

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

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Our business involves a variety of risks and uncertainties, known and unknown, including, among others, the risks discussed below. These risks should be carefully considered together with the other information provided in this Annual Report on Form 10-K and in our other filings with the SEC. Our failure to adequately anticipate or address these risks and uncertainties may have a material, adverse impact on our business, reputation, revenues, financial condition, profitability, and cash flows. Additional risks and uncertainties not presently known or knowable to us, or that we currently believe to be immaterial, may also adversely affect our business. Business and Economic Risks **COVID-19, and similar public health crises, could have a material, adverse impact on us. Since early 2020, businesses, communities, and governments worldwide have taken, and continue to take, a wide range of actions to mitigate the spread and impact of COVID-19, leading to an unprecedented impact on the global economy. We continue to be subject to risks related to the COVID-19 pandemic, and risks that may result from future pandemics, epidemics, or other public health crises. The nature and extent of these risks are highly uncertain and unpredictable and may vary greatly by region. Although many countries and hospitals have seen a decline in cases, and thus, many countries, businesses, and hospitals, including ourselves, have begun to remove or reduce COVID-19 related restrictions, the potential for additional or renewed impact or related fallout from new variants or local outbreaks of COVID-19 remains, particularly in light of the enhanced exposure risks faced by our customers and their workforces. Risks related to COVID-19 and other public health crises have and could continue to impact our activities in a number of ways, including by impacting:**

- Our product sales. Local lockdowns, capacity constraints on healthcare systems, residual shortages in hospital staffing, and other factors resulting from COVID-19 and similar public health crises have and could impact our revenue. These crises can cause a reduction in demand for certain products and services due to factors such as reduced elective and non-emergency procedure volumes, healthcare worker shortages, changes in hospital utilization rates, reduced sales force access to hospitals, and reduced customer spending. In addition to COVID-19's impact on demand and procedure volumes, we have observed downstream financial effects from the pandemic, including an increase in delays or difficulty in collecting outstanding receivables, particularly with governmental payors in regions heavily impacted by COVID-19 and the related macroeconomic fallout.
- Our business operations. COVID-19 and similar public health crises present the potential to impact our workforce availability and that of our business partners. We have observed this risk with our customers and suppliers, which can impact operations, and also with certain regulators and Notified Bodies that we rely on, which in turn increases the risks we face with respect to timely review and approval of new and renewal regulatory approvals for our products.
- Our manufacturing operations. The COVID-19 pandemic and the related macroeconomic fallout has continued to impact the global supply chain; the impact on workforces, material availability, demand, and costs has reportedly continued or worsened in many cases. Although we have yet to experience any material effects on our supply chain, we have faced increasing costs and face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may continue even after COVID-19's risk as a global pandemic has subsided.
- Our workforce. As some global economies have begun to emerge from the COVID-19 downturn, increased opportunities for remote work, the Great Resignation, and increasing compensation pressure have resulted in a competition for talent at all levels and an unprecedented number of career changes. The resulting worker shortages and increased labor costs have impacted supply chains, distribution channels, and employers' ability to adequately staff their operations. While the effect appears to be waning somewhat, this has impacted not only our own ability to attract and retain employees, but also the ability of our customers who face increasing staffing pressures throughout their healthcare organizations.
- Our research and development projects. COVID-19 and similar public health crises have impacted and can impact our R & D projects, including by impacting the timelines for our clinical research projects and the timing of and need for spending. Enrollment and timelines for our clinical trials have been, and might continue to be, impacted as healthcare providers re-prioritize resources, address staffing shortages, and limit access to healthcare facilities. The extent to which COVID-19, its variants, or any future public health crises impact our operations or our recovery from the impact of COVID-19, will depend largely on future developments that are highly uncertain and unpredictable and may vary greatly by region. This impact and any such adverse developments or prolonged periods of uncertainty could adversely affect our financial performance.

