~~70~~ **75** million credit facility (the" Credit Facility") with Oberland Capital, from which we drew proceeds of $ 50 million, which were used and will continue to be used for working capital, capital expenditures and general corporate purposes. As our debt obligations mature or if our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, sell assets, seek additional capital, or restructure or refinance our indebtedness. Our ability to restructure or refinance our debt 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. If we raise funds by selling additional equity, such sale would result in dilution to our shareholders. There is no assurance that if we are required to secure funding, we can do so on terms acceptable to us, or at all. **Failure to successfully manage the transition associated with the recent management changes and the search and appointment of a permanent CEO could have an adverse impact on our business. Karen Zaderej informed the Company' s board of directors of her intention to retire from her role as the Chief Executive Officer in January 2025. The Board has begun the search for a permanent CEO. In addition, on December 6, 2023, Peter Mariani was replaced by Nir Naor as the Company' s Chief Financial Officer. Moreover, Mike Donovan, our VP of Operations announced his intention to retire from his role in March 2024. Mr. Donovan' s duties will be transitioned to Todd Puckett in March 2024. Leadership transitions can be inherently difficult to manage and competition for qualified executives can be intense, and there are a limited number of people with the requisite knowledge and experience. The transition to a permanent CEO may cause disruption to our business due to, among other things, diverting management' s attention away from the Company' s financial and operational goals or causing a deterioration in morale. During the transition period there may be uncertainty among investors, customers, and other third parties, concerning our future direction and performance. It may also be more difficult for us to recruit and retain other personnel until a permanent CEO is identified. Our success will be dependent on continued acceptance of our products by the medical community. Our success is dependent on continued acceptance of our products by the medical community, which will depend on our ability to demonstrate that our products are an attractive alternative to existing or new nerve reconstruction treatment options, including both surgical techniques and products. Our ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost- effectiveness, including insurance reimbursement, of our nerve repair products. For P38 example, although our Avance Nerve Graft follows stringent safety standards, including sterilization by gamma irradiation, we believe that a small portion of the medical community has lingering concerns over the risk of disease transmission through the use of allografts in general. If the medical community and patients do not ultimately accept our products as safe and effective or we are unable to raise awareness of our products and processes, our ability to sell the products may be materially and adversely affected, and our business, results of operations, financial condition, and prospects may be adversely affected.** We are highly dependent on the continued availability of our facilities and could be harmed if the facilities are unavailable for any prolonged period of time and we may not experience the operating efficiencies anticipated with the transition to our APC Facility. ~~Our~~ **We have completed renovation of our** APC Facility **and transferred the** ~~is expected to be fully renovated as our new processing facility for~~ Avance Nerve Graft **tissue** ~~before December 31, 2023, which is the termination date of the CTS Agreement. We anticipate beginning to transfer the~~ processing **and packaging** ~~of Avance Nerve Graft from CTS~~ to ~~our~~ **the** APC Facility **but expect to continue to rely on the CTS** ~~over in mid- 2023. During this time, both facilities~~ **facility** ~~will be operational. However, renovations and the regulatory process~~ for ~~approval~~ **the processing** of **Avive** ~~facilities, whether licensed or owned, is time- consuming and unpredictable~~ . We may not experience the anticipated operating efficiencies as we commence processing operations at the APC Facility. It could cause a significant disruption in service to our customers if we were to lose, even temporarily, the availability of our production or distribution facilities. ~~Moreover, changing facilities may require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive.~~ If we are not able to comply with the applicable regulatory requirements or produce product that meets our requirements and specifications, **it could delay or disrupt our BLA approval and** we will be subject to the same risks that we would be subject to should third parties be unable to comply with the applicable regulatory requirements or produce product meeting our requirements or specifications, as described above. If we fail to achieve the operating efficiencies that we anticipate, our business, results of operations, financial condition, and prospects could be adversely impacted. In operating our new processing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, raw material supply, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing processing operations and we may not achieve the operating efficiencies that we anticipate from the APC Facility, which may negatively affect our business, results of operations, financial condition, and prospects. Any failure in the physical infrastructure of our facilities, including the APC Facility and the facility we license from CTS, could lead to significant costs and disruptions that could reduce our revenue and harm both our business reputation and financial results. Any natural or man- made event that impacts our ability to utilize our facilities could have a material impact on our business, results of operations, financial condition, and prospects. Although we

have business interruption insurance that would cover certain costs in instances other than service agreement termination, it may not cover all costs nor help to regain our standing in the market. In addition, we may plan to expand the APC facility or open additional office, lab or distributions space in the future, and our ability to license, renovate, rebuild, or find acceptable service facilities takes a considerable amount of time and expense. Delays, interruptions, or the cessation of production by our third-party suppliers **, including products supplied by single suppliers,** of important materials may prevent or delay our ability to manufacture or process the final products. Most of the raw materials used in the process for Avance Nerve Graft are available from more than one supplier. However, there are materials within the manufacturing and production process that come from single suppliers **, some of which are outside of the U. S.,** or certain supplies may be difficult to procure due to supply chain shortages or changes in global trade regulations. Macroeconomic factors could cause disruptions in the supply chain and impair our ability to obtain the materials needed for our product line. We do not have written contracts that guarantee supply with any of our suppliers, and at any time they could stop supplying our orders. FDA review of a new supplier may be required if these materials become unavailable from our current suppliers. Although there may be other suppliers that have equivalent materials that would be available to us, if FDA review is required, it could take several months or years to obtain, if approval is able to be obtained at all. Any delay, interruption, or cessation of production by our third- party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay our ability to manufacture products. **We are working on identifying and contracting with additional suppliers to reduce our dependence on single source suppliers and service providers.** In addition, an uncorrected impurity, a supplier' s variation in a raw material or testing, either unknown to us or incompatible with our manufacturing process, or any other problem with our materials, testing or components, would prevent or delay our ability to process tissue. These delays may limit our ability to meet demand for our products and delay our clinical trials, which would have a material adverse impact on our business, results of operations, financial condition, and prospects. Technological change and competition for newly developed products could reduce demand for our products. **P39** The medical technology industry is intensely competitive. We compete with both U. S. and international entities that engage in the development and production of medical technologies and processes, including: • biotechnology, orthopedic, pharmaceutical, biomaterial, chemical, and other companies; • academic and scientific institutions; and • public and private research organizations. Our products compete with autograft, hollow- tube conduits, commercially available wraps, and amnion products, as well as with alternative medical procedures. For the foreseeable future, we believe a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation and its drawbacks. In addition, many members of the medical community will continue to prefer the use of hollow- tube conduits due in part to their familiarity with these products and the procedures required for their use. Also, steady improvements have been made in synthetic human tissue substitutes, which could compete with our products in the future. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human or animal tissue. Although our growth strategy contemplates the introduction of new technologies, the development of these technologies is a complex and uncertain process, which require a high level of innovation, as well as the ability to accurately predict future technology and market trends. We may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new technologies or enhancements to existing products in a timely and cost- effective manner, if at all. There can be no assurance that in the future our competitors will not develop products that have superior performance or are less expensive relative to our products, rendering our products obsolete or noncompetitive. In this regard, Integra and Baxter each have or will commercialize a product consisting of a hollow tube conduit filled with material which they suggest is superior to their current hollow conduit products. Additionally, in 2022, ~~BioCircuit~~ **Biocircuit** received 510 (k) clearance for a SIS- based nerve wrap with integrated microhooks that enable suture- free coaptation of peripheral nerves potentially allowing for simpler, consistent quick repairs compared to using typical hollow tube conduits and nerve wraps. Also in 2022, L & C Bio Co. LTD from South Korea registered as a human nerve allograft processor and distributor with the FDA, however, such a product is not currently sold in the U. S. market, and we believe such product would require a biologics license for commercialization. Moreover, a Chinese company provides a human peripheral nerve allograft in China; however, such product is not sold in our markets of interest because of the protection afforded by our IP. Due to our resource allocation, size, and relatively early stage, we may face competitive challenges from these new products or existing products and barriers that are difficult to overcome and could negatively impact our growth. We must maintain high quality processing of our products. Our Avance Nerve Graft is processed through our Avance Method, which requires careful calibration and precise, high- quality processing and manufacturing. Achieving precision and quality control requires skill and diligence by our personnel. If we fail to achieve and maintain these high levels of quality control and processing standards, including avoidance of processing errors, defects, or product failures, we could experience recalls or withdrawals of our product, delays in delivery, cost overruns or other problems that would adversely affect our business. We cannot completely eliminate the risk of errors, defects or failures and could experience quality system issues where corrective actions must be taken. In addition, we may experience difficulties in scaling- up processing of our Avance products, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures, and lack of skilled personnel. If we are unable to process and produce our human tissue products on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if we experience unanticipated technological problems or delays in production, our business, results of operations, financial condition, and prospects would be adversely affected. Our revenue depends upon prompt and adequate reimbursement from public and private insurers and national health systems. Political, societal, economic, and regulatory influences are fundamentally changing the U. S. healthcare industry. The ability of a hospital or an ambulatory surgery center to pay fees for our products depends in part on the availability of adequate coverage and reimbursement from third- party payors for our products specifically, the procedures associated with the use of our products, or both. Providers that purchase our products generally rely on third- party payors to reimburse all or part of the costs and fees associated with the procedures performed with our products or the products themselves. Therefore, adequate coverage

