Risk Factors Comparison 2025-02-28 to 2024-02-29 Form: 10-K

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Investing in our securities involves a high degree of risk. You should consider the following information about the risks described below, together with the other information contained in this **Annual** Report **on Form 10- K** and in our other public filings in evaluating our business. The following factors, among others, could cause our actual operating results to differ materially from those indicated or suggested by forward- looking statements made in this **Annual** Report **on Form 10- K** or presented elsewhere by management. Investors should consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are not material may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment. Risks Related to Our Business We face ~~external~~ competition from other **medical device** companies ~~, technologies such as GLP- 1' s,~~ and alternative medical ~~procedures~~ **technologies,** and we may not be able to compete effectively. ~~Companies that may not be deemed competitors in the peripheral vascular device space may develop technologies, products or services that may impact the use of our products and services. For example, certain therapeutic treatments, such as drugs used to treat diabetes or weight loss such as GLP- 1' s, may enhance patient health and lower the occurrence and severity of vascular disease. If we do not introduce new products, services and enhancements in a timely manner, there may be a decrease in the use of certain of our products and services, in which case our operating results could suffer.~~ The segments in which we primarily operate are ~~also~~ competitive, subject to change, and affected by new product introductions. ~~Although~~ **Our competitors vary by product line, as** no company **directly** competes against us ~~in~~ **with respect to** all ~~of~~ our **offerings. Certain competitors: •** ~~products, a number of device manufacturers~~ have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, **and** larger research and development or regulatory staffs **and resources** ; **•** have ~~established~~ **stronger** reputations **and relationships** with our target customers; ~~and~~ **•** have developed ~~larger~~ **more extensive** distribution channels **; •** ~~than ours. Our competitors could elect to devote additional resources to the specific segments in which we operate. Also, although we currently have leading positions in the segments for some of our products, this is not true for all of our products. Certain competitors~~ are **or may be** able to manufacture and distribute products more efficiently at lower costs and ~~may~~ offer comparable products at lower prices **; •** ~~. Certain competitors may also~~ have greater experience in developing and improving products, obtaining regulatory approvals, ~~obtaining favorable reimbursement,~~ and manufacturing and marketing products **; •** ~~. For example, vascular surgeons may choose to utilize our competitors' new or enhanced products for carotid stenting instead of our carotid enterectomy products. In addition, certain competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization, before us. Further, if the trend towards endovascular procedures versus open vascular procedures continues or accelerates, this could harm our results. The vascular disease market is characterized by extensive research efforts and technological progress. Competitors~~ may develop technologies and products that are safer, more effective, easier to use, or less expensive than ours **; and •** ~~. In addition, many~~ **may** ~~of~~ **obtain patent protection** ~~our~~ **or regulatory approval or clearance, or achieve product commercialization, before us. Our open vascular surgical** products ~~face competition from alternative~~ **additionally compete to varying degrees with endovascular devices, and we may experience sales erosion to the extent industry trends favor endovascular** procedures. **We are also potentially vulnerable to companies outside of the peripheral vascular device space that may develop technologies, products, procedures, or services that may impact the demand for or use of our products and services. To the extent we experience** ~~Increased~~ **increased** ~~competition~~ **competitive pressures, whether direct or indirect, we** could ~~also result in~~ **suffer loss of sales and market share or need to undertake competitive countermeasures, such as** price reductions ~~or loss of market share. If we do not comply with international regulatory requirements to market our products outside the U. S. or are required to modify our operations or products as a result of such requirements~~ , ~~our business will be harmed. Sales of medical devices outside the U. S. are subject to international regulatory requirements~~ that ~~vary from country to country. These requirements and timing may differ from our experiences with the U. S. FDA. In some countries, we rely on our international distributors to obtain premarket approvals, complete product registrations, and comply with clinical trial requirements. Failure to satisfy foreign regulations might impact our ability to sell our products in these countries. There can be no assurance that we will be able to obtain or maintain the required international regulatory approvals. Our devices are currently regulated in the EU and the UK under the MDD and the MDR. In order to market our medical devices in the EU, we are required to obtain CE marks, which denote conformity to the essential requirements of the MDD or MDR, and manufacturers of higher- risk devices generally must use a " Notified Body " — an appointed independent third party to assess conformity. We currently use three Notified Bodies. We have received CE marks under the MDD to sell most of our products and have recently received our first three CE marks under the MDR for our Pruitt F3 Shunt, Flexeel Shunt and XenoSure Biologic Patch. The EU adopted new regulations for medical devices, the MDR, which replace the MDD and which took effect as of May 26, 2021. The final deadline for compliance with MDR was revised to December 31, 2027 and December 31, 2028. Our products will eventually be fully subject to the MDR, which requires all of our products to obtain a new CE mark in accordance with MDR. Some of our Notified Bodies have already begun to impose these more rigorous requirements on us. Nearly all of our products have been submitted to our Notified Bodies for review under the MDR. If we fail to obtain new CE marks under the MDR, future sales of our products in the EU** could be adversely impacted. As a result....., we may be required to cease - **cause** ~~all or~~ **our** ~~part of our operations~~ - **operating** for some period of time until we..... could have a negative impact on our results ~~of operations~~ **to decline** . If we are unable to ~~expand our~~ **source, acquire and integrate new**

businesses, product ~~and service offerings~~ **lines, or technologies** , we may not achieve our growth objectives and our results of operations could suffer. ~~Treatment of peripheral vascular and cardiovascular disease includes both open vascular surgery and minimally invasive endovascular procedures, and most of our products are used primarily or exclusively in open surgery procedures.~~ We **have limited internal research and development resources and capabilities. We have historically introduced few internally- developed new devices to** market ~~and sell our products primarily to vascular surgeons. We estimate that in 2023 over 95 % of our sales were from devices used in open surgical procedures~~ . A ~~core component~~ **significant portion** of our growth **has been** ~~strategy is the acquisition of complementary product lines, principally in open vascular surgery. The number of appropriately sized targets in open vascular surgery could be limited, and if we are unable to execute our acquisition strategy, growth of our sales may be inhibited. We may not be able to compete effectively unless we can keep pace with existing or new products, services and technologies in the vascular device market and the minimally invasive endovascular procedure segment, in particular. Our success in developing and commercializing new products and new versions of our existing products and services, or acquiring new products, is affected by our ability to: • recognize in a timely manner new market trends and customer needs; • identify products or services that address those trends or needs; • identify and execute on suitable acquisition targets; • obtain regulatory clearance or approval; • develop cost- effective manufacturing processes for such products; and • introduce such products, services and technologies. If we are unable to expand our product or service offerings, whether through internal development or by acquisition, we may not grow sales and our operating results and stock price could suffer. If we are unable to increase our selling prices to customers, or if we are required to make price concessions, our sales growth could be reduced and our operating results could suffer. In the years ended December 31, 2023, 2022 and 2021, a material portion of our sales growth was~~ driven by ~~higher average selling prices, particularly with respect to valvulotome and carotid shunt sales. In the past, we have been able to rely upon our well- known brands and established reputation to increase prices. Also, we may become unable to implement further price increases: • if healthcare spending is reduced, particularly in the U. S., in response to government- enacted healthcare reform, general economic conditions, or the influence of accountable care organizations; • if the reimbursement rates for the medical procedures in which our products are used are reduced or limited; • if competitors introduce lower- priced products of comparable safety and efficacy; or • if customers engage in information sharing regarding competitive pricing of medical devices. Marketplace changes might also place pressure on pricing as hospitals join group purchasing organizations, integrated delivery networks and managed care organizations. Due to pricing pressures, surgeons may even perform alternative procedures. If we become unable to raise prices it could reduce our rate of net sales growth and harm our operating results. We are implementing a new enterprise resource planning system, and challenges with the implementation of the system may impact our business and operations. We are implementing a new enterprise resource planning system (ERP). ERP implementations are complex, time- consuming, labor intensive, and involve substantial expenditures. The new ERP is critical to our ability to gather important information, obtain and deliver products, send invoices, fulfill contractual obligations, maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, and otherwise operate our business. ERP implementations also require transformation of internal processes. Any such implementation involves risks, including loss of information and potential disruption in operations. The implementation and maintenance of the new ERP system may be subject to delays and cost overruns. Any disruptions, delays or deficiencies in the implementation of the new ERP system could affect our ability to process orders, ship products, send invoices, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, including reports required by the SEC such as the evaluation of our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, and otherwise operate our business. Additionally, if we do not implement the new ERP as planned, the effectiveness of our internal control over financial reporting could be adversely affected. We may experience significant fluctuations in our quarterly and annual results. Fluctuations in our quarterly and annual financial results have resulted and will continue to result from numerous factors, including: • changes in demand for the products and services we sell; • increased product and price competition, due to market conditions, the regulatory landscape or other factors; • our pricing strategy with respect to different product lines and services; • productivity of our sales force; •~~ acquisitions ~~of businesses or products or divestitures or discontinuations of products; • effects of domestic and foreign economic and political conditions and exchange rates; • the relocation and integration of manufacturing or processing operations; • regulatory actions that may necessitate recalls of our products or warning letters; • changes to the regulatory status of our products; • the payment or cessation of quarterly cash dividends, and / or the amount and frequency at which to increase them; • costs incurred by us to terminate contractual and other relationships, including those of distributors / agents; • we have not focused on Group Purchasing Organization (GPO) contracts, which may reduce unit sales; • our ability to collect accounts receivable in selected countries outside of the U. S.; • changes in laws in the jurisdictions in which we do business; • the expiration, elimination or utilization of deferred tax assets such as net operating loss carry- forwards; and • the loss of any significant customer, especially in regard to any product or service that has a limited customer base. These factors, some of which are not within our control, may cause the price of our common stock to fluctuate. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop. We believe the quarterly comparisons of our financial results are not always meaningful and should not be relied upon as the sole indicator of our performance. We may not be able to maintain our historic levels of profit growth. Our annual operating income for 2023 was 37 % higher than 2022. This was due in part to substantial investments we made in growing our sales force and our direct labor pool in 2022 and 2023. There can be no assurance that we will be able to achieve this level of profit growth in 2024 or in future years. If we are unable to effectively manage our operating expenses, we may need to implement cost- cutting measures to maintain profitability. Decreased investment levels could inhibit future growth. Additionally, our ability to maintain and increase profitability will be influenced by many factors, including: • the level and timing of future sales, manufacturing costs and operating expenses; • our ability to restrain or reduce operating expenses; • the productivity of our direct sales force; • fluctuations in foreign currency exchange~~

~~rates; • market acceptance of our new products and services; • our ability to successfully build direct sales organizations in new markets; • our ability to successfully acquire and develop competitive products • our ability to successfully integrate acquired businesses; • the impact on our business of competing products, technologies, and procedures; • our ability to obtain or maintain regulatory approvals for our products; • reimbursement rates for the medical products and procedures; • the cost of litigation, if any; and • changes in tax laws. Our dependence on sole- and limited- source suppliers could hinder our ability to deliver our products and services to our customers and could harm the results of operations. We rely on sole- and limited- source suppliers for many of our important components and certain products. For example, we rely on a sole- source supplier for ovine material used in our Omniflow II graft. With respect to our RestoreFlow allografts, we rely on tissue procurement organizations to provide donated tissue to us. While we have relationships with multiple tissue procurement organizations, we cannot be sure that a sufficient supply of suitable human tissue will be available to us, in which case our allograft preservation service revenues could be adversely affected. When we acquire a product line, we often enter into an agreement with the seller for a defined period for supply of the acquired product until we can transfer manufacturing to our facilities. Those arrangements are always sole source supply arrangements. The supplier may not allocate sufficient resources to the manufacture of our product. Additionally, there is a risk if the supplier does not have the financial means to continue to supply product. For example, in the case of our 2019 acquisition of the CardioCel and VascuCel biologic patches, Anteris has agreed to continue to supply those products until January 2025. If Anteris fails to meet its obligations under the supply agreement, then we may experience interruptions in our supply. If we have insufficient supply of an acquired product, this could lead to loss of sales and our results of operations could be harmed. There are relatively few, or in some cases no, alternative, validated sources of supply for these materials and products. We do not always have supply agreements in place with suppliers, instead placing orders on an as-needed basis. At any time, these suppliers could discontinue or become incapable of the manufacture or supply of these materials or products. We do not ordinarily carry a significant inventory of these materials and products. Identifying and qualifying additional or replacement suppliers, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption from our suppliers or failure to obtain replacement suppliers would interrupt our ability to manufacture our products and result in production delays and increased costs. This could lead to loss of sales and customers, and our results of operations could be harmed. In some cases, changes to raw material suppliers or use of alternative raw materials may require significant testing and subsequent regulatory approval. Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business. We rely upon a combination of information technology systems and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including, but not limited to, information about our business, financial information, personal data, intellectual property, and, in some very limited instances, patient data). Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, data loss, or malicious attacks resulting from inadvertent or intentional actions by our employees, vendors, or other third parties. In addition, due to our international presence and mobile sales force, we have implemented remote work arrangements for certain employees, and those employees may use outside technology and systems that are vulnerable to security breaches, service interruptions, data loss or malicious attacks, including by third parties. While we have invested, and continue to invest, in our information technology and information security systems and employee information security training, there can be no assurance that our efforts will prevent all security breaches, phishing / fraud attempts, service interruptions, or data losses~~ . Although we are not aware of having experienced..... To expand our product offerings, we have completed 24 acquisitions **since** ~~, and a key part of our strategy is to acquire additional businesses, products, or~~ **our** ~~technologies. We~~ **founding, we** have not completed an acquisition since 2020. ~~If~~ **Acquisition targets in the open vascular surgery space may be limited, and even to the extent that we are able to identify acquisition opportunities, there may be reasons that** we are unable to **consummate acquisitions, including, without limitation, an inability to agree upon acceptable acquisition terms, the presence of competitive bids, and regulatory or antitrust challenges. If we are unable to** complete **future potential** acquisitions **,** ~~on satisfactory terms or~~ **our ability to** ~~at all, our growth --~~ **grow may** ~~objectives and sales could~~ be **inhibited** ~~negatively affected~~ . Even ~~if~~ **to the extent** we complete acquisitions, we may experience: • difficulties in integrating ~~any~~ acquired businesses, personnel, and products into our existing business; • difficulties or delays in integrating manufacturing operations into our existing business or successfully replicating manufacturing processes at new manufacturing facilities on a cost- effective basis; • ~~degradation~~ **decline** in our corporate gross margin due to lower margins associated with ~~our~~ acquired devices; • ~~the sudden~~ reduction in volume from ~~a~~ key ~~customer~~ **customers** , particularly where the acquired company had concentrated sales; • diversion of management' s time from other business concerns; • higher costs of integration than anticipated; • unanticipated liabilities included as part of the acquisition; • disputes or litigation with former owners related to contingent payments, liabilities assumed **,** or other matters; • challenges in complying with regulatory requirements to which we were not previously subject; • increased regulatory scrutiny; • challenges in transferring, maintaining or obtaining regulatory approvals for acquired products; • difficulties in retaining key employees of the acquired business; • difficulties ~~if the acquired company is remote to our Burlington, Massachusetts, headquarters; • difficulties~~ or delays in transitioning clinical studies or unfavorable results from such clinical studies; • loss of key suppliers or issues with the ongoing supply of the acquired product from its former owners; • charges related to the acquisition of in- process research and development; **or** • dilution as a result of equity financing **or the incurrence of additional debt** required to fund acquisition costs ~~; or • debt, because of financing to fund acquisitions, which would be senior to our common stock, would require interest payments to our lenders, and could restrict our ability to pay dividends to our shareholders~~ . We could also discover deficiencies withheld from us due to fraud or otherwise not uncovered in our due diligence, including deficiencies in internal controls, data adequacy and integrity, product quality, and regulatory compliance, as well as undisclosed contractual or other liabilities and product liabilities, any of which could result in us becoming subject to penalties or other liabilities. Any of these difficulties could negatively impact our ability to realize the

intended and anticipated benefits from ~~our~~ acquisitions **. If we are unable to increase ~~or~~ our selling prices to customers, or if we are required to make price concessions, our sales growth could be reduced and our operating results could suffer. In recent years a material portion of our sales growth has been driven by higher average selling prices, particularly with respect to our valvulotome and carotid shunt products. We cannot guarantee that we will be able to continue to increase selling prices at the same pace. The following factors, among others, could inhibit our ability to increase price, in the** future **: • customer tolerance for additional price increases; • competitive pressures discussed above in these Risk Factors; • product defects, failures, or recalls negatively affecting the reputation of our business or products; • reductions in healthcare spending, particularly in the United States, in response to government- enacted healthcare reform, general economic conditions, or the influence of accountable care organizations; • reductions to reimbursement rates for the medical procedures in which our products are used; and • certain marketplace changes, such as hospitals joining group purchasing organizations, integrated delivery networks, and managed care organizations. If we are unable to raise prices in the future or unable to do so at the same pace as we have done in the recent past, we may experience a reduction in our net sales growth and our operating results could suffer. Additionally, even to the extent we are able to increase prices in the future, certain customers may respond to price increases by reducing or eliminating purchases with us, which could negate or reduce the financial benefit of those price increases. We may not be able to maintain our historic levels of profit growth. Our operating income grew 42 % in 2024 and 37 % in 2023. This growth resulted principally from the growth of our sales force, average selling price increases, and operating expense restraint. If we are unable to replicate these favorable factors (or others) in 2025 or future years, our operating income growth could slow or disappear. Other factors that may affect our profitability growth include: • the level and timing of future sales, manufacturing costs, and operating expenses; • changes to our pricing strategy; • the productivity and growth of our direct sales force; • fluctuations in foreign currency exchange rates; • market acceptance of our new products and services; • our ability to successfully build direct sales organizations in new markets; • our ability to successfully acquire and develop products; • our ability to successfully integrate acquired businesses; • the impact on our business of competing products, technologies, and procedures; • our ability to obtain or maintain regulatory approvals; • reimbursement rates for our medical products and procedures; • the cost of litigation, if any; and • changes in tax laws. Operating income growth may also vary significantly quarter- to- quarter due to quarterly fluctuations in our business that may be driven by the timing of, among other things,** acquisitions **, new product introductions, product discontinuations, product recalls, regulatory approvals, sales incentive programs, litigation, changes to tax law, and changes to our sales force or other personnel** . Our ~~data losses.Although~~ we are not aware of having experienced any prior material data breaches,regulatory non- compliance incidents ~~,~~or cyber security incidents,we may in the future be impacted by such an event,exposing our clients and us to a risk of someone obtaining access to our information,to information of our clients or their customers,or to our intellectual property ~~;~~**,** disabling or degrading service ~~;~~**,** or sabotaging systems or information.Any such security breach could result in a loss of confidence in the security of our services ~~;~~**,** damage our reputation ~~;~~**,** disrupt our business ~~;~~**,** require us to incur significant costs of investigation,remediation and / or payment of a ransom ~~;~~**,** lead to legal liability ~~;~~**,** negatively impact our future sales ~~;~~**,** and result in a substantial financial loss. ~~Some of~~ **We may experience difficulties in sourcing,acquiring and integrating businesses and products into** our **business** ~~devices are sold to a different call point~~ , ~~and~~ **or** we may not **realize the anticipated benefits of these acquisitions** ~~be successful in selling to that newer call point~~ . ~~In terms of marketing~~ **To expand our product offerings,** call point focus ~~on~~ **is** the vascular surgeon ~~with a product portfolio largely used in open vascular surgical procedures may be too narrow, which may adversely affect our future sales. The treatment of peripheral vascular disease continues to shift from open vascular surgery to minimally invasive endovascular procedures. For example, some vascular surgeons have begun using transcarotid arterial revascularization, a new minimally invasive procedure, to treat carotid artery disease in lieu of a procedure in which our carotid shunts and vascular patches are used. We market and sell our products primarily to vascular surgeons, and the majority of our marketing efforts and sales relate to products used in open vascular surgery rather than in endovascular procedures. We estimate that in 2023, over 95 % of our net sales were from devices used in open surgical procedures. Demographic trends and other factors, such as reimbursement rates, are driving vascular surgeons to increasingly specialize in certain kinds of procedures, such as the creation and maintenance of dialysis access sites and endovascular therapies. Vascular surgeon training programs may focus on those therapies to the exclusion of open vascular procedures. If there is a decline in vascular surgeons training in open vascular procedures in favor of training in minimally invasive endovascular procedures, this could limit the number of vascular surgeons using our products due to lack of open vascular skills. If this trend continues, it could lead to the fragmentation of our customer base, which would reduce cross-selling opportunities, which could negatively impact our business. Some of our devices are sold to a different call point from that of most of our product lines, and we