We are subject to a variety of risks due to our international operations and continued global expansion. Our international operations subject us to a number of risks, which may vary significantly from the risks we face in our US operations, including:

- Greater difficulties and costs associated with staffing (at all levels), establishing and maintaining internal controls, managing foreign operations and distributor relationships, and selling directly to customers;
- Broader exposure to corruption and expanded compliance obligations, including under the Foreign Corrupt Practices Act, the UK Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, the European Union's General Data Protection Regulation, and other emerging corruption and data privacy regulations;
- Overlapping and potentially conflicting, or unexpected changes in, international legal and regulatory requirements or reimbursement policies and programs;
- Longer and more expensive collection cycles in certain countries, particularly those in which our primary customers are government-funded hospitals;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the US Dollar and **other** inflationary pressures **in Latin America**;
- Potential adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, **including particularly impacting our Latin American business as well as** impact felt through our supply chain; our exposure may be increased through our limited ability to raise prices and through global expansion where business occurs with, or pricing is set directly by, government entities, or we are party to long term pricing

agreements with governments or local distributors, impacting our ability to pass on rising costs; • Potential adverse tax consequences of overlapping tax structures or potential changes in domestic and international tax policy, laws, and treaties; and • Potential adverse financial and regulatory consequences resulting from Brexit. **As an example of this risk, via a Ministerial Decree of July 6, 2022, published September 15, 2022, the Italian government stated that the spending ceiling for medical devices at the national and regional levels had been exceeded, requiring medical device companies to pay back alleged overpayments the government claims companies received between 2015 and 2018. Currently, Artivion's repayment exposure for this period is estimated at approximately € 400, 000, which is subject to change as judicial challenges and negotiations between us, industry, US government representatives, and the Italian government are ongoing.** Our operations and performance have been , and may continue to be , impacted by regional and global geopolitical conditions, domestic and foreign trade and monetary policies, and other factors beyond our control. As an example of these risks, Russia's military attacks on Ukraine have triggered significant sanctions from the US and foreign governments and retaliatory actions from Russia, resulting in significant banking and trade disruptions. **The More recently, war has also been declared in the Gaza Strip resulting in an expanding regional crisis. These wars have** resulted in significant devastation to the people and infrastructure in the region, significantly impacting trade and transportation which may impact our global supply chain, increase prices, and limit our ability to continue to do business in affected regions. To date, sanctions and other disruptions in the **Eastern European** region have not materially impacted our business or ability to supply products to Russia, Belarus, Ukraine, and the region generally; however, continuation or escalation of the **war wars in Ukraine or the Middle East,** or increased export controls or additional sanctions imposed on or by **Russia impacted countries,** **its their** allies, or related entities could adversely affect our financial performance. Although we do not have any direct operations in Russia **or,** Ukraine, **Israel, or Gaza, the NEXUS and NEXUS DUO (the "NEXUS Products") are solely manufactured by Endospan in Herzliya, Israel. Although we have not experienced any material disruption of supply from Endospan, the conflict in and around Israel is rapidly evolving. Ultimately,** it is difficult to predict the ultimate course of **the these war wars** and we may face business operations and supply chain disruptions as a result, including disruptions related to shortages of materials **and finished goods,** higher costs of materials and freight, freight delays, increased energy costs or energy shortages, travel disruptions, currency fluctuation, and disruptions to banking systems or capital markets. We operate in highly competitive market segments, face competition from large, well- established medical device companies and tissue service providers with greater resources and we may not be able to compete effectively. The market for our products and services is competitive and affected by new product introductions and activities of other industry participants, **including the introduction of novel products and therapies aimed at unrelated disease states or even overall patient health. In addition, such products and therapies like the recently introduced GLP- 1 drugs, which we believe have or will have little to no actual impact on demand for our products, can lead to investor and customer confusion and impact the perceived demand for our products.