and reimbursement from third- party payors, including government payors such as Medicare and Medicaid, are important for obtaining product acceptance and widespread adoption in the marketplace. When our products are used in the operating room of a hospital, they are commonly treated as general supplies utilized in surgery, and the cost is included in payment to the facility for the procedure. When Avance Nerve Graft and Axoguard **P40** Connector are used in an outpatient setting where the nerve repair is the primary reason for the procedure, facilities may use a Category I CPT code to facilitate payment. In January 2018, the American Medical Association created a Category I CPT code (64912) specific to nerve repair with nerve allograft (Avance Nerve Graft) and a separate code (64913) for each additional strand of allograft used in a procedure. Category I CPT codes are used by providers to facilitate payment to the provider (either hospital or ambulatory surgery center) for outpatient procedures. Additionally, Category I CPT codes are used to facilitate payment to the surgeon, for both time spent in outpatient and inpatient procedures. Prior to January 2018, there was no designated Category I CPT code for nerve repair cases that included nerve allograft. The Category I CPT code specific to nerve repair with nerve allograft, has allowed for nerve allograft repair cases to be uniquely identified in the Medicare claims data. This in turn allowed CMS visibility to nerve allograft nerve procedure costs, and thereby confirm that nerve allograft qualified as a device intensive procedure. Another important change in nerve repair reimbursement occurred in January 2020, when most direct repair procedures were moved from the higher paying level 2 nerve repair Ambulatory Payment Category 5432 to the lower paying level 1 Ambulatory Payment Category 5431, thus aligning payment rates more consistently with the lesser costs of a direct repair. As a result of the allograft device intensive status and direct repair Ambulatory Payment Category realignment, CMS reimbursement rates for nerve repair in the outpatient setting have changed significantly during the last two years. With the new 2023 CMS reimbursement rates for nerve repair in the outpatient setting that became effective January 1st, reimbursement for procedures using Avance have increased 35 % in hospital outpatient centers and 115 % in ambulatory surgery centers since 2019. During this same timeframe, reimbursement rates for procedures involving conduits and connectors also increased 35 % in hospital outpatient centers and 49 % in ambulatory surgery centers. While Medicare patients represent a relatively small percentage of trauma cases, CMS' direction often influences commercial payor policies and payments. The process for securing coding for a product or procedure is separate from the process of securing coverage and establishing a reimbursement payment rate. In the U. S., coverage and reimbursement for medical devices varies among payors. In addition, payors review coverage policies on an ongoing basis and can change or deny coverage for these new products and procedures without notice. We estimate that commercial payors covering a significant number of U. S. covered lives have legacy non- coverage policies relating to our Avance Nerve Graft and our Axoguard product lines, designating these products investigational or experimental. Some commercial payors do not currently cover or reimburse our products because they have determined insufficient evidence of favorable clinical outcomes is available. Although some payors consider Avance Nerve Graft and our Axoguard product lines investigational or experimental at this time, these payors may in the future determine sufficient evidence has been developed to cover and reimburse our products and related procedures. In partnership with healthcare providers, we are working actively to reverse these non-coverage decisions and have been successful with several regional plans. However, we cannot provide assurance that we will continue to be successful in these efforts. If we are not successful in reversing existing non- coverage policies, or if other third-party payors issue similar policies, this could have a material adverse effect on our business and operations. Further, third- party payors who currently cover and reimburse customers for procedures using our products may in the future choose to decrease current levels of reimbursement or eliminate reimbursement altogether, which would cause our business to suffer. The amount of reimbursement received by our customers from third- party payors is dependent generally on fee schedules established by these payors for the existing CPT codes. For governmental payors, such as Medicare and Medicaid, the fee schedule amount is determined by statutory and regulatory formulas as previously discussed. For commercial payors, the reimbursement amount generally is dependent upon the specific contract terms between the provider and payor. We cannot provide assurance that government or commercial payors will continue to reimburse for procedures with our products using the existing codes, nor can we provide assurance that the payment rates will be adequate. If providers and physicians are unable to obtain reimbursement for the procedure at adequate levels when use of our products is included, this could have a material adverse effect on our business and operations. Hospitals and ambulatory surgery centers may not purchase our products if they do not receive payment sufficient to cover the cost of our products and related procedures. In addition, in the event that the current coding and / or payment methodology for these procedures changes, this could have a material effect on our business, results of operations, financial condition, and prospects. Additionally, healthcare law and policy changes may have a material adverse effect on our revenues. See: " Risk Factors – Healthcare law and policy changes may have a material adverse effect on us. " Negative publicity concerning methods of donating human tissue and screening of donated tissue may reduce demand for our products and negatively impact the supply of available donor tissue. We are highly dependent on our ability to recover human peripheral nerve tissue from tissue donors for our Avance Nerve Graft product. The availability of acceptable donors is relatively limited, and this availability is impacted by regulatory changes, **P41** general public opinion of the donation process, and our reputation for handling the donation process. Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue, including bones and tendons, may limit widespread acceptance of our Avance Nerve Graft. Unfavorable reports of improper or illegal tissue recovery practices, both in the U. S. and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies and donated tissue use. Potential patients may not be able to distinguish our products, technologies, and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports could make families of our potential donors or donors themselves from whom we are required to obtain consent before processing tissue reluctant to agree to donate tissue to for- profit tissue processors. Any disruption in the supply caused by these publicity issues could have a material impact for our business, results of operations, financial condition, and prospects. The failure of third parties to perform many necessary services for the commercialization of

our products, including services related to recovery / acquisition **, sterilization** , distribution, and transportation, would impair our ability to meet commercial demand. We rely upon third parties for certain recovery / acquisition, **sterilization,** distribution, and transportation services for our products. For example, the Avance Nerve Graft processing consists of several steps, and we use a number of recovery and / or acquisition agencies to supply the human tissue needed for these products. While we believe our current contracts and the ability to enter into future contracts will provide us with the tissues required for the products, we cannot be sure that we will be able to obtain the tissue that we need in the future. Disruptions in the tissue supply may adversely impact both tissue products and our overall business. If any of the third parties that we rely upon in our recovery / acquisition, distribution or transportation process fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties, experience delays due to macroeconomic factors, ~~such as the ongoing COVID- 19 pandemic,~~ or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand may be significantly impaired, which could have a material adverse impact on our business, results of operations, financial condition or prospects. We are dependent on our relationships with independent agencies to generate a material portion of our revenue. We derive material revenue through our relationships with independent agencies. In ~~2022~~ **2023** , approximately ~~┼~~10 % ~~┼~~of global product revenue was generated through independent agencies. If certain agency relationships were terminated or discontinued for any reason, it could adversely affect our ability to generate revenue and profit. If we require additional agencies, we may not be able to find additional agencies who will agree to market and distribute our products on commercially reasonable terms, if at all. If we are unable to establish new agency relationships or renew certain current distribution agreements on commercially acceptable terms, our business, results of operations, financial condition, and prospects could be materially and adversely impacted. If we do not manage product inventory in an effective and efficient manner, it could adversely affect profitability. Many factors affect the efficient use and planning of product inventory, such as our ability to predict demand for donor tissue, prepare manufacturing to meet that demand and product mix and handle product expiration. We may be unable to manage our inventory efficiently, keep inventory within expected budget goals, keep our work- in- process inventory on hand or manage it efficiently, control expired product or keep sufficient product on hand to meet demand. Finally, we can provide no assurance that we can keep inventory costs within our target levels, particularly in light of overall cost increases due to global inflation. Failure to do so may materially and adversely impact our business, results of operations, financial condition, and prospects. ~~Our~~ **There may be significant fluctuations in our** operating results ~~could~~ **. Significant quarterly fluctuations in our results of operations may** be **caused by, among other factors,** ~~adversely impacted if we are unable to effectively manage and sustain our future growth or~~ **our volume of revenue, seasonal changes in nerve repair activity, timing of** ~~scale~~ **sales force expansion, unforeseen restrictions on** our ~~operations~~ **ability to access healthcare providers such as inflationary pressures, competitive factors and general economic conditions** . There can be no assurance that ~~we will be able to manage our future growth efficiently or profitably. Our business is unproven on a large scale, and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If we are unable to scale our production capabilities efficiently or maintain pricing without significant discounting, we may fail to achieve expected operating margins, which would have a material and adverse effect on our operating results. Growth may also stress our ability to adequately manage our operations, quality of products, safety, and regulatory compliance. Failure to implement necessary procedures, equipment, or processes or to hire the necessary personnel in a timely and effective manner could result in higher costs or an inability to meet market demand and could have a material adverse impact on our business, results of operations, financial condition, and prospects. Additionally, our future growth will increase the demands placed on our third- party suppliers, and there is no guarantee that our suppliers will be able to support our anticipated growth. If growth significantly decreases, it will negatively impact our cash reserves, and we may be required to obtain additional financing, which may increase indebtedness or result in dilution to shareholders. Further, there can be no assurance that we would be able to obtain additional financing on acceptable terms, if at all. There may be significant fluctuations in our operating results. Significant quarterly fluctuations in our results of operations may be caused by, among other factors, our volume of revenue, seasonal changes in nerve repair activity, timing of sales force expansion, unforeseen restrictions on our ability to access healthcare providers such as during the COVID- 19 pandemic, inflationary pressures, competitive factors and general economic conditions. There can be no assurance that~~ the level of revenue and profit, if any, we achieve in any particular fiscal period, will not be significantly lower than in other comparable fiscal periods. Our expense levels are based, in part, on our expectations as to future revenue. As a result, if future revenue is below expectations, net income or loss may be disproportionately affected by a reduction in revenue, as any corresponding reduction in expenses may not be proportionate to the reduction in revenue **. We may not be successful in our efforts to build a pipeline of additional product candidates. We may not be able to continue to identify and develop new product candidates in addition to our current pipeline. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for P42 clinical development or achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price** . We may be unsuccessful in commercializing our products outside the U. S. To date, we have focused our commercialization efforts in the U. S., except for minor revenue in certain foreign countries. We intend to expand distribution and sales outside the U. S. and will need to comply with applicable foreign regulatory requirements, including obtaining the requisite approvals to do so. The regulatory environment for our portfolio of products is complex. Avance Nerve Graft is distributed in Canada, the UK, and certain other countries. We received approval to distribute Avance Nerve Graft in Germany in December 2019. Avance use in Spain currently requires approval for each case to be approved by tissue authorities under an alternative therapies designation. The Axoguard Nerve Connector and Nerve Protector CE Mark has been renewed as of May 2021 by Cook Biotech ~~. In January 2020, the UK exited the E. U. (" Brexit ") following a transition period that ended on December 31, 2020. Brexit could continue to disrupt~~