may not be successful in selling to that call point~~ . Some of our products are sold to a call point that is different from ~~our~~ **this** main call point ~~focus~~ . For example, historically, a significant portion of ~~our~~ CardioCel sales have been to **the** pediatric cardiac ~~surgeons~~ - **surgeon** ~~while the majority of our marketing efforts and sales relate to products used by vascular surgeons. As a result, our sales representatives call predominantly on vascular surgeons and to a lesser extent, cardiac and neuro surgeons~~ . Our success in selling products like CardioCel ~~in the cardiac space~~ will depend, in part, on our sales representatives devoting a portion of their time and establishing relationships with pediatric cardiac surgeons. If they do not undertake these activities or are unsuccessful in doing so, then this could lead to **lower** ~~the loss of~~ CardioCel sales. Cross-selling opportunities to pediatric cardiac surgeons are limited **at LeMaitre** . ~~Conversely~~ **Also** , if our sales representatives spend less time focused on vascular surgeons, the sales of our vascular products could decrease. Our tissue processing and preservation services are subject to a variety of risks, including those related to the procurement of human tissue and regulatory requirements. Our ability to successfully provide RestoreFlow allograft processing, preservation and distribution services may be affected by the following: • maintenance of quality standards and controls to mitigate the risk that processed tissue cannot be sterilized; •

compliance with regulatory and legal requirements specific to human tissue or changes in those requirements; • maintenance of our AATB accreditation, FDA establishment registration and state licensures; • the degree to which ~~our~~ **the** tissue procurement organizations **with which we work** are successful in procuring the gift of tissue donation; • procurement from tissue procurement organizations of adequate amounts of human tissue of a type and quality that meets our specifications; • processing human tissue in a cost- effective manner; • controlling turnover in a workforce skilled in tissue processing and cryopreservation; and • compliance of our tissue procurement organizations to current good tissue practices. Our failure in any one or more of these areas could adversely impact our ability to provide processing, preservation **,** and distribution services related to allografts and therefore our business and operations. Any disruption in our manufacturing facilities could harm our results of operations. Our principal worldwide executive, distribution, and manufacturing operations are located in five leased facilities in Burlington, Massachusetts. We also have a manufacturing site in North Brunswick, New Jersey as well as a tissue processing, preservation and distribution facility in Fox River Grove, Illinois. These facilities and the equipment we use to manufacture our products and services would be difficult to replace and could require substantial lead- time to repair or replace in the event of a natural or man- made disaster. In ~~such~~ **the** event **of a disaster** , we ~~could not~~ **may be required to** shift production or processing to alternate manufacturing facilities, and we would be forced to rely on third- party manufacturers, if available ~~at all~~ . Although we carry insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses, including potential damage to our reputation, and may not continue to be available to us on acceptable terms, or at all. ~~We carry significant amounts of finished goods which could also help mitigate these issues. Certain of our products contain materials derived from animal sources and may become subject to additional regulation. Our AlboGraft vascular grafts, Artegraft biologic patch, XenoSure biologic patch, and CardioCel and VascuCel patch products contain bovine tissue or material derived from bovine sources, and our Omniflow II Biosynthetic Vascular Graft contains ovine tissue. Products that contain materials derived from animal sources are increasingly subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans. This public scrutiny has been acute in Japan and Western Europe with respect to products derived from animal sources because of concern that bovine materials infected with the agent that causes bovine spongiform encephalopathy, otherwise known as BSE or mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt- Jakob Disease, an ultimately fatal disease with no known cure. Cases of BSE in cattle discovered in Canada and the U. S. have also increased awareness of the issue in North America. Certain regions or countries have issued regulations that require products to be processed from bovine tissue sourced from countries, like Australia or New Zealand, where no cases of BSE have occurred. Products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries. Significant new regulations, or a ban of our products, could impair our current business.~~ The risks inherent in operating internationally and the risks of selling and shipping our products and of purchasing our components and products internationally may adversely impact our net sales, results of operations, and financial condition. We derive a significant portion of our net sales from outside of the **United States** ~~U. S.~~ . For the year ended December 31, ~~2023~~ **2024** , ~~39~~ **41** % of our net sales were **international** ~~outside of the U. S.~~ . Our international sales operations expose us and our representatives, agents, and distributors to risks inherent in operating in foreign jurisdictions. These risks include: **• fluctuations in foreign currency exchange rates;** • the imposition of additional U. S. and foreign governmental controls or regulations, including export licensing requirements, duties and tariffs, and other trade restrictions; • the risk of non- compliance with the Foreign Corrupt Practices Act or other anti- corruption laws by our personnel, distributors, and other agents; • changing medical device regulations that may impede our ability to register our products in ~~a~~ **one or more** ~~jurisdiction~~ **jurisdictions** ; • the imposition of U. S. ~~and /~~ or international sanctions against a country or party with whom we do business; • changes in third- party reimbursement policies; • clawback of funds spent on healthcare in excess of budgeted amounts by foreign governments; • the imposition of restrictions on the activities of foreign agents, representatives, and distributors; • scrutiny of foreign tax authorities, which could result in fines, penalties, and additional taxes; • pricing pressure; • laws and business practices favoring local companies; • longer payment cycles; • difficulties in enforcing agreements and collecting receivables; • difficulties in enforcing or defending intellectual property rights; • exposure to different legal, data privacy **,** and political standards; and • political, economic, ~~and /~~ or social instability. We cannot assure you that one or more of these factors will not harm our business. Any material decrease in our international sales would adversely impact the results of operations. **We may experience disruptions to** ~~Material adverse developments in global economic conditions, or~~ **our international business to** the ~~occurrence of~~ **extent we transition our sales strategy in** certain ~~other world events~~ **international jurisdictions from a distributor- based approach to a direct sales model. We will typically enter new international markets by engaging a third- party distributor to conduct sales on our behalf. From time to time** , ~~could affect demand~~ **we may choose to transition select international markets to a direct sales model. Local law** ~~for~~ **or contractual terms may require us to compensate the distributor that is being eliminated, and we may incur new** ~~our~~ **or** ~~products,~~ **sometimes unexpected costs associated with setting up a local entity and employing local staff. An** increase **in** our **near- and long- term** costs of **doing** ~~operation and harm our~~ business **in the relevant market may therefore occur** . ~~The global macro environment continues to be challenging.~~ **Additionally, we may not have adequate knowledge of** ~~For~~ **or experience in** ~~example, Russia' s invasion on Ukraine has triggered significant sanctions from~~ the **relevant market such that** ~~U. S. and Europe which has negatively impacted our operations. Similar conflicts or~~ **our** ~~tensions exist in Israel and Palestine, China and Taiwan and elsewhere. These sanctions, or non- compliance with sanctions, could result in operational delays, increased costs or fines, or material decreases in our international~~ sales **may decline in the relevant market after going direct** ~~, all of which could have an adverse effect on our business~~ . The use or misuse of our products and the tissues we distribute may result in injuries that lead to product liability ~~suits~~ **lawsuits or legal actions** , which could be costly to our business. If our products or the tissue we process are defectively designed, manufactured, processed **,** or labeled ~~,~~ **;** contain defective components **;** ~~, or~~ are misused ~~,~~ **;** or found to have caused or