** We face intense competition in virtually all of our product lines. A significant percentage of market revenues from competitive products are generated by Baxter, Ethicon (a Johnson & Johnson Company), Medtronic, plc, Abbott Laboratories, Edwards Lifesciences Corp., C. R. Bard, Inc. ~~;~~ (a subsidiary of Becton, Dickinson and Company), Integra Life Sciences Holdings, LifeNet, Corcym, Anteris Technologies, Inc., **Elutia (formerly Aziyo Biologics),** Cook Medical, Gore & Associates, Terumo, LeMaitre Vascular, Inc., Maquet, Inc., Pfizer, Inc., and BioCer Entwicklungs- GmbH. Several of our competitors enjoy competitive advantages over us, including: • Greater financial and other resources for research and development, commercialization, acquisitions, and litigation and to weather the impacts of COVID- 19 and increased workforce competition; • Greater name recognition as well as more recognizable trademarks for products similar to products that we sell; • More established record of obtaining and maintaining regulatory product clearances or approvals; • More established relationships with healthcare providers and payors; • Lower cost of goods sold or preservation costs; and • Larger direct sales forces and more established distribution networks. We are significantly dependent on our revenues from tissue preservation services and are subject to a variety of risks affecting them. Tissue preservation services are a significant source of our revenues, and as such, we face risks if we are unable to: • Source sufficient quantities of some human tissue or address potential excess supply of others. We rely primarily upon the efforts of third parties to educate the public and foster a willingness to donate tissue. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue; • Compete effectively, as we may be unable to capitalize on our clinical advantages or our competitors may have advantages over us in terms of cost structure, pricing, back- office automation, marketing, and sourcing; or • Mitigate sufficiently the risk that tissue can become contaminated during processing; that processed tissue cannot be end- sterilized and hence carries an inherent risk of infection or disease transmission or that our quality controls can eliminate that risk. **As an example of these risks, in the fourth quarter of 2020 we became aware that a supplier shipped to us a lot of saline solution that we use in our tissue processing that contained some contamination. The contamination was identified by our routine quality controls. While we were able to mitigate the impact of this contamination through our own efforts and additional testing that was reviewed with the FDA, the contaminated solution impacted a small percentage of the tissue processed with this lot of solution, requiring us to write-off approximately \$ 826, 000 in contaminated tissues in the fourth quarter of 2020. The written off and temporarily quarantined tissue impacted our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021. See also, Part I, Item 1A, " Risk Factors — Operational Risks — We are dependent on our specialized workforce."**In addition, US and foreign governmental authorities have adopted laws and regulations that restrict tissue preservation services. Any of these laws or regulations could change, including becoming more restrictive, , or our interpretation of them could be challenged by governmental authorities. We are significantly dependent on our revenues from BioGlue and are subject to a variety of related risks. BioGlue is a significant source of our revenues, and as such, any risk adversely affecting our BioGlue products or business would likely be material to our financial results. We face the

following risks ~~related~~ **relating** to BioGlue: • Competing effectively with our major and start up competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition; • We may be unable to obtain approval to commercialize BioGlue in certain non- US countries as fast as our competitors do ~~of their products~~ or at all. We also may not be able to capitalize on new BioGlue approvals, including for new indications, in non- US countries; and • BioGlue contains a bovine blood protein. Animal- based products are subject to increased scrutiny from the public and regulators, who may seek to impose additional regulations, regulatory hurdles or product bans in certain countries on such products; BioGlue is a mature product and other companies may use the inventions disclosed in expired BioGlue patents to develop and make competing products. **As an example of this risk, our BioGlue CE Mark expired in December 2021. Delays in renewing the CE Mark and challenges securing certain related derogations ultimately impacted the availability of BioGlue in certain European markets and other markets reliant on the CE Mark, impacting our revenue from BioGlue in those markets. See also, Part I, Item 1A, “ Risk Factors — Industry Risks — Our products and tissues are highly regulated and subject to significant quality and regulatory risks.” (further discussing the impact of and risks relating to the BioGlue CE Mark).** We are significantly dependent on our revenues from aortic stent grafts and are subject to a variety of related risks. Aortic stent grafts are a significant source of our revenues, and as such, any risk adversely affecting aortic stent grafts would likely be material to our financial results. We face risks ~~related~~ **relating** to aortic stent grafts based on our ability to: • Compete effectively with some of our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition; • Develop innovative, high quality, and in- demand aortic repair products; • Respond adequately to enhanced regulatory requirements and enforcement activities, and particularly, our ability to obtain regulatory approvals and renewals globally; • Meet demand **and manage inventory** for aortic stent grafts as we seek to expand our business globally; and • Maintain a productive working relationship with our Works Council in Germany. We are significantly