~~trade between the UK and the E. U. or other nations, as the UK pursues independent trade regulations. It is still unclear exactly how Brexit will affect legislative and regulatory systems within the UK, as many decisions are left to be made that will determine how far the UK will choose to diverge from existing E. U. rules. Therefore, we cannot be sure what changes could occur or the cost of regulatory compliance with both the UK and the E. U. going forward. Until such time as we can obtain, if at all, the necessary registrations and approvals for our products, material expansion beyond the U. S. will be limited. Finally, the cost of regulatory compliance for sales outside the U. S. can be significant and time consuming~~ . Further, we will need to either enter into distribution agreements with third parties or develop a direct sales force in foreign markets. If we do not obtain adequate levels of reimbursement from third- party payers outside of the U. S., we may be unable to develop and grow our revenue internationally. Outside of the U. S., reimbursement systems vary significantly by country. Many ex- U. S. markets have government- managed healthcare systems that govern reimbursement for medical devices, implants, and procedures. Some ex- U. S. reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If we are unable to successfully commercialize our products internationally, our long- term growth prospects may be limited. We incur costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. As a public company, we incur legal, accounting, and other expenses to comply with relevant securities laws and regulations, including without limitation, the requirement of establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management devotes substantial time and financial resources to these compliance initiatives. Failure to comply with public company requirements could have a material adverse effect on our business. In addition, activity by shareholders or others that bring into question aspects of our business, financial reporting, or management' s integrity, whether based on facts, beliefs or baseless and contrived for individual economic gain, can have a negative impact on the price of our stock and can result in substantial time and financial resources being expended to address the situation. Changes in the tax code could have a material adverse effect on our results of operations, financial condition, liquidity, and capital investments. In recent years, political discourse has centered on potential changes in tax laws or tax rulings. Certain of these changes could negatively affect our financial condition. In addition, our ability to use net operating loss and tax credit carryforwards and certain built- in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code, and it is possible that certain transactions or a combination of certain transactions may result in material additional limitations on our ability to use our net operating loss and tax credit carryforwards. Risks Related to the Regulatory Environment in which We Operate Our ~~.Our~~ Avance Nerve Graft product is currently distributed pursuant to enforcement discretion and a transition plan with the FDA,however we expect to **complete** ~~file a BLA by~~ the ~~end~~ **rolling BLA submission for the Avance Nerve Graft in the third quarter** of **2024** ~~this year~~ .If the FDA does not approve our BLA **,approves a narrower indication than Avance Nerve Graft' s current use** or **otherwise** limits use of our Avance Nerve Graft product it would have a significant impact on our revenues and thus would have a material adverse effect on us.The FDA considers our Avance Nerve Graft product to be a biological product,subject to BLA approval requirements.Although the Avance Nerve Graft product has not yet been approved by the FDA through a BLA,it is currently distributed under the controls applicable to an HCT / P regulated under section 361 of the Public Health Service Act and 21 CFR Part 1271 of FDA' s regulations,subject to FDA' s enforcement discretion and our compliance with a transition plan established by the FDA.See " Business — Government Regulations — U.S.Government Regulation Overview." We have continued to communicate with CBER since the acceptance of the transition plan on clinical trial design,pre- clinical studies,CMC for Avance Nerve Graft,and other issues related to the effective IND.Subject to the FDA' s enforcement discretion,we can commercially distribute Avance Nerve Graft until the FDA makes a final determination on an Avance Nerve Graft BLA submission,assuming we remain in compliance with the transition plan and exercise due diligence in executing the transition **P43** plan.In the event that the FDA becomes dissatisfied with our progress or actions with respect to the transition plan or the FDA changes its position for any reason regarding its use of enforcement discretion to permit us to distribute the Avance Nerve Graft product in accordance with the transition plan,we would no longer be able to distribute Avance Nerve Graft,which would have a material adverse effect on our operations and financial viability.In addition,if we do not meet the conditions of the transition plan,or fail to comply with applicable regulatory requirements,the FDA could impose civil penalties,including fines,product seizures,injunctions,or product recalls and,in certain cases,criminal sanctions.We ~~plan~~ **expect** to ~~submit~~ **complete** the **rolling** BLA ~~by~~ **submission for** the ~~end~~ **Avance Nerve Graft in the third quarter** of ~~2023~~ **2024** ,and if the FDA does not approve the BLA **,narrows the Avance Nerve Graft indication,takes negative action on the BLA,** or limits the use of our Avance Nerve Graft product **for any other reason** ,our operations and financial viability would be significantly negatively impacted as we may no longer be able to distribute our Avance Nerve Graft product or the demand for the Avance Nerve Graft product could drop due to limitations on use.These consequences also would have a material adverse effect on our operations and financial viability.Additionally,approximately 60 % of our total revenues are from sales of Avance Nerve Graft,any change in position by the FDA regarding its use of enforcement discretion to permit the sale of Avance Nerve Graft or a negative **action on the** BLA **could** ~~resolution will~~ have a material negative impact on our revenues and our operations.For additional information see:" Risk Factors- Approximately 60 % of our total revenues are from sales of Avance Nerve Graft." **Our** ~~We have suspended market availability of our Avive Soft Tissue Membrane and there is no guarantee it will be placed back on the market.Effective June 1,2021,we voluntarily suspended the market availability of Avive Soft Tissue Membrane.The decision to suspend market availability of~~ business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and could result in negative effects on our business. We are subject to extensive regulation by foreign and domestic government entities, including compliance with regulations governing appropriate relationships with healthcare professionals, such as physicians, hospitals, and those to whom and through whom we may market our products. We are subject to various federal, state, and territorial laws in the U. S. and other jurisdictions in which we conduct business. These include, for example, anti- kickback laws, false claims laws, healthcare fraud, waste, and abuse laws, and anti- bribery laws such as the U. S. Foreign Corrupt Practices Act. Violations of these laws

can be punishable by criminal and / or civil sanctions, including, in some instances, fines, imprisonment and, within the U. S., exclusion from participation in government healthcare programs, including Medicare, Medicaid, and Veterans Administration health programs. These laws are administered and enforced by, among others, the DOJ, which issued new compliance guidance in 2020, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, and their respective counterparts in the applicable foreign jurisdictions in which we conduct business. Many of these agencies have increased their enforcement activities with respect to drug and medical device manufacturers in recent years. There can also be changes to the regulations by foreign and domestic government entities that require us to update or upgrade business processes or to perform additional validation activities for product or processes. Compliance with such changes can be costly to implement or result in non- compliance, thus restricting the ability to distribute tissue or sell products, which could have a material adverse effect on our business, results of operations, financial condition, and prospects. Our products are also subject to regulation by the FDA in the U. S. The FDA regulates the development, pre- clinical and clinical testing, requirements for commercial marketing and distribution, manufacturing and quality, safety, labeling, and promotion of medical products including human cells, tissues and cellular and tissue- based products (HCT / Ps), medical devices, and biological products. The FDA requires the **pre- market** approval of a biological product, like Avance Nerve Graft, through a BLA **,** prior to marketing. Although the Avance Nerve Graft product has not yet been approved by FDA through a BLA, FDA outlined a transition plan subject to FDA enforcement discretion, that we: (1) transition to compliance with section 501 (a) (2) (B) of the FD & C Act, the cGMP regulations in 21 CFR Parts 210 and 211 and the applicable regulations and standards in 21 CFR Parts 600- 610 prior to initiation of a phase 3 clinical trial designed to demonstrate the safety, purity, and potency of Avance Nerve Graft; (2) conduct a phase 3 clinical trial to demonstrate safety, purity, and potency of Avance Nerve Graft under an SPA; (3) continue to comply with the requirements of 21 CFR Part 1271; and (4) exercise due diligence in executing the transition plan. See " Business — Government Regulations — U. S. Government Regulation Overview. " The FDA also regulates medical devices, for example the Axoguard products, and generally requires them to be cleared through the 510 (k) pre- market notification process prior to marketing or through other pre- market approval processes. The FDA' s pre- market review process for new and modified existing devices that precedes product marketing can be time consuming and expensive. Some of the future products and enhancements to such products that we expect to develop **,** and market may require marketing clearance or approval from the FDA. There can be no assurance, however, that clearance or approval will be granted with respect to any of our medical device products or enhancements of marketed products or that our Avance Nerve Graft will meet FDA' s requirements for continued marketing and transition to a BLA or ultimately an approved BLA. FDA review of our devices or biological products may encounter significant delays during FDA' s pre- market review process that would adversely affect our ability to market our **P44** products or enhancements. In addition, there can be no assurance that our products, including the Avance Nerve Graft, or enhancements will not be subject to a lengthy and expensive approval process with the FDA. **Moreover** ~~In addition~~ , **the** FDA could decide to revoke its enforcement discretion or change the terms of enforcement discretion for Avance Nerve Graft at any time **. In addition, any products regulated solely under Section 361 of the Public Health Service Act are a product category under close scrutiny by FDA for compliance with the regulatory requirements and potentially subject to regulatory change in the future. Failure to comply with applicable regulatory requirements could expose us to potential compliance actions by FDA or other regulators and could risk the commercial availability of the product** . It is possible that if regulatory clearances or approvals to market a product are obtained from the FDA, the clearances or approvals may contain limitations on the indicated uses of such product and other uses may be prohibited. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. The FDA may require post marketing clinical studies or other activities that may add cost or limit marketing of the product. Furthermore, the FDA could limit or prevent the distribution of our products, and the FDA has the authority to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect our business, results of operations, financial condition, and prospects. We, and our facilities, may be inspected by the FDA from time to time to determine compliance with various regulations relating to specifications, development, documentation, validation, testing, manufacturing, quality control and product labeling. A determination that we are in violation of such regulations could lead to imposition of civil penalties, including fines, product recalls or product seizures and, in certain cases, criminal sanctions . Our Avance Nerve Graft product is..... operations, financial condition, and prospects . Our Axoguard products are subject to FDA and international regulatory requirements. Our Axoguard product line is regulated as a medical device in the U. S. and international countries where we market Axoguard products. In the U. S., Axoguard product line is regulated under the FD & C Act and subject to pre- market notification and clearance requirements under section 510 (k) of the FD & C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. In the rest of the world, each region (such as the E. U.) or country has their independent international regulations such as the Medical Device Regulations (CE Mark) in Europe, UK Medicines and Healthcare products Regulatory Agency (MHRA), and Taiwan Pharmaceutical Affairs Act. We distribute Axoguard Nerve Connector and Axoguard Nerve Protector products for Cook Biotech, and Cook Biotech is responsible for the regulatory compliance of these products. In the U. S., Cook Biotech has obtained a 510 (k) pre- market clearance for Axoguard Nerve Connector from the FDA for porcine (pig) small intestine submucosa for the repair of peripheral nerve transections where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510 (k) pre- market clearance for Axoguard Nerve Protector for the repair of peripheral nerve damage in which there is no gap or where a gap closure is achieved by flexion of the extremity. In countries where Axoguard is marketed, Cook Biotech has obtained regulatory clearance with the same indications except for Europe and the UK. For the CE Mark, the Axoguard Nerve Protector indication is the same; however, for Axoguard Nerve Connector, the indication is more specific- " The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm. " We are ~~responsible for~~ the ~~regulatory compliance~~ **authorization holder** of the Axoguard Nerve Cap **and**