contributed to injuries or death, we may become subject to costly litigation. Although we offer training for physicians, we do not require that physicians be trained in the use of our products, and physicians may use our products incorrectly or in procedures not contemplated by us. We are from time to time involved in product liability claims. Product liability claims could divert management' s attention from our core business, damage our reputation, be expensive to defend, and result in sizable damage awards against us. We cannot assure you that our product liability insurance coverage will be sufficient to satisfy claims made against us. Further, we may not be able to maintain the same level of coverage, and we may not be able to obtain adequate coverage at a reasonable cost and on reasonable terms, if at all. Additionally, if any such product liability claim or series of claims is brought against us for uninsured liabilities or is in excess of our insurance coverage, our business could be harmed. From time to time, we are involved in litigation where the outcome is uncertain and which could entail significant expense. We are subject, from time to time, to legal proceedings and litigation, including, but not limited to, actions relating to product liability, employment matters, intellectual property, contract disputes **,** and other commercial matters. Because the outcome of litigation is inherently difficult to predict, it is possible that the outcome of litigation, or even simply the defense of litigation, could entail significant cost for us, divert management' s attention, and adversely affect our reputation. The fact that we operate in international markets also increases the risk that we may face legal exposure as we seek to comply with a large number of varying legal and regulatory requirements. If any such proceedings were to result in an unfavorable outcome, it could adversely affect our results of operations. Risks Related to the Regulatory Environment Oversight of the medical device industry might..... differs from that of our competitors. Our business is subject to complex, costly, and burdensome regulations. We could be subject to significant penalties if we fail to comply. The production and marketing of our products and services and our ongoing research and development are subject to extensive regulation and review by numerous governmental authorities both in the **United States** ~~U. S.~~ and abroad. U. S. and foreign regulations applicable to medical devices and human tissues are wide-ranging and govern, among other things, the testing, marketing, and premarket clearance or approval of new medical devices and services related to human tissue, as applicable, in addition to regulating manufacturing and processing practices, reporting, promotion and advertising, importing and exporting, labeling, and record- keeping procedures. Within recent years, there has been an increase in the scope and enforcement of data privacy laws in the jurisdictions in which we do business. The European Parliament adopted the General Data Protection Regulation ~~(~~**, or** GDPR ~~)~~, effective May 2018. The California Consumer Privacy Act ~~(~~**, or** CCPA ~~)~~, effective January 2020, requires covered companies to provide, among other things, new disclosure to consumers about such companies' data collection, as well as new use and sharing practices. Following the passage of the CCPA, several other U. S. states passed similar data privacy laws ~~, most of which went into effect in 2023 or go into effect in 2024~~ . In 2023, Europe finalized the first- ever comprehensive legal framework for governance of the use of artificial intelligence, the EU Artificial Intelligence Act, with ~~an anticipated~~ **a rolling** effective date **commencing** in ~~2026~~ **2025** . Compliance with these varying regimes has caused and will cause us to incur additional costs, including as may result from any non- compliance or asserted non- compliance. Our failure to comply with applicable regulatory requirements could result in governmental agencies or a court taking action, including any of the following: • issuing public warning letters to us; • imposing fines and penalties on us; • issuing an injunction preventing us from selling or distributing our products; • bringing civil or criminal charges against us; • ordering a recall of, or detaining or seizing, our products or cryopreserved human tissue; or • withdrawing or denying approvals or clearances for our products. If any or all of the foregoing were to occur, our business, results of operations, and brand could be materially adversely affected. If we are not successful in obtaining additional and maintaining current clearances and approvals from **U. S.** governmental agencies for our medical devices, we might not be able to sell our products, and our future growth might be hampered. Each medical device that we wish to market in the **United States** ~~U. S.~~ generally must receive either 510 (k) clearance or **PMA** approval ~~of a premarket application (PMA)~~ . Either process can be lengthy and expensive. The FDA' s 510 (k) clearance procedure usually takes three to twelve months. Although 510 (k) clearances have been obtained for nearly all of our current products that require such clearances, the FDA may condition, limit or prohibit our sales of these products if safety or effectiveness problems develop with the devices. Our new products or significantly modified existing products could be denied 510 (k) clearance. The PMA approval process is more costly, lengthy, and uncertain. It generally takes from six months to three years. Achieving premarket approval typically requires extensive clinical trials and may require the filing of numerous amendments. We do not have significant experience in obtaining PMA approval or conducting these studies for our products. The FDA ~~has previously proposed changes for which FDA clearance to market would possibly require clinical data, more extensive manufacturing information and post market data. As part of the 510 (k) reform, the FDA proposes to issue regulations defining grounds and procedures for rescission of 510 (k) applications that have previously been cleared to market. The FDA~~ may also require the more extensive PMA process for certain products. Our ability to market our products outside the United States is also subject to regulatory approval, including our ability to demonstrate the safety and effectiveness of our products in the clinical setting. Even if regulatory approval or clearance of a product is granted, the approval or clearance could limit the uses or the claims for which the product may be labeled and promoted, which may limit the market for our products. If we do not obtain and maintain foreign regulatory or FDA approval with respect to our products, as applicable, we will not be able to sell our products, and our future growth could be affected. If we or some of our suppliers fail to comply with the FDA' s **QSR** ~~Quality System Regulation~~ and other applicable requirements, our manufacturing or processing operations could be disrupted, and we may become subject to a variety of FDA enforcement actions. We are subject to inspection and marketing surveillance by the FDA to determine our compliance with all regulatory requirements. If the FDA finds that we have failed to comply with any regulatory requirements, it can institute a wide variety of enforcement actions, including, but not limited to, warning letters, fines **,** and penalties, injunctions, civil or criminal charges, mandatory recalls, and withdrawal of clearances to sell products. We and some of our suppliers must comply with the FDA' s **QSR** ~~Quality System Regulation~~ , which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage, and shipping of medical

devices. Our Fox River Grove **, Illinois** operations must comply with the FDA' s current Good Tissue Practices. The FDA enforces its regulations through pre- announced and unannounced inspections. We are subject to such inspections by the FDA and other regulatory bodies. The timing of future audits is unknown, and it is possible that audits may result in one or more unsatisfactory results. If we or one of our suppliers fails an inspection, or if a corrective action plan adopted by us or one of our suppliers is not sufficient, the FDA may bring an enforcement action against us. We participate in the MDSAP, which allows manufacturers to undergo a universal quality system audit that is accepted in the U. S., Japan, Australia, Canada and Brazil in lieu of individual routine audits by each regulator. Maintenance of this certification is a requirement to maintain sales in certain geographies **,** including Canada. Failure to maintain this certification in good standing could result in suspension of our sales efforts in Canada or other geographies. We are also subject to the FDA' s general prohibition against promoting our products for unapproved or off- label uses and to the medical device reporting regulations that require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. We must also file reports with the FDA of some device corrections and removals, and we must adhere to the FDA' s rules on labeling and promotion. If we fail to comply with these or other FDA requirements or fail to take adequate corrective action in response to any significant compliance issue raised by the FDA, the FDA can take significant enforcement actions, which could harm our business, results of operations, and our reputation. In addition, most other countries, such as Japan, require us to comply with manufacturing and quality assurance standards for medical devices that are similar to those in the **United States** ~~U. S.~~ before marketing and selling our products in those countries ~~of operations.