dependent on our revenues from On- X products and are subject to a variety of related risks. On- X products are a significant source of our revenues, and as such, any risk adversely affecting our On- X products or business would likely be material to our financial results. We face risks based on our ability to: • Take **further** market share in the mechanical heart valve market based on the FDA’ s approved lower INR indication for the On- X aortic heart valve or complete the associated FDA mandated post- approval studies; • Address clinical trial data or changes in technology that may reduce the demand for mechanical heart valves, such as data regarding transcatheter aortic valve replacement, or “ TAVR ” devices; • Manage risks associated with less favorable contract terms for On- X products on consignment at hospitals; **and** • Respond adequately to enhanced international regulatory requirements or enforcement activities ~~; and~~ **• Receive timely renewal certifications in certain markets**. Continued fluctuation of foreign currencies relative to the US Dollar could materially, adversely affect our business. The majority of our foreign product revenues are denominated in Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar- denominated and euro- denominated product sales are made to customers in other countries who must convert local currencies into US Dollars or Euros in order to purchase these products. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Additionally, as a result of global inflationary pressures, and in some cases, currency crises, it is possible that foreign currency controls, the development of parallel exchange rates, or highly inflationary economies could arise in certain countries. Fluctuations in exchange rates of Euros or other local currencies in relation to the US Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows. Our charges resulting from acquisitions, restructurings, and integrations may materially, adversely affect the market value of our common stock. We account for the completion of acquisitions using the purchase method of accounting. Our financial results could be adversely affected by a number of financial adjustments required by purchase accounting such as: • We may incur ~~added~~ **additional** amortization expense over the estimated useful lives of some acquired intangible assets; • We may incur additional depreciation expense as a result of recording purchased tangible assets; • We may be required to incur material charges relating to any impairment of goodwill and intangible assets; • Cost of sales may increase temporarily if acquired inventory is recorded at fair market value; • If acquisition consideration consists of earn- outs, our earnings may be affected by changes in estimates of future contingent consideration; or • Earnings may be affected by transaction and integration costs, which are expensed immediately. As an example of this risk, ~~in the fourth quarter of 2021,~~ we fully impaired the value of a securities purchase option agreement with Endospa (“ Endospa Option ”) and fully wrote- down the value of an agreement for a secured loan from Artivion to Endospa (“ Endospa Loan ”), primarily driven by a decrease in forecasted operating results. This impairment, and other potential risks like those mentioned above, may adversely affect the market value of our common stock. **Public health crises have, may continue to have, and could have a material, adverse impact on us. Beginning in early 2020 businesses, communities, and governments worldwide began taking a wide range of actions to mitigate the spread and impact of COVID- 19, leading to an unprecedented impact on the global economy. We continue to be subject to risks relating to the COVID- 19 pandemic and its impact on broader macroeconomic trends, and risks that may result from future pandemics, epidemics, or other public health crises. The nature and extent of these risks are uncertain and may vary greatly by region, but COVID- 19 and similar public health crises have impacted and can impact our workforce, business and manufacturing operations, and our R & D pipeline. Because of our role in the healthcare industry, we are particularly susceptible to the impact public health crises have on healthcare systems globally, including impacts on system capacity and procedure volumes, shortages in healthcare staffing, and restrictions on travel and non- critical hospital access, all of which have had, may continue to have, and could have an impact on our business operations and sales, particularly through reductions in demand for certain products and services due to reduced procedure volumes, or through downstream financial impact from delays or difficulty collecting outstanding receivables. This impact on healthcare system capacity may also impact our R & D pipeline by impacting timelines for R**