Axoguard HA Nerve Protector . We have obtained ~~a~~ 510 (k) pre- market clearance for Axoguard Nerve Cap **, indicated** to protect a peripheral nerve end and **to** separate the nerve from ~~the~~ surrounding environment ~~and to prevent or~~ to reduce the development of symptomatic or painful neuroma **. We have obtained two 510 (k) pre- market clearances for Axoguard HA Nerve Protector, The first 510 (k) K223640 was cleared on April 7, 2023, indicated for the management and protection of peripheral nerve injuries where there is no gap. The second 510 (k) K231708 was cleared on October 12, 2023 expanding the indication to the management and protection of peripheral nerve injuries where there is no gap, or following closure of the gap** . If we or Cook Biotech fail to comply with applicable regulatory requirements, the regulatory bodies in each country could deny or withdraw regulatory clearance / approval for the Axoguard products, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions. ~~Defective~~ **Our Axotouch** ~~products~~ **product** ~~could lead~~ **is subject** to ~~recall or~~ **FDA and** other **regulatory requirements** ~~negative business conditions~~ . ~~If our~~ **Our Axotouch** ~~products~~ **product is regulated as** ~~are defective or otherwise pose safety risks, the FDA could require their recall, or we may initiate~~ a **Class I exempt** ~~voluntary recall of our products. The FDA may require recall of a marketed~~ medical device product, such as the Axoguard products..... recall, the FDA can order one under ~~the above- referenced circumstances or take other enforcement actions, such as product seizure. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency or to remedy a violation of~~ the FD & C Act **and not subject** ~~that may pose a risk~~ to **pre** ~~health. A government~~ **market notification** ~~mandated, government- requested, or voluntary recall could occur as a result of an~~ **and** ~~unacceptable risk to health, reports~~ **clearance requirements under section 510 (k)** of ~~safety issues~~ **the FD & C Act** , ~~failures, manufacturing errors, design or labeling defects or~~ **21 CFR Part 820 (Quality System Regulation) and** other ~~deficiencies, and issues. Recalls and other field corrections for any of our products would divert managerial and financial resources and have an adverse effect on our business, results of operations, financial condition, and prospects. A recall could adversely impact our reputation with customers and our sales. If the~~ FDA ~~were to disagree with our internal determinations and decision making relative to potential recalls (including corrections and removal), we could be subject to further regulatory or enforcement action against. If our products cause or contribute to a death, a serious injury, or any adverse reaction involving a communicable disease, or malfunction in certain ways, we will be subject to reporting~~ regulations ~~, which can result in voluntary corrective actions or agency enforcement actions~~ . ~~See " Business — Regulation — Education Grants, U. S. Anti- kickback, False Claims and Other Healthcare Fraud and Abuse Laws. "~~ If we fail to **comply** ~~report these events to the FDA within~~ -- **with applicable regulatory requirements** ~~the required timeframes, or at all~~ , the FDA could ~~take regulatory~~ **require a 510 (k)** ~~or~~ **for the** ~~enforcement action against us. Any adverse event involving our products~~ - **product** ~~could result in future voluntary corrective actions~~ , ~~such as~~ **or impose civil penalties, including fines, product seizures or product** recalls **and** ~~or customer notifications~~ , ~~or agency~~ **in certain cases, criminal** ~~action~~ **sanctions** , **which** ~~such as inspection, mandatory recall, or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of time and capital, distract management from operating our business, and~~ may adversely ~~impact~~ **affect** our ~~reputation,~~ business, results of operations, financial condition, and prospects. Our operations must comply with FDA and other governmental requirements. **P45** Our operations require us to comply with the FDA' s and other governmental authorities' laws and regulations on ~~the~~ topics including the manufacture and production and sales and marketing of medical products, and compliance efforts related to such laws is costly, and failure to comply could subject us to enforcement action. See " Business — Government Regulations — Education Grants, U. S. Anti- kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Fraud, Abuse and False Claims." Enforcement actions could impair our ability to produce products in a cost- effective and timely manner to meet customer demands. We may also be required to bear other costs or take other actions that may have an adverse impact on our future revenue and our ability to generate profits. Furthermore, our key material suppliers, licensors and or other contractors may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce products on a timely basis and in the required quantities, if at all. Healthcare providers and facilities, and third- party payors, often play a primary role in the recommendation and prescription of any currently marketed products and product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare providers and facilities, third- party payors and customers, and our sales, marketing, and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. In addition, our operations are also subject to various federal and state fraud and abuse, and payment transparency laws and regulations. Payments made to physicians and other healthcare providers, and other financial interests, have been the subject of a range of federal and state laws. The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, or the Sunshine Act, was created under the Affordable Care Act (" ACA"). The Sunshine Act, among other things, imposes reporting requirements on drug manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, including physician assistants, nurse practitioners, and other mid- level healthcare practitioners, and their immediate family members. Reporting relative to these mid- level practitioners began in 2022 for payments or other transfers of value in 2021, which could increase the likelihood of a mistake in submission or failure to submit the required information by that group. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $ 150, 000 per year and up to an additional aggregate of $ 1 million per year for " knowing failures, " for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Additionally, certain states also mandate implementation of compliance programs, impose restrictions on marketing practices and / or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other HCPs. In addition to the federal fraud, waste, and abuse laws noted, there are analogous state laws and regulations, such as state anti- kickback and false claims laws, and other state laws addressing the medical product and healthcare industries, which may apply