~~ Oversight of the medical device industry might affect the manner in which we may sell medical devices and compete in the marketplace.There are laws and regulations that govern how healthcare companies may market their products and services to healthcare professionals,including for example,the federal Anti- Kickback Statute,the federal False Claims Act,the federal Health Insurance Portability and Accountability Act of 1996,state law equivalents to these federal laws that are meant to protect against fraud and abuse ~~,~~ and analogous laws in foreign countries.Violations of these laws are punishable by criminal and civil sanctions and debarment from state or federal healthcare programs.Although we strive to comply with those laws and regulations,we cannot assure you that government officials will not assert that we are in violation of those laws or regulations.Federal and state laws are also sometimes open to interpretation,and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that **of our competitors.** . Even after our products have received marketing approval or clearance, our products and the tissue we process may be subject to recall. Licenses, registrations, approvals **,** and clearances could be withdrawn or suspended due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. Our products, services, marketing, sales ~~and~~ **,** development activities, and manufacturing processes are subject to extensive and rigorous regulation by the FDA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. If those regulatory bodies feel that we have failed to comply with regulatory standards, there can be no assurance that any approval, licensure **,** or registration will not be subsequently withdrawn, suspended or conditioned upon extensive post- market study requirements, even after having received marketing approval or clearance or licenses and registrations. Further, due to the interconnectedness of the various regulatory agencies, particularly within the EU, there is also no assurance that withdrawal or suspension of any of our approvals, licenses **,** or registrations by any single regulatory agency will not precipitate one or more additional regulatory agencies from also withdrawing or suspending their approval, license **,** or registration. In the event that any of our products prove to be defective, we can voluntarily recall, or the FDA or foreign equivalent could require us to ~~implement a~~ recall, any of our products. In the EU and UK, adverse event reporting requirements mandate that we report incidents which led or could have led to death or serious deterioration in health. Recalls, whether voluntary or required, could result in significant costs to us and significant adverse publicity. In severe instances, the FDA may also issue a warning letter and / or destruction of defective product and / or order the suspension or cessation of manufacturing of defective product. Additionally, if someone is harmed by a malfunction or a product defect, we may experience product liability claims for such defects. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital and may harm our financial results. Future recalls or claims could also result in significant costs to us and significant adverse publicity, which could harm our ability to market our products in the future. **Certain of** ~~Domestic and foreign legislative or~~ **our** ~~administrative reforms resulting~~ **products contain materials derived from animal sources and may become subject to additional regulation. Our AlboGraft vascular grafts, Artegraft vascular graft, XenoSure biologic patch, and CardioCel and VascuCel biologic patch products contain bovine tissue or material derived from bovine sources, and our Omniflow II Biosynthetic Vascular Graft contains ovine tissue. Products that contain materials derived from animal sources are increasingly subject to scrutiny** in ~~restrictive reimbursement practices~~ **the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission** of ~~third~~ **disease from animals to humans. This public scrutiny has been acute in Japan and Western Europe with respect to products derived from animal sources because of concern that bovine materials infected with the agent that causes bovine spongiform encephalopathy, otherwise known as BSE or mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt** - ~~party payors~~ **Jakob Disease,** ~~and~~ - **an ultimately fatal disease with no known cure. Cases of BSE in cattle discovered in Canada and the United States have also increased awareness of the issue in North America. Certain regions or countries have issued regulations that require products to be processed from bovine tissue sourced from countries like Australia or New Zealand where no cases of BSE have occurred. Products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries. Significant new regulations, or a ban of our products, could impair our current business. We may incur additional costs or encounter supply challenges if chemicals or substances used in the manufacture, packaging, or sterilization of our products are restricted or banned as a result of environmental concerns. Certain of our products are manufactured, packaged, or sterilized using chemicals or**

substances that have drawn environmental concern. To the extent that the use of such chemicals or substances is restricted or banned, options to replace such chemicals or substitutes may not be readily available to us. Per- and polyfluoroalkyl substances, or PFAS, are a group of chemicals that are used in a broad range of consumer and industrial products, including medical devices and related packaging. In October 2023, the Environmental Protection Agency, or EPA, released final rules requiring companies to report the manufacture or import of PFAS- containing products. Multiple states have also instituted bans on PFAS- containing products and mandated reporting on usage. These requirements collectively impose a high compliance burden, and further regulation of PFAS usage is expected. Although we have not been materially affected by PFAS regulations to date, the ultimate impact and associated cost ~~containment measures~~ **of compliance is uncertain. Certain of our products are sterilized using ethylene oxide, or EtO. Concerns over EtO being released into the environment at unsafe levels have led to a range of regulatory proposals and actions; various regulatory enforcement activities against EtO facilities, including closures and temporary closures; and lawsuits against EtO service providers. The U. S. has a limited number of EtO facilities. Any permanent or temporary closures or disruption to the operations of these facilities** could **impair** ~~decrease the demand or~~ **our** ~~prices for~~ **ability to sterilize certain of** our products **, which could negatively affect our sales** . Our **human tissue** ~~products and our allograft preservation~~ **cryopreservation** services are ~~purchased principally~~ **subject to a wide variety of federal, state, and international regulations, and our failure to comply would impair our ability to operate in that space and negatively affect our operating results. The FDA regulates human tissue pursuant to Section 361 of the Public Health Services Act, which in turn provides the regulatory framework for regulation of human cellular and tissue products. The FDA regulations focus on donor screening and testing to prevent the introduction, transmission, and spread of HIV- 1 and- 2, Hepatitis B and C, and other communicable diseases and disease agents. The regulations set minimum requirements to prevent the transmission of communicable diseases from human tissue used for transplantation. The regulations define human tissue as any tissue derived from a human body which is (a) intended for administration to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease and (b) recovered, preserved, stored, or distributed** by ~~hospitals~~ **methods not intended to change tissue function or characteristics. The FDA definition excludes, among other things, tissue that currently is regulated as a human drug, biological product, or medical device, and it also excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ. The current regulations applicable to human tissues include requirements** ~~or~~ **for** ~~physicians~~ **donor suitability, processing standards, establishment registration, product listing, testing, and screening for risks of communicable diseases. The FDA periodically audits our tissue preservation facilities for compliance with its requirements and has the authority to enjoin the distribution, force a recall, or require the destruction of tissues that do not meet its requirements. Our activities in preserving and transporting human hearts and certain other organs are also subject to federal regulation under the National Organ Transplant Act, or NOTA,** which ~~typically bill various third-~~ **makes it unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. NOTA excludes from the definition of " valuable consideration " reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ. The purpose of this statutory provision is to allow for compensation for legitimate services. We believe that, to the extent our activities are subject to NOTA, we meet this statutory provision relating to the reasonableness of our charges. Some states have enacted statutes and regulations governing the preservation, transportation, and storage of human organs and tissues. The activities we engage in require us to be either licensed or registered as a clinical laboratory or tissue bank under California, Delaware, Florida, Georgia, Illinois, Maryland, New York, and Oregon law. We have such licenses or registrations, and we believe we are in compliance with applicable state laws and regulations relating to clinical laboratories and tissue banks that store, preserve, and distribute donated human tissue designed to be used for medical purposes in human beings. The Human Tissue Act 2004, or the HT Act, covers England, Wales, and Northern Ireland and established the Human Tissue Authority, or the HT Authority, to regulate activities concerning the removal, storage, use, and disposal of human tissue. Our office in the UK is licensed by the HT Authority for the import, storage, and distribution of human tissue from our tissue banking operations in the United States. As such, we are subject to periodic inspections and required to demonstrate continued compliance with the laws promulgated under the HT Act. While we believe we are in compliance with the patchwork of laws and regulations that apply to our human tissue cryopreservation services, we cannot guarantee that is the case, and any failure to comply could result in the suspension of licenses, fines, and penalties, any of which would have a negative impact on our ability to conduct our business and our operating results. Risks Related to Our Debt Servicing our 2. 