& D and clinical research projects and timelines associated with regulatory reviews for new and updated devices. The extent to which COVID- 19, its variants, or any future public health crises and the recoveries therefrom impact our operations and broader macroeconomic conditions, will depend largely on future developments that are highly uncertain and unpredictable and may vary greatly by region. This impact and any such adverse developments or prolonged periods of uncertainty could adversely affect our financial performance. Operational Risks We are heavily dependent on our suppliers and contract manufacturers to provide quality products. The materials and supplies used in our product manufacturing and tissue processing are subject to regulatory requirements and oversight. If materials or supplies used in our processes fail to meet these requirements or are subject to regulatory enforcement action, they may have to be scrapped, or our products or tissues could be rejected during or after processing, recalled, or rejected by customers. In these cases, we may have to immediately scrap raw or in- process materials ~~or and~~ expense the costs of manufacturing or preservation. As an example of this risk, in the fourth quarter of 2020 we became aware that a supplier shipped to us a lot of saline solution that we use in our tissue processing that contained some contamination. The contamination was identified by our routine quality controls. While we were able to mitigate the impact of this contamination through our own efforts and additional testing that was reviewed with the FDA, the contaminated solution impacted a small percentage of the tissue processed with this lot of solution, requiring us to write- off those contaminated tissues in the fourth quarter of 2020 and impacting our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021. In addition, if these materials or supplies, or changes to them, do not receive regulatory approval or are recalled, if the related suppliers and / or their facilities are shut down temporarily or permanently, for any reason, or if the related suppliers are otherwise unable or unwilling to supply us, we may not have sufficient materials or supplies to manufacture our products or process tissues. In addition, we rely on contract manufacturers to manufacture some of our products or to provide additional manufacturing capacity for some products. If these contract manufacturers fail to meet our quality standards or other requirements or if they are unable or unwilling to supply the products, we may not be able to meet demand for these products. Our ability to fully recover all possible losses from these suppliers and contract manufacturers may have practical limitations imposed by factors like industry standard contractual terms or the financial resources of the adverse party. ~~As a further example of this risk, our supplier of TMR handpieces was informed in the fourth quarter of 2021 that the sole- source manufacturer of tubing used in the handpiece assembly had gone out of business, requiring us to work with our supplier to identify and qualify a new supplier before a disruption in handpiece availability occurs. In February 2023 we were notified that the sole- source manufacturer had gone out of business and, because a new supplier has yet to be identified and qualified, our handpiece supply would cease, effective immediately, and be disrupted in 2023 and potentially beyond.~~ Finally, the COVID- 19 pandemic, the ~~war wars~~ in Ukraine **and the Gaza Strip**, work force shortages, exchange rates, and inflation continue to impact the global supply chain; their impact on workforces, global mobility, material availability, demand, and shipping and reorder times and reliability has reportedly continued or worsened in many cases. The ongoing ~~war wars in Ukraine~~ may add to or exacerbate challenges faced by the global supply chain. See Part I, Item 1A, “ Risk Factors – Business and Economic Risks – ” We are subject to a variety of risks due to our international operations and continued global expansion. ” Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after COVID- 19’ s risk as a global pandemic and the ~~war wars~~ in Ukraine **and Gaza** have subsided. We are dependent on single and sole- source suppliers and single facilities. Some of the materials, supplies, and services used in our product manufacturing and tissue processing, as well as some of our products, are sourced from single- or sole- source suppliers. As a result, our ability to negotiate favorable terms with those suppliers may be limited, and if those suppliers experience operational, financial, quality, or regulatory difficulties, or if those suppliers and / or their facilities refuse to supply us or cease operations temporarily or permanently, or if those suppliers take unreasonable business positions, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We **also** could ~~also~~ be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. As an example of these risks, in 2019 we lost our supply of handpieces for cardiac laser therapy resulting from a manufacturing location change at our supplier that ultimately required a **Premarket Approval (“ PMA ”)** supplement and FDA approval before handpiece manufacturing and distribution could resume. Even though the FDA approved the PMA- S, our supplier was unable to fully resume production due to **supply- related** factors outside of our control. ~~Due to these and other supplier issues, we had virtually no supply eventually abandoned the business as of June 2023. As a result, we wrote- off handpieces all of our CardioGenesis cardiac laser therapy assets and recorded an expense of \$ 390, 000 during the first three quarters of twelve months ended December 31, 2021- 2023 . Although handpiece supply resumed on our Consolidated Statements a limited basis since the last quarter of Operations and Comprehensive Loss 2021, we remain dependent on a sole- source manufacturer for these handpieces.~~ By way of additional non- limiting examples, our BioGlue product has three main product components: bovine protein, a cross linker, and a molded plastic resin delivery device. The bovine protein and cross linker are obtained from a small number of qualified suppliers. The delivery devices are manufactured by a single supplier, using resin supplied by a **different** single supplier. We purchase grafts for our On- X AAP from a single supplier and various other components for our On- X valves come from single- source suppliers. Our preservation services business and our ability to supply needed tissues is dependent upon donation of tissues from human donors by donor families. Donated human tissue is procured from deceased human donors by **organ and tissue procurement organizations (“ OPOs ”)** and tissue banks. We must rely on the OPOs and tissue banks that we work with to educate the public on the need for donation, to foster a willingness to donate tissue, to follow our donor screening and procurement procedures, and to send donated tissue to us. We have active relationships with approximately 60 OPOs and tissue banks throughout the US. As with any vendor, we believe