to items or services reimbursed by any third- party payor, including commercial insurers, and in some cases may apply regardless of payor, i. e., even if reimbursement is not available. Some state laws require pharmaceutical or device companies to comply with the industry' s voluntary compliance guidelines (the PhRMA Code and AdvaMed Code) and the relevant compliance program guidance promulgated by the federal government (HHS- OIG) in addition to other requirements, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Distribution of our human tissue products outside the U. S. are subject to foreign regulatory requirements that vary from country to country. In the E. U., human tissue regulations, if applicable, differ from one E. U. member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E. U., as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive, and unpredictable. Our products are subject to E. U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue- based products. In addition, some E. U. member states have their own tissue banking regulations. The inability to meet foreign regulatory requirements could materially affect our future growth and compliance with such requirements could place a significant financial burden on us. As a result of Brexit, we cannot be sure what changes could occur or **what** the cost of regulatory compliance with the UK **would be** . Accordingly, the cost of regulatory compliance for sales outside the U. S. can be significant and time consuming. Finally, ~~regulations~~ **regulatory expectations** in both the U. S. and other countries are subject to constant change. There can be no assurance that we can meet the requirements of future regulations **and guidance** or that compliance with current regulations **and guidance** assures future capability to distribute and sell our products **product** ,such as the Axoguard products,in the event that it determines the medical device presents a reasonable probability of serious adverse health consequences or death.However,most device recalls do not rise to this level of health significance and result from voluntary action.The FDA has authority to recall biological products when a batch,lot or other quantity of the product presents an imminent or substantial hazard to the public health.However,in such circumstances,the FDA usually initially requests voluntary recalls of biological products,such as the Avance Nerve Graft.If a company does not comply with an FDA request for a recall,the FDA can order one ~~under~~ . Clinical trials can be long and expensive, and results are ultimately uncertain. We are required to perform a clinical trial for our Avance Nerve Graft under FDA' s statutory requirements to obtain approval of a BLA for the product. This trial is subject to FDA approval and there is a risk that the FDA may not agree that the data supports the conclusions of the study which could jeopardize our ability to obtain regulatory approval and continue to market our Avance Nerve Graft product. The results of pre- clinical studies do not necessarily predict future clinical trial results and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre- clinical studies and clinical trials and may require the company to pursue additional pre- clinical studies or clinical trials, or not approve our BLA. If we are unable to demonstrate the safety, purity and potency of our product through our clinical trials, we will be unable to obtain regulatory approval to market the Avance Nerve Graft, and we will not be able to continue to provide it. We expect to ~~submit~~ **complete** the **rolling** BLA **submission** for the Avance Nerve Graft ~~by~~ **in** the ~~end~~ **third quarter** of ~~2023~~ **2024** ~~and expect the BLA to cover the use of Avance Nerve Graft in the whole body for peripheral nerve repair~~ . We will provide the FDA with supportive clinical evidence based on published literature **, preclinical data** and the RANGER study **data** ~~for qualifying peripheral nerve repairs from multiple areas in the body~~ . The FDA ~~may~~ **could take negative action on the BLA or could** approve the BLA but restrict the Avance Nerve Graft labeling if the FDA does not agree with the ~~additional~~ data **is sufficiently supportive of the application** . ~~We believe that restrictions~~ **Restrictions** to our labeling could have an adverse effect on Avance Nerve Graft commercialization. We rely on third parties to conduct our clinical trials, and they may not perform as contractually required or expected. We rely on third parties, such as contract research organizations (" CROs "), medical institutions, clinical investigators, and contract laboratories to conduct our clinical trials and certain nonclinical studies. We and our CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice (" GCP "). The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If we or our CROs fail to comply with applicable FDA regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our applications. We cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that our clinical trial complies or complied with clinical trial regulations, including GCP. In addition, our clinical trial must be conducted with product produced under applicable GCP regulations. Failure to comply with the clinical trial regulations, including GCP, may require us to repeat clinical trials, which would delay the regulatory approval process. Further, if these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, need to be replaced, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our non- clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we would not be able to obtain regulatory approval for our products on a timely basis, if at all, and our business, results of operations, financial condition, and prospects would be adversely affected. Furthermore, our third- party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. U. S. governmental regulation could restrict the use of our Avance Nerve Graft product, restrict our procurement of tissue or increase costs. In addition to the FDA requirements for biological products, Avance Nerve Graft will continue to be subject to various requirements for human tissue under 21 CFR Part 1271. Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT / P. The first regulation requires that companies that produce and distribute HCT / Ps register with the FDA. The second regulation provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the " Donor Eligibility " rule. The third regulation governs the processing and distribution of the tissues and is often referred to as the " Current Good Tissue

Practices ” rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, the three basic requirements of 21 CFR Part 1271 are **P48** designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which we operate and have led to increased enforcement actions, which affects the conduct of our business. In addition, guidance was issued by the FDA in November 2017 and revised in July 2020 on Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue- Based Products: Minimal Manipulation and Homologous Use, which could have potential implications on future HCT / P products being evaluated by us. Additional regulations or guidance documents may be implemented by the FDA in the future. These changes may impose new documentation requirements, process changes or testing that could increase costs, and regulatory burden. See “ Business — Government Regulations. ” These regulations can also increase the cost of tissue recovery activities. Finally, Avance Nerve Graft is subject to certain state and local regulations, as well as compliance with the standards of the tissue bank industry’ s accrediting organization, the AATB. The procurement and transplantation of allograft nerve tissue is also subject to federal law pursuant to the National Organ Transplant Act (“ NOTA ”), a criminal statute that prohibits the purchase and sale of human organs used in human transplantation, including nerve and related tissue, for “ valuable consideration. ” NOTA only permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation, and storage of human nerve tissue. We make payments to certain of our clients and tissue banks for their services related to recovering allograft nerve and umbilical cord tissue on our behalf. If NOTA is interpreted or enforced in a manner that prevents us from receiving payment for services we render or prevents us from paying tissue banks or certain of our clients for the services they render for us, our business, results of operations, financial condition, and prospects could be materially and adversely affected. We have engaged, through marketing employees, independent sales agents and sales representatives, in ongoing efforts designed to educate the medical community as to our products’ benefits, and we intend to continue our educational activities. Although we believe that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of our products, payments in connection with such education efforts are not exempt from NOTA’ s restrictions and our inability to make such payments in connection with these education efforts may prevent us from paying our sales representatives and could adversely affect our business, results of operations, financial condition, and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft nerve tissue- based material that our processing technologies may generate. Assuming that NOTA applies to our processing of allograft nerve and umbilical cord tissue, we believe that we comply with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be adopted in the future, which would call into question one or more aspects of our method of operations. Other regulatory entities include state agencies with statutes covering tissue banking. Regulations issued by Florida, New York, California, and Maryland, among other states, are particularly relevant to our business. Most states do not currently have tissue banking regulations. However, incidents of allograft related issues in the industry may stimulate the development of regulation in other states. It is possible that third parties may make allegations against us or against donor recovery groups or tissue banks about non- compliance with applicable FDA regulations or other relevant statutes or regulations. Allegations like these could cause regulators or other authorities to take investigative or other action or could cause negative publicity for our business and the industry in which we operate. ~~Our Axotouch product is subject to FDA and other regulatory requirements. We believe our Axotouch product is regulated as a Class I exempt medical device under the FD & C Act and not subject to pre- market notification and clearance requirements under section 510 (k) of the FD & C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. If we fail to comply with applicable regulatory requirements, the FDA could require a 510 (k) for the product, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions, which may adversely affect our business, results of operations, financial condition, and prospects.~~ In the U. S. there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products. ~~Since enactment of the ACA in 2010 there have been a number of legal challenges as well as other legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In June 2021, however, the Supreme Court issued its opinion in California v. Texas, upholding the constitutionality of the ACA. The full effects of the ACA may be unknown as the statutory provisions are fully implemented, and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could potentially alter coverage and marketing requirements, thereby affecting our pricing and market share if individuals lose coverage for certain benefits.~~ In the future, there may continue to be additional proposals relating to the reform of the U. S. healthcare system. Future legislation, federal agency regulations and Presidential Executive Orders may impact the healthcare system in ways important to our business. Adoption of certain proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could also limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations, financial condition, and prospects. Additionally, initiatives sponsored by government agencies, legislative bodies, and the private sector in the U. S. and elsewhere to limit the growth of healthcare costs, especially for drugs and biologics, including price regulation and policies **P49** regarding generic drugs and biosimilars, are ongoing in markets where we do business. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (“ IRA ”) was signed into law. The IRA includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government, including allowing Medicare to negotiate prices for certain prescription drugs, requiring drug

manufacturers to pay a rebate to the federal government if prices for single- source drugs and ~~biologicals~~ **biologics** covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI- U), and limiting out of pocket spending for Medicare Part D enrollees **. Implementation of the drug price negotiation provisions of the IRA began in 2023 and will continue to be implemented over the next several years. Multiple pharmaceutical manufacturers have challenged the law in court, largely on constitutional grounds. These suits will continue through 2024 and the ultimate effects of such legal challenges are unclear. At this time, we continue to evaluate the effect of the IRA on our business operations and financial condition and results as the full impact of the IRA remains uncertain** . Additionally, on October 14, 2022, President Biden signed Executive Order 14087 on " Lowering Prescription Drug Costs for Americans. " The Executive Order specifically requests that the Center for Medicare and Medicaid Innovation consider " models that may lead to lower cost sharing for commonly used drugs and support value- based payment that supports high- quality care. " Continued government efforts to lower healthcare costs would affect our market materially. We could experience an adverse impact on operating results due to increased pricing pressure in the U. S. and in other markets. Governments, hospitals, pharmacy benefit managers ~~(" PBMs ")~~, and other third- party payors could reduce the amount of approved reimbursement for our products, deny coverage altogether, or impose new requirements on manufacturers to justify their prices. Reductions in reimbursement levels or coverage or other cost- containment measures could unfavorably affect our future operating results. We could be subject to civil or criminal penalties if we are found to have violated laws protecting the confidentiality of health information, which could increase our liabilities and harm our reputation or our business. There are a number of federal and state laws protecting the confidentiality of certain health information and restricting the use and disclosure of that protected information. In particular, the U. S. Department of Health and Human Services promulgated privacy rules under the Health Insurance Portability and Accountability Act (" HIPAA "). These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation, and have a material adverse effect on our business, results of operations, financial condition, and prospects. Risks Related to Our IP Failure to protect our IP rights could result in costly and time- consuming litigation and our loss of any potential competitive advantage. Our success will depend, to a large extent, on our ability to successfully obtain and maintain patents, prevent misappropriation or infringement of IP, maintain trade secret protection, and conduct operations without violating or infringing on the IP rights of third parties. See " Business — Intellectual Property. " There can be no assurance that our patented and patent- pending technologies will provide us with a competitive advantage, that we will be able to develop or acquire additional technology that is patentable, or that third parties will not develop and offer technologies which are similar to ours. Moreover, we can provide no assurance that confidentiality agreements with our employees, consultants and other parties, agreements to protect trade secrets or similar agreements intended to protect unpatented technology or prevent unauthorized use, disclosure, or misappropriation will not be breached by those third parties. IP litigation is extremely expensive and time- consuming, and it is often difficult to predict the outcome of such litigation. A failure by us to protect our IP, or a breach by third parties of agreements aimed at protecting our IP, could have a materially adverse effect on our business, results of operations, financial condition, and prospects. Future protection for our proprietary rights is uncertain and may impact our ability to successfully compete in our industry. The degree of future protection for our proprietary rights is uncertain. We cannot ensure that: • We, or our licensors, were the first to make the inventions covered by each of our patents; • We, or our licensors, were the first to file patent applications for these inventions; • Others will not independently develop similar or alternative technologies or duplicate any of our technologies; • Any of our pending patent applications will result in issued patents; **P50** • Any of our issued patents or those of our licensors are valid and enforceable; • Any patents issued to us **,** or our collaborators will provide any competitive advantages or will not be challenged by third parties; • We will develop additional proprietary technologies that are patentable; • The patents of others will not have a material adverse effect on our business rights; or • The measures we rely on to protect our IP underlying our products are adequate to prevent third parties from using, disclosing, or misappropriating that IP, all of which could harm our ability to compete in the market. Our commercial success depends in part on our ability and the ability of our collaborators and licensors to avoid infringing patents and proprietary rights of third parties, which could expose us or our collaborators and licensors to litigation or commercially unfavorable licensing arrangements. Third parties may accuse us or collaborators and licensors of employing their proprietary technology without authorization in our products, or in the materials or processes used to make our products. Any legal action against our collaborators, licensors or those claiming damages and / or seeking to enjoin our commercial activities relating to the affected products, materials and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators and licensors to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. We cannot predict whether we or our collaborators and licensors would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If we were unable to obtain such a license, we and our collaborators and licensors may be unable to continue to utilize the affected materials or processes, or manufacture or market the affected products, or we may be obligated by a court to pay substantial royalties and / or other damages to the patent holder. Even if we were able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair our prospects for profitability. Accordingly, we cannot predict whether, or to what extent, the commercial value of the affected product or products or our prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other IP claims, with or without merit, can be expensive and time- consuming to litigate and can divert management' s attention from our core business. We and our collaborators and licensors may be unable to obtain and enforce IP rights to adequately protect our products and related IP, which could materially and adversely impact our business,