50 % convertible senior notes requires a significant amount of cash, and we may not have sufficient cash flow to** ~~party --~~ **pay** ~~payors~~ **our debt. In December 2024, we completed an offering of $ 172, 500, 000 of 2. 50 % convertible senior notes due 2030, or the Convertible Notes, pursuant to, and governed by, an indenture, dated as of December 19, 2024, between us, as issuer, and U. S. Bank Trust Company, National Association, as trustee. The Convertible Notes provide for ongoing interest payments and payment at maturity of the principal amount plus any accrued but unpaid interest. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to many factors, including economic, financial, competitive, and others, some of which are beyond our control. If our business does not generate cash flow from operations sufficient to service our debt and make necessary capital expenditures, we may be required to adopt one or more alternatives** , such as **selling assets** ~~governmental programs (e. g., Medicare~~ **restructuring debt** , ~~Medicaid~~ **or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Notes, which mature in 2030, will depend on the capital markets and our financial condition at such times. We may not be able to engage in any**

of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations and limit our flexibility in planning for and reacting to changes in our business. We may not have the ability to raise the funds necessary to repurchase the Convertible Notes as required upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Convertible Notes. Holders of the Convertible Notes will have the right to require us to repurchase their Convertible Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100 % of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change may also constitute ~~and~~ **an** ~~comparable foreign programs)~~ **event of default or prepayment under** , ~~private~~ **and result in the acceleration of the maturity of, our then- existing indebtedness. We cannot guarantee that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any Convertible Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions under our then existing credit facilities or other indebtedness, if any, may not allow us to repurchase the Convertible Notes upon a fundamental change. Our failure to repurchase the Convertible Notes upon a fundamental change when required would result in an event of default with respect to the Convertible Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes. The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our liquidity. In the event the conditional conversion feature of the Convertible Notes is triggered, holders will be entitled to convert their Convertible Notes at any time during specified periods at their option. The conversion rate is 8. 3521 shares of common stock per each $ 1, 000 principal amount of Notes, or approximately $ 119. 73 per share, a 30 % premium over the closing price on the date of pricing of the Convertible Notes. If one or more holders elect to convert their Convertible Notes, we will settle conversions of the Convertible Notes by paying or delivering, as applicable, cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election. Full or partial cash settlement could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current, rather than long- term, liability, which would result in a material reduction of our net working capital. Transactions relating to the Convertible Notes may affect the value of our common stock. The conversion of some or all of the Convertible Notes would dilute the ownership interests of existing common stockholders to the extent we satisfy our conversion obligation by delivering shares of our common stock upon any conversion of such Convertible Notes. The Convertible Notes may become in the future convertible at the option of their holders under certain circumstances. If holders of the Convertible Notes elect to convert their Convertible Notes, we may settle our conversion obligation by delivering to them a significant number of shares of our common stock, which would cause dilution to our existing stockholders. Risks Related to Human Resources If we are not able to navigate executive officer transitions and retain key personnel, our business may be harmed. Each of our Chief Executive Officer, Chief Financial Officer, President, and Senior Vice President, Operations have significant tenure with the company; are highly knowledgeable of the Company' s business, operations, budgeting, strategy, product offerings, resources, and personnel; maintain key external relationships on behalf of the Company; and have been integral to the success of the Company. The unexpected or unplanned departure of one or more of them could be disruptive to day- to- day operations. Significant resources and attention may need to be expended at the executive and Board levels to identify and onboard successors in the event of an unexpected or unplanned departure. Joseph P. Pellegrino, Jr. has served as our Chief Financial Officer since 2007 and a member of our Board of Directors since 2016. In August 2024, Mr. Pellegrino announced that he will retire as Chief Financial Officer as of March 7, 2025. He will remain a member of the Board of Directors. Mr. Pellegrino will be replaced by Dorian LeBlanc. The loss of key personnel could be disruptive to our operations and materially adversely affect our financial performance. We do not carry, nor do we currently intend to obtain, significant key- person life** insurance ~~plans~~ **on officers or other employees. Our success will depend on attracting** and ~~managed care plans~~ **retaining qualified personnel and rapidly replacing and developing new management, as needed** . The ~~ability~~ **number** of ~~our customers~~ **potential employees who have the extensive knowledge needed** to ~~obtain~~ **develop, sell, and maintain our offerings is limited, and competition for their services is intense. There can be no guarantee that we will be able to attract and retain such personnel. If we are unable to do so, our business, operating results, and financial condition could be materially adversely affected. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and difficulty in retaining highly skilled employees with** appropriate ~~reimbursement for products~~ **qualifications. Employee equity awards may provide less of** ~~and~~ **an** ~~services from third~~ **employee retention benefit if the price of our common stock is unable to grow beyond the record highs it has recently achieved. The price of our common stock experienced significant gains in 2024, reaching an all - time high** ~~party payors contributes to the success of our products and services because. Reimbursement varies by country and can impact the acceptance of new technology. Implementation of healthcare reforms~~ in ~~the U~~ **November 2024 of $ 108** . ~~S~~ **09, nearly double where the stock began at the beginning of the year** . **Our** ~~and in major overseas markets~~ **market** ~~such as Germany, Japan and France may limit, reduce~~ **capitalization currently exceeds $ 2 billion. A meaningful portion of compensation provided to** ~~or our eliminate reimbursement~~ **more senior employees is provided in the** ~~for~~ **form of equity awards that consist of restricted stock units,** ~~our~~ **or RSUs, performance** ~~products and services. Major third - party payors~~ **based restricted stock units,** ~~for~~ **or PSUs** ~~hospital services in the U. S. and abroad continue to work to contain healthcare costs. For example , in an~~ **and stock options. These rewards are partially** ~~effort to decrease costs, certain hospitals and other customers may resterilize our products~~ intended ~~for a single use~~ **to encourage retention. Historically we have enjoyed high levels of employee retention,**