these relationships with our OPOs are critical in the preservation services industry and that the breadth of these existing relationships provides us with a significant advantage over potential new entrants to this market. We also use various raw materials, including medicines and solutions, in our tissue processing. Some of these raw materials are manufactured by single suppliers or by a small group of suppliers. Our aortic stent graft systems consist of two main product components: the stent graft and the delivery system. The stent graft is manufactured from several different raw materials that are manufactured internally or at various external suppliers, including single suppliers. The delivery systems we manufacture are comprised of several different raw materials and subassemblies. Our internal manufacturing processes include injection molding and machining of plastic parts, suturing of stent grafts, processing of Nitinol, and weaving of textiles. Our conventional polyester grafts consist of two main product components: polyester fabric and collagen coating. The polyester fabric is woven from a few different yarns that are supplied by an external supplier. The collagen suspension we manufacture is comprised of a collagenous tissue that is supplied by a single supplier. The conventional ePTFE grafts we manufacture are comprised of various raw materials supplied by several suppliers. For some products the ePTFE grafts are heparin coated. For these products, the heparin suspension we manufacture is comprised of a heparin solution that is also supplied by an external supplier. ~~Our E-ventus DX bridging stent is supplied by an external supplier and our supply agreement expired at the end of 2022.~~ We have three internal manufacturing facilities: Austin, Texas for On- X products, Hechingen, Germany for internally manufactured aortic stent grafts, and Kennesaw, Georgia for all other products and services. Certain aortic stent graft assemblies are manufactured for us by a contract manufacturer in Slovakia. The AMDS product is solely manufactured by a supplier in Charlotte, North Carolina, **and** the ~~CardioGensis handpieces~~ **NEXUS Products** are solely manufactured by a supplier in Merrillville, Indiana, **and** the ~~NEXUS product is solely manufactured by Endospan in Herzliya, Israel.~~ If one of these suppliers or facilities ceases operations temporarily or permanently, for any reason including a pandemic **, war, work stoppage,** or climate change related event, our business could be substantially disrupted. Although we work diligently to maintain adequate inventories of raw materials, components, supplies, subassemblies, and finished goods, there can be no assurance that we will be able to avoid all disruptions to our global supply chain, or disruptions to our sterilization or distribution networks. Any of these disruptions could have a material, adverse effect on our revenues, reputation, or profitability. **We are dependent on our specialized workforce.** Our business and future operating results depend in significant part upon the continued contributions of our specialized workforce, including key personnel, qualified personnel with medical device and tissue processing experience, and senior management with experience in the medical device or tissue processing space, some of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel. Our primary facilities are in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where the supply of qualified medical device and tissue processing and other personnel is limited, competition for such personnel is significant, and we cannot ensure that we will be successful in attracting or retaining them. We face risks if we lose any key employees to other employers or due to severe illness, death, or retirement, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees. This risk was exacerbated by the pandemic ~~and is expected to continue~~ **continues**, ~~as the to be impacted by changes in macroeconomic conditions.~~ **Competition** for talent in the medical device industry and in the workforce generally has intensified substantially. As global economies have begun to emerge from the COVID-19 downturn, the expiration of COVID-19 related hiring freezes, the Great Resignation, increased opportunities for remote work, and increasing compensation pressure have resulted in a competition for talent and an unprecedented number of career changes. ~~The resulting competition~~ and worker shortages at all levels have impacted supply chains and distribution channels and our ability to attract and retain the specialized workforce necessary for our business and operations. We continue to evaluate expansion through acquisitions of, or licenses with, investments in, and distribution arrangements with, other companies or technologies, which may carry significant risks. One of our growth strategies is to pursue select acquisitions, licensing, or distribution rights with companies or technologies that complement our existing products, services, and infrastructure. In connection with one or more of these