results of operations, financial condition, or prospects. The patent protection for our products may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue. The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition , and we may not be able to recover our development costs. For example, the material U. S. patents covering the formulations used in our Axoguard product line, which are held by Cook Biotech, have expired. Expiration of these patents could adversely affect our ability to successfully execute our business strategy to maximize the value of Axoguard products and could materially and adversely impact our business, results of operations, financial condition, and prospects. Others may claim an ownership interest in our IP or claim that we infringe on their IP rights, which could expose us to litigation and have a significant adverse effect on our prospects. A third party may claim an ownership interest in one or more of our patents or other IP. While we believe we own the right, title, and interest in the patents for which we or our licensors have applied and our other IP (including that which is licensed from third parties) and is presently unaware of any claims or assertions by third parties with respect to our patents or IP, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or IP. Also, a third party may bring legal actions against us claiming we infringed their IP rights and seek monetary damages and / or enjoin clinical testing, manufacturing, and marketing of the affected product or products. There are many issued patents and pending patent applications in the U. S. and in other jurisdictions, owned by third parties, potentially covering various medical devices and biological products. There may be patents owned by third parties that we are currently unaware of, with issued claims that cover one or more of our current or future products or use or manufacture of those products. Since patents may take many years to issue, there may be pending patent applications owned by third parties that may lead to issued claims that cover one or more of our current or future products or use or manufacture of those products. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any of these actions were successful, in addition to any **P51** potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross- licenses to our patents. We cannot, however, assure that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other IP rights, which could have a material and adverse effect on our business, results of operations, financial condition, and prospects. Further, the outcome of IP litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts or the scope or meaning of patent claims upon which experts may reasonably disagree. ~~We depend on the maintenance of exclusive licenses. We depend fundamentally on keeping and satisfying the terms of exclusive licenses of our nerve repair technologies from UFRF and UTA. Nonetheless, a disagreement between us and either licensor could have a negative impact on our ability to effectively operate our business. In addition, we could learn that the technologies we have licensed do not perform as purported, are not efficacious, or are not the property of the licensor, any of which would have an immediate and negative impact on our business.~~ Our trademarks are valuable, and our business may be adversely affected if trademarks are not adequately protected. In the U. S. and other countries, we currently hold trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third- party objection, which could prevent the maintenance or issuance of the same. As our products mature, our reliance on our trademarks to protect our brand, increase our name recognition and, in part, differentiate us from our competitors increases. As a result, if our trademark applications are not successful and if we are unable to prevent third parties from adopting, registering, or using trademarks, including trade dress, that infringe, dilute, or otherwise violate our trademark rights, our business, results of operations, financial condition, and prospects could be materially adversely affected. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. New legislation or court precedent on patent law in the U. S. and in other jurisdictions may increase the uncertainties and costs for us to obtain and enforce patent claims broad enough to exclude others from making, using, or selling our current and future products. These changes in the patent law may also increase the uncertainties associated with the potential third party patent infringement claims against our current and future products. Depending on decisions by the U. S. Congress, the U. S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways to weaken our ability to obtain and enforce patent rights relevant to our products, and / or our ability to defend our business against third party infringement claims in the future. Risks Related to Financing Our Business Our credit facility and payment obligations under the Revenue Participation Agreement with Oberland Capital contain operating and financial covenants that restrict our business and financing activities, require cash payments over an extended period of time and are subject to acceleration in specified circumstances, which may result in Oberland Capital taking possession and disposing of any collateral. Our credit facility with Oberland Capital contains restrictions that limit our flexibility in operating our business. Under the terms of the credit facility, we must maintain, and cause our subsidiaries to maintain, certain covenants, including with respect to limitations on new indebtedness, restrictions on the payment of dividends and maintenance of revenue levels. Our credit facility is collateralized by all of our assets including, among other things, our IP. If we breach certain of our debt covenants and are unable to cure such breach, revert to the provided liquidity covenant or are not granted waivers in relation to such breach, it may constitute an event of default under the credit facility, giving Oberland Capital the right to require us to repay the then- outstanding debt immediately. If we are unable to pay the outstanding debt immediately, Oberland Capital could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness. A breach of the covenants contained in the credit facility documents and the acceleration of its repayment obligations by Oberland Capital could have a material adverse effect on our business, financial condition, results of operations, and prospects. In connection with the credit facility, we entered into a Revenue Participation

Agreement (“ RPA ”) with Oberland Capital. Pursuant to the RPA, we agreed to pay an additional quarterly royalty payment as a percentage of our net revenue, up to $ 70 million in any given fiscal year, subject to certain limitations set forth therein, during the period commencing on the later of (i) April 1, 2021 and (ii) the date of funding of a loan under the credit facility and ending on the date upon which all amounts owed under the Term Loan Agreement have been paid in full. Payments commenced on September 30, 2021 **,** with the royalty structure resulting in approximately 1. ~~0~~ **5** % per year of additional payments on the outstanding principal amount of the loans. The credit facility and RPA could have important negative consequences to the holders of our securities. For example, a portion of our cash flow from operations will be needed to make payments to Oberland Capital and will not be available to fund **P52** future operations. Additionally, we may have increased vulnerability to adverse general economic and industry conditions. Payment requirements under the credit facility and RPA will increase our cash outflows. Additionally, the credit facility and RPA contain complex provisions, which, if interpreted differently, could materially increase the amount of the payments due to Oberland Capital. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets, or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our shareholders. There is no assurance that if we are required to secure funding, we can do so on terms acceptable to us, or at all ~~. Further, our credit facility uses the London Interbank Offering Rate (“ LIBOR ”) as a benchmark for establishing the interest rate. In March 2021, the U. K. Financial Conduct Authority announced that all LIBOR settings will either cease to be provided by any administrator or no longer be representative immediately after December 31, 2021 for sterling, euro, Swiss franc and Japanese yen settings, as well as the one- week and two- month U. S. dollar settings, and immediately after June 30, 2023 for the remaining U. S. dollar settings. While we have not yet incorporated LIBOR- replacement provisions into our credit facility, we will need to do so before June 30, 2023. The discontinuation and replacement of LIBOR or any other benchmark rates may have an unpredictable impact on contractual mechanics in the credit markets or cause disruption to the broader financial markets. Additionally, uncertainty as to the nature of such potential discontinuation and replacement, including that any benchmark may not be the economic equivalent of LIBOR or not achieve market acceptance similar to LIBOR, may negatively impact the cost of our variable rate debt~~ . We may need to raise additional funds to finance our future capital or operating needs, which could have adverse impacts on our business, results of operations and the interests of our shareholders. We may need to seek to raise funds through the issuance of public or private debt or the sale of equity to achieve our business strategy. If we raise funds, this could dilute the interests of our shareholders. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital. Risks Related to Our Common Stock An active trading market in our common stock may not be maintained. The trading market in our common stock has been volatile. The quotation of our common stock on The Nasdaq Capital Market does not assure that a meaningful, consistent, and liquid trading market will exist. We cannot predict whether an active market for our common stock will be maintained in the future. An absence of an active trading market could adversely affect our shareholders’ ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of December 31, ~~2022~~ **2023** , approximately ~~34~~ **28** . ~~9~~ **1** % of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5 % or more of our securities and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these shareholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price. The price of our common stock could be volatile due to a number of factors, which could lead to losses by investors and costly securities litigation. Our common stock is listed on The Nasdaq Capital Market under the symbol “ AXGN. ” The stock market in general, and the market for medical technology companies in particular, have experienced and could in the future experience volatility that has often been unrelated to the operating performance of particular companies. The trading price of our common stock has experienced volatility and is likely to continue to be volatile in response to a number of factors including, without limitation, the following: • Fluctuations in price and volume due to investor speculation, including short sales, social media speculation and other factors that may not be tied to our financial performance; • Our performance in the execution of our business plan; • Financial viability; • Actual or anticipated variations in our operating results; • Announcements of developments by us or our competitors; • Market conditions in our industry; • Announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; **P53** • Adoption of new accounting standards affecting our industry; • Additions or departures of key personnel; • Introduction of new products by us or our competitors; • Sales of our common stock or other securities in the open market; • Regulatory developments in both the U. S. and foreign countries; • Performance of products sold and advertised by licensees in the marketplace; • Economic and other external factors; • Period- to- period fluctuations in financial results; and • Other events or factors, including the other factors described in this “ Risk Factors ” section, many of which are beyond our control. The stock market is subject to significant price and volume fluctuations. Such fluctuations have and could expose us to securities class action litigation, which could adversely impact our business, results of operations, financial condition, and prospects. We do not anticipate paying any cash dividends in the foreseeable future. The operation and expansion of our business will continue to require funding. We do not anticipate that we will pay any cash dividends on our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions,