particularly at senior levels. If we are unable to grow the price of ~~or~~ **our common stock** ~~purchase reprocessed products from third- party reprocessors. Further legislative or administrative reforms to the reimbursement systems in the U. S. and abroad~~ , ~~or adverse decisions relating to our products by administrators of these~~ -- **the** ~~systems in coverage or reimbursement,~~ **retention value of employee equity awards** could **be diminished and** ~~reduce reimbursement for procedures using our medical devices or~~ **our employee retention** ~~result in the denial of coverage for those procedures. Examples of these reforms or adverse decisions include price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed- care arrangements. Any of such reforms or adverse decisions~~ could **suffer** ~~have an adverse impact on the prices our customers are willing to pay for our products~~ . Risks Related to Intellectual Property If we fail to adequately protect our intellectual property rights, or prevent use of our intellectual property by third parties, we could lose a significant competitive advantage and our business may suffer. Our success depends in part on maintaining and enforcing our intellectual property rights. We take precautionary steps to protect our technological advantages and intellectual property. We rely upon patent, trade secret, copyright, know- how, and trademark laws, as well as license agreements and contractual provisions, to establish our intellectual property rights and protect our products. These measures may only provide limited protection. We have ~~few patents on our technology~~ **a relatively limited intellectual property portfolio** . Even where we do have patents, the issuance of a patent is not always conclusive as to its validity or enforceability. Our patents could be circumvented or designed around by third parties. Furthermore, patents expire after a certain duration, depending on the jurisdiction in which they are issued. To the extent any manufacturers are successful in challenging our patents or they enter the market following the expiration of our patents, this could have an adverse impact on our business. **In the absence of patent** ~~We may not be able to effectively protect~~ **protection** ~~our rights in unpatented technology~~ , **we avail ourselves of** trade ~~secrets~~ - **secret** , ~~and~~ ~~confidential~~ **confidentiality** ~~information~~ **arrangements where appropriate** . We have a policy of requiring ~~key~~ employees and consultants and corporate partners with access to trade secrets or other confidential information to execute confidentiality agreements. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment. We also generally require consultants to assign to us any inventions made during their engagement with us. There can be no assurance, however, that these ~~agreements~~ **arrangements** will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer, or disclosure of **trade secrets,** confidential information **,** or inventions ~~. In addition, the laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the U. S. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products, or services and our competitors could commercialize similar technologies, which could result in a decrease in our sales and market share~~ . If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs, and we may have to redesign or discontinue selling the affected product. Companies operating in our industry often seek patent protection for their novel product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. We face the risk of claims that we have infringed on third parties' intellectual property rights, and we cannot assure you that our products or methods do not infringe the patents or other intellectual property rights of third parties. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could: • be expensive and time consuming to defend; • result in us being required to pay significant damages; • harm our reputation; • cause us to cease making or selling products; • require us to redesign, reengineer, or rebrand our products, which may not be possible; • require us to enter into royalty or licensing agreements in order to obtain the right to use a third party' s intellectual property, which agreements may not be available on terms acceptable to us or at all; • divert the attention of our management and key personnel from other tasks important to the success of our business; or • result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation. It is also possible that a third party could claim that our manufacturing ~~process~~ **processes** violates an existing patent or other intellectual property rights. If we were unsuccessful in defending such a claim, we may be forced to stop production at one or more of our manufacturing facilities. In addition, new patents obtained by our competitors could threaten a product' s continued life in the market even after it has already been introduced. If our business is successful, the possibility may increase that others will assert infringement claims against us. If we believe our product is or may be the subject of a patent or other intellectual property rights of a third party, we may attempt to reach a license agreement with them to manufacture, market, and sell ~~these~~ -- **the** ~~products~~ - **product** . If we fail to reach an agreement, we could be required to pay significant damages to third parties for past use of the asserted intellectual property and may be forced to cease making or selling **the** ~~products~~ - **product** that ~~incorporate~~ **incorporates** the challenged intellectual property ~~. In addition, we may become subject to interference proceedings conducted in the United States Patent Office or opposition proceedings conducted in foreign patent offices challenging the priority of invention or the validity of our patents~~ . Risks Related to Our Common Stock Our stock price may be volatile, and an investment in our common stock could suffer a decline in value. There can be significant volatility in the market price and trading volume of equity securities that is unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our common stock. Some factors that may have a significant effect on our common stock market price include: • actual or anticipated fluctuations in our operating results or future prospects; • changes in our growth rates; • our announcements or our competitors' announcements of new products; • the public' s reaction to our press releases, our other public announcements, and our filings with the SEC; • our determination whether ~~or not~~ to continue the payment of quarterly cash dividends; • our determination whether ~~or not~~ to undertake or continue a share repurchase program; • strategic actions by us or our competitors, such as acquisitions, divestitures **,** or restructurings; • dilutive issuances of additional securities; • new laws or regulations or new interpretations of existing laws or regulations applicable to our business; • the discontinuation of a product line or other revenue generating activity; • adverse regulatory actions which may necessitate recalls of our products or services or warning letters that

negatively affect the markets for our products or services; • sales of common stock by us or our directors, officers, or principal stockholders; • control by our affiliates and insiders of a significant percentage of our common stock; • reduced or lower volume of trading in our common stock; and • our inclusion in or removal from stock market indices, such as the S & P 600 or Russell 2000. The stock market has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. The market price of our common shares may also fluctuate significantly due to a variety of factors unrelated to our financial results, including political instability, natural disasters, pandemics, war and / or events of terrorism; comments by securities analysts; and general market conditions in our industry or in the economy as a whole. Broad market and industry factors may affect the market price of companies' stock, including ours, regardless of actual operating performance. In the past, following periods of volatility in the overall market and the market price of a particular company' s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management' s attention and resources. Our ~~chief~~ **Chief** ~~executive~~ **Executive** ~~officer~~ **Officer** has significant voting power and may take actions that may not align with the interests of our other stockholders. Our ~~chief~~ **Chief** ~~executive~~ **Executive** ~~officer~~ **Officer** controls approximately ~~11~~ **8. 5** % of our outstanding common stock as of December 31, ~~2023~~ **2024** . As a result, he could have significant influence on matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock, and may not be fully aligned with the interests of other stockholders. We have not established a minimum dividend payment level for our common stockholders and there are no assurances of our ability to pay dividends to common stockholders in the future. In February 2011, our Board of Directors adopted a quarterly dividend program for the purpose of returning capital to our stockholders. However, we have not established a minimum dividend payment level for our common stockholders and our ability to pay dividends may be harmed by the risks and uncertainties described in this Annual Report on Form 10- K and in the other documents we file from time to time with the SEC. Future dividends, if any, will be authorized by our Board of Directors. In addition, financial covenants in ~~our~~ **any future** credit facility may restrict our ability to pay future quarterly dividends. We can provide no assurance of our ability to pay dividends in the future. Item 1B. Unresolved Staff Comments