transactions, we may: • Issue additional equity securities that would dilute our stockholders' ownership interest; • Use cash we may need in the future to operate our business; • Incur debt, including on terms that could be unfavorable to us or debt we might be unable to repay; • Structure the transaction resulting in unfavorable tax consequences, such as a stock purchase that does not permit a step-up in basis for the assets acquired; • Be unable to realize the anticipated benefits of the transaction; or • Assume material unknown liabilities associated with the acquired business. We may not realize all the anticipated benefits of our business development activities. As part of our efforts to drive growth by pursuing select acquisition, license, and distribution opportunities that are aligned to our objectives and complement our existing products, services, and infrastructure or to divest non-core product lines, we have completed several transactions in recent years and may pursue similar additional transactions in the future. Examples of these activities include the following: • On ~~December 1, 2017 we acquired JOTEC AG, a Swiss entity that we converted to JOTEC GmbH and subsequently merged with our Swiss acquisition entity, Jolly Buyer Acquisition GmbH and its subsidiaries;~~ • On September 11, 2019 we entered into various agreements with Endospan, an Israeli medical device manufacturer (the "Endospan Transaction"). The Endospan Transaction included an exclusive distribution agreement for NEXUS in Europe, the Endospan Loan, and a security purchase option agreement for Artivion to purchase all the outstanding Endospan securities from Endospan's existing security holders upon FDA approval of **the NEXUS Products**; • On September 2, 2020 we acquired 100 % of the outstanding shares of Ascyrus, the developer of AMDS; and • On July 28, 2021 we entered into various agreements with Baxter and SMI related to the sale of our PerClot assets to Baxter and the termination of our existing material agreements with SMI. Our ability to realize the anticipated business opportunities, growth prospects, cost savings, synergies, and other benefits of these **and other** transactions depends on a number of factors including our ability to: • Leverage our global infrastructure to sell and cross-market the acquired products; • Drive adoption of **the NEXUS Products** and AMDS in the European and other markets, including our ability to manage the

substantial product training, implant support, and proctoring requirements for NEXUS procedures; • Bring acquired products to the US market, including our acquired aortic stent grafts; • Harness the aortic stent graft product pipeline and our research and development capabilities; • Obtain regulatory approvals in relevant markets, including our ability to timely ~~obtain FDA PMA for PerClot under the terms of the Baxter Transaction and to~~ obtain or maintain CE Mark product certifications for pipeline and current products; • Execute on development and clinical trial timelines for acquired products; • Manage global inventories, including our ability to manage inventories for product lines with large numbers of product configurations and manage manufacturing and demand cycles to avoid excess inventory obsolescence due to shelf life expiration, particularly for processed tissues and aortic stent grafts; • Carry, service, and manage significant debt and repayment obligations; and • Manage the unforeseen risks and uncertainties related to these transactions, including any related to intellectual property rights. Additionally, our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the Endospa Transaction depends on a number of additional factors including Endospa's ability to: (a) comply with the Endospa Loan and other debt obligations, and avoid an event of default; (b) successfully commercialize **the NEXUS Products**, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for **the NEXUS Products**; (d) meet quality and regulatory requirements for **the NEXUS Products**; (e) manage any intellectual property risks and uncertainties associated with **the NEXUS Products**; (f) obtain FDA approval of **the NEXUS Products**; (g) remain a going concern; and (h) develop **the NEXUS Products, and other** product improvements to meet competitive threats and physician demand. As an example of this risk, the forecasted operating results related to NEXUS decreased ~~in the fourth quarter of 2021~~, resulting in an impairment ~~in to~~ the **carrying** value of the Endospa Option, and a full write-down of the value of the Endospa Loan, reflecting decreased expectations with respect to the anticipated benefits of the Endospa Transaction. Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues, and diversion of management's time and energy. The benefits of these transactions may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share, decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of a transaction, we could experience an interruption or loss of momentum in our existing business activities. We may not realize all the anticipated benefits of our corporate rebranding and it may result in unanticipated disruptions to our on-going business. In order to reflect our evolution to focus on providing innovative technologies to surgeons who treat patients with aortic disease, we changed our name to Artivion, Inc., effective January 18, 2022 (the "Corporate Rebrand"). The Corporate Rebrand also involved the adoption of a new ticker symbol on the New York Stock Exchange, "AORT ~~↔~~". We may face unanticipated disruptions to our business arising from the Corporate Rebrand, and it may expose us to additional risks, including: • Disruptions ~~