restrictions imposed by applicable law, and other factors our board of directors deems relevant. Accordingly, if any investor purchases shares of common stock, realization of a gain on such investment will depend on the appreciation of the price of our common stock, which may never occur. Anti- takeover provisions in Minnesota law may deter acquisition bids for us that you might consider favorable. We are governed by the provisions of Sections 302A. 671, 302A. 673 and 302A. 675 of the Minnesota Business Corporation Act (the " MBCA "). These provisions may discourage a negotiated acquisition or unsolicited takeover of us and deprive our shareholders of an opportunity to sell their common stock at a premium over the market price. In general, Section 302A. 671 of the MBCA provides that a corporation' s shares acquired in a control share acquisition have no voting rights unless voting rights are approved in a prescribed manner. A " control share acquisition " is a direct or indirect acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20 % or more in the election of directors. In general, Section 302A. 673 of the MBCA prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term " business combination " includes mergers, asset sales, and other transactions resulting in a financial benefit to the interested shareholder. An " interested shareholder " is a person who is the beneficial owner, directly or indirectly, of 10 % or more of a corporation' s voting stock or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in question, was the beneficial owner, directly or indirectly, of 10 % or more of the corporation' s voting stock. Section 302A. 673 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder' s acquisition of shares before the interested shareholder becomes an interested shareholder. If a tender offer is made for our common stock, Section 302A. 675 of the MBCA precludes the offeror from acquiring additional shares of stock (including in acquisitions pursuant to mergers, consolidations, or statutory share exchanges) within two years following the completion of the tender offer, unless shareholders selling their shares in the later acquisition are given the opportunity to sell their shares on terms that are substantially the same as those contained in the earlier tender offer. Section 302A. 675 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding its current and former officers) approves the proposed acquisition before any shares are acquired pursuant to the earlier tender offer. **P54** ~~General Risk Factors Legal proceedings that we become involved in from time to time could adversely affect our business operations or financial condition.~~ We are subject to legal proceedings from time to time. Legal proceedings, if decided adversely to or settled by us, and not covered by insurance, could result in liability material to our financial condition, results of operations or cash flows. Likewise, regardless of outcome, legal proceedings could result in substantial costs and expenses, affect the availability or cost of some of our insurance coverage and significantly divert the attention of our management. There can be no assurance that we will be able to prevail in, or achieve a favorable settlement of, any pending or future legal proceedings to which we become subject. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees. We may seek to expand our business in ways that could result in diversion of resources and extra expenses. We may in the future pursue acquisitions of businesses, products and technologies, establish joint venture arrangements, or make minority equity investments to expand our business. We are unable to predict whether or when any prospective acquisition, equity investment or joint venture will be completed. The process of negotiating potential acquisitions, joint ventures or equity investments, as well as the integration of acquired or jointly developed businesses, technologies or products may be prolonged due to unforeseen difficulties and may require a disproportionate amount of our resources and management' s attention. We cannot assure you that we will be able to successfully identify suitable acquisition or investment candidates, complete acquisitions or investments, or integrate acquired businesses or joint ventures with our operations. If we were to make any acquisition or investment or enter into a joint venture, we may not receive the intended benefits of the acquisition, investment or joint venture or such an acquisition, investment or joint venture may not achieve comparable levels of revenues, profitability or productivity as our existing business or otherwise perform as expected. The occurrence of any of these events could harm our business, financial condition or results of operations. Future acquisitions, investments or joint ventures may require substantial capital resources, which may require us to seek additional debt or equity financing. Future acquisitions, joint ventures or minority equity investments by us could result in the following, any of which could seriously harm our results of operations or the price of our stock: • issuance of equity securities that would dilute our current shareholders' percentages of ownership; • large one- time write- offs or equity investment impairment write- offs; • incurrence of debt and contingent liabilities; • difficulties in the assimilation and integration of operations, personnel, technologies, products and information systems of the acquired companies; • inability to realize cost efficiencies or synergies, thereby incurring higher operating expenditures as a result of the acquisition; • diversion of management' s attention from other business concerns; • contractual disputes; • risks of entering geographic and business markets in which we have no or only limited prior experience; and • potential loss of key employees of acquired organizations. We may be subject to future product liability litigation, which could be expensive, and our insurance coverage may not be adequate. Although we are not currently subject to any product liability proceedings and have no provision for product liability disbursements, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage of our products. Although we currently carry product liability insurance in an amount **,** we believe is consistent with industry averages, our insurance coverage and any provision we may maintain in the future for product related liabilities may not be adequate and our business, results of operations, financial conditions, and prospects could suffer material adverse consequences. Loss of key members of management, who we need to succeed, could adversely affect our business. Our future success depends on the continued efforts of the members of our executive management team. Competition for experienced management personnel in the healthcare industry is intense. If one or more of our executives or other key personnel **P55** are unable or unwilling to continue in their present positions, or if we are unable to attract and retain high quality executives or key personnel in the future, our business,

results of operations, financial conditions, and prospects may be adversely affected **. We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price. We provide financial guidance about our business and future operating results. In developing this guidance, our management makes certain assumptions and judgments about our future operating performance, including projected hiring of sales professionals, continued increase of our market share, and continued stability of the macro- economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, the market price of our common stock could decline.** . Our business and financial performance could be adversely affected, directly or indirectly, by natural or man-made disasters or other similar events. Neither the occurrence nor the potential impact of risks such as earthquakes, hurricanes, floods and other natural disasters, fire, power shortages, geopolitical unrest, war, terrorist attacks and other hostile acts, epidemics or pandemics such as COVID- 19 pandemic, outbreaks of RSV and the flu, nuclear disasters, international hostilities or other criminal activities and other events beyond our control and the control of the third parties on which we depend can be predicted. However, these occurrences could impact us directly as a result of damage to our facilities or by preventing us from conducting our business in the ordinary course, or indirectly as a result of their impact on our customers, suppliers, or other counterparties. We could also suffer adverse consequences to the extent that these disasters affect the financial markets or the economy in general or in any particular region. Additionally, climate change could present immediate and long- term risks to our industry and our customers. The potential for increased severe weather events could have a material adverse effect on our operations and infrastructure or the operations and infrastructure of our suppliers. In addition, the effects of climate change could include long- term changes in temperature levels and water availability, increased energy costs, and increased supply costs impacted by those increasing energy costs. Our ability to mitigate the adverse consequences of such occurrences is in part dependent on the quality of our resiliency planning, and our ability, if any, to anticipate the nature of any such event that occurs. The adverse impact of natural or man- made disasters also could be increased to the extent that there is a lack of preparedness on the part of national or regional emergency responders or on the part of other organizations and businesses that we deal with, particularly those that we depend upon but have no control over. Our business, results of operations, financial condition, and prospects could be adversely affected, directly or indirectly, by the effects of an increased focus on environmental, social and governance issues. Recently, shareholders have had an increased focus on environmental, social and governance (" ESG") issues, focusing on how companies are addressing climate change, diversity, and human rights, among other ESG- related issues. Our failure to comply with stakeholder expectations and standards regarding ESG issues, which are still evolving and can vary considerably, or the perception that we have not responded appropriately to ESG- related issues, could result in reputational harm, and could have an adverse effect on our business, results of operations, financial condition, and prospects. The cost of mitigating or responding to ESG issues could be significant; however, these costs are too uncertain to predict. In addition, the approaches taken by the U. S. or foreign governments to regulate ESG issues, which may include legislative or regulatory changes, and new reporting requirements, could adversely impact our business, results of operations, financial condition, and prospects, and are too uncertain to predict. We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability **and tensions** , Russia' s ongoing invasion of Ukraine and illegal annexation of Ukrainian territories, and record inflation and could materially and adversely affect our business, financial condition and results of operations. We are exposed to the risk of changes in social, geopolitical, legal, and economic conditions. The global economy has been, and may continue to be, negatively impacted by Russia’ s invasion of Ukraine and illegal annexation of Ukrainian **P56** territories. The negative impacts arising from the war and sanctions and export restrictions imposed by various countries, including those imposed by Russia, may include reduced consumer demand, supply chain disruptions, increased cybersecurity risks, and increased costs for transportation, energy, and raw materials. **Additionally, further escalation of trade tensions between the U. S. and China, escalation of tensions between China and Taiwan, further escalation in the conflict between the State of Israel and Hamas, as well as further escalation of tensions between the State of Israel and various countries or terror organizations in the Middle East and North Africa, could result in a global economic slowdown and long- term changes to global trade.** Although ~~none of our~~ **we do not have material** operations ~~are~~ in Russia ~~or~~ **,** Ukraine **, China, Taiwan, Israel, or other countries in the Middle East and North Africa** , further escalation of geopolitical tensions could have a broader impact that expands into other markets where we ~~do business~~ **have material operations** , which may adversely affect our business, financial condition and results of operations. Further, changes in domestic and global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause changes in fiscal and monetary policy. Additionally, our ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. Impacts from inflationary pressures, such ~~an~~ **as** increasing costs for research and development of our products, administrative and other costs of doing business, could adversely affect our business, financial condition and results of operations. Additionally, our customers could experience financial and operational pressures as a result of labor shortages, the supply chain disruptions, and increased inflation, which could impact their ability to access capital markets and other funding sources, increase cost of funding, or impede their ability to comply with debt covenants, which in turn could impede their ability to provide patient care, conduct further research and development, marketing and commercialization efforts, or impact their profitability. To the extent that our customers continue to face such financial pressures, it could impact their willingness to spend on our products and services, which could adversely affect our business,

financial condition and results of operations. Although, to date, our business has not been materially impacted by Russia' s ongoing invasion of Ukraine and illegal annexation of Ukrainian territories, geopolitical tensions **between China and the U. S. geopolitical tensions between China and Taiwan, the escalation of the conflict between the State of Israel and Hamas** , or record inflation, it is impossible to predict the extent to which our operations could be impacted in the short and long term, or the ways in which such matters may impact our business. Changes in U. S. trade policy, threats of international tariffs, and changes to the U. S. political landscape may adversely affect our business, results of operations, financial condition, and prospects. Rising threats of international tariffs, including tariffs applied to goods traded between the U. S. and China, could materially and adversely affect our business, results of operations, financial condition, and prospects. Over the past several years, legislative and executive action from U. S. and foreign leaders has led to both threats of and the imposition of tariffs on certain materials and products. The U. S. and China imposed tariffs or announced proposed tariffs to be applied in the future to certain of each other' s exports ~~. In November 2022, the Biden Administration extended the tariffs implemented by former President Trump on COVID- 19 related products. We cannot be certain, however, if the Biden administration will choose to have these tariffs remain in place or what impact, if any they may have on our business~~ . Changes in political conditions in China and changes in the state of China- U. S. relations, including the current trade tensions, are difficult to predict and could adversely affect our operations or financial condition. We cannot predict the extent to which the U. S. or other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon the import or export of our products in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U. S. economy, which in turn could have a material adverse effect on our business, results of operations, financial condition, and prospects ~~. The Biden administration continues to contemplate significant policy changes, including healthcare regulatory changes, which may impact our business, results of operation, financial condition, and prospects. These effects could be exacerbated by volatile economic, political and market conditions, such as social unrest, civil insurrection, and political action~~ . Our results of operations could be negatively affected by potential fluctuations in foreign currency exchange rates. We are exposed to the effects of changes in foreign currency exchange rates. We are exposed to the risk of an increase or decrease in the value of the foreign currencies relative to the U. S. Dollar, which could increase the value of our expenses and decrease the value of our revenue when measured in U. S. Dollars. As a result, our results of operation may be influenced by the effects of future exchange rate fluctuations and such effects may have an adverse impact on our common stock price. ~~Global markets and foreign currencies, including the Euro and the British Pound, were adversely impacted, as a result of Brexit and volatility in foreign currencies is expected to continue as a result of Brexit.~~ Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, results of operations, financial condition or prospects. We may have exposure to additional tax liabilities as a result of our foreign operations. We are subject to income taxes in the United States and various foreign jurisdictions. We have operations in Canada, Germany, UK, Spain, and several other European, Asian, and Latin American countries. Significant judgment is required in **P57** determining our worldwide provision for income taxes and other tax liabilities. In the ordinary course of a global business, there are many intercompany transactions and calculations where the ultimate tax determination is uncertain. We are regularly under audit by tax authorities. Our intercompany transfer pricing may be reviewed by the U. S. Internal Revenue Service and by foreign tax jurisdictions. Although we believe that our tax estimates are reasonable, due to the complexity of our corporate structure, the multiple intercompany transactions and the various tax regimes, we cannot assure you that a tax audit or tax dispute to which we may be subject will result in a favorable outcome for us. If taxing authorities do not accept our tax positions and impose higher tax rates on our foreign operations, our overall tax expenses could increase. Our failure to protect our technology systems and comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our business, results of operations, financial condition, and prospects. We rely on information technology systems, including technology from third- party vendors, to process, transmit and store electronic information in our day- to- day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber- attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards and the increasing need to protect patient and customer information. **We expend significant resources to comply with applicable data privacy and security laws and regulations (together with applicable industry standards) and minimize the risk of security breaches, including deploying additional personnel and protection technologies, training employees annually, and engaging third- party experts and contractors. Significant and increasing investments of time and resources by management and Board have been, and will continue to be, required to anticipate and address cybersecurity risks and incidents. However, given that the techniques used to obtain unauthorized access or to sabotage systems change frequently, and often are not identified until they are launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures in time to stop a cyber incident.** Any failure by us to maintain or protect our information technology systems and data integrity could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber- attacks, intrusions, or other breaches could adversely impact our business, results of operations, financial condition, and prospects **and potentially subject us to fines and penalties** . In the U. S., federal and state privacy and security laws require certain of our operations to protect the confidentiality of personal information, including patient medical records and other health information. Limiting and / or restricting the use of certain personal data and information, as well as added transparency obligations to data subjects is

becoming an increasing focus as evidenced by the implementation of the California Consumer Privacy Act (" CCPA ") which became effective on January 1, 2020. In Europe, E. U. member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the E. U. is governed by the European Union General Data Protection Regulation (" GDPR "). The GDPR imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third- party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E. U. to the U. S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to 4 % of the annual global revenue of the noncompliant company. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management' s attention and increase our cost of doing business. **Additionally** ~~Compliance with applicable data privacy and security laws and regulations (together with applicable industry standards) may increase our costs of doing business. In this regard and in light of the CCPA' s implementation~~ , we expect that there will be other proposed laws, regulations and industry standards relating to privacy and data protection in the U. S., the E. U. and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business results of operations, financial condition, and prospects. We are dependent on internal information and telecommunications systems, and any failure of these systems, including system security breaches, data protection breaches or other cybersecurity attacks, may negatively impact our business and results of operations. Cyber- attacks and other tactics designed to gain access to and exploit sensitive information by breaching mission critical systems of large organizations are constantly evolving and have been increasing in sophistication in recent years. High profile security breaches leading to unauthorized release of sensitive information have occurred with increasing frequency at a number of major U. S. companies, despite widespread recognition of the cyber- attack threat and improved data protection methods. While to date we have not experienced a significant data loss, significant compromise or any material financial losses related to **P58** cybersecurity attacks, our systems, those of our customers, and those of our third- party service providers are under constant threat. Cybercrime, including phishing, social engineering, attempts to overload our servers with denial- of- service attacks, or similar disruptions from unauthorized access to our systems, could cause us critical data loss or the disclosure or use of personal or other confidential information. Outside parties may attempt to fraudulently induce employees to disclose personally identifiable information or other confidential information which could expose us to a risk of loss or misuse of this information. **Although we incur significant expenses to minimize the risk of security breaches, given that the techniques used to obtain unauthorized access or to sabotage systems change frequently, and often are not identified until they are launched against a target, we may be unable to anticipate these techniques of implement adequate preventive measures in time to stop or effectively mitigate a cyber incident.** We are dependent on internal information and telecommunications systems, and we are vulnerable to failure of these systems, including through system security breaches, data protection breaches or other cybersecurity attacks. If these events occur, the unauthorized disclosure, loss or unavailability of data and disruption to our business may have a material adverse effect on our reputation and harm our relationships with vendors and customers. Additionally, these events may lead to financial losses from remedial actions, or potential liability from fines, including in relation to noncompliance with the GDPR, as well as possible litigation and punitive damages. Failures of our internal information or telecommunications systems may prevent us from taking customer orders, shipping products and billing customers. Sales may also be impacted if our customers are unable to access our pricing and product availability information. The occurrence of any of these events could have a material adverse impact on our business and results of operations. Our management has broad discretion in the use and placement of our cash and cash equivalents and, despite management' s efforts, cash and cash equivalents may be used in a manner that does not increase the value of shareholders' investments or placed in otherwise reputable financial institutions that fail. ~~.~~Our management has broad discretion in the use and placement of our cash and cash equivalents, and investors must rely on the judgment of management regarding the use and placement of such cash and cash equivalents. Management may invest our cash and cash equivalents in short- term or long- term, investment- grade, interest- bearing securities. These investments may not yield favorable returns to shareholders. If we do not invest or apply our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause our stock price to decline. Furthermore, the most reputable financial institutions may fail ~~, as evidenced by SVB~~ . Despite the judgment of management regarding the placement of cash and cash equivalents in deemed reputable financial institutions, events outside of our control could occur, the result of which could result in us not having access to our cash and cash equivalents. Our business and stock price may be adversely affected if our internal controls are not effective. Section 404 of the Sarbanes- Oxley Act of 2002 requires that public companies conduct a comprehensive evaluation of their internal control over financial reporting. To comply with this statute, each year we are required to document and test our internal control over financial reporting and our management is required to assess and issue a report concerning it. Although we have systems in place to strengthen our internal control over financial reporting, we cannot assure you that we will not discover material weaknesses in the future or that no material weakness will result from any difficulties, errors, delays, or disruptions while we implement and transition to new internal systems. The existence of one or more material weaknesses could result in errors in our financial statements, and substantial costs and resources may be required to rectify these or other internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, we may be unable to obtain additional financing to operate and expand our business and our business, results of operations, financial condition, and prospects could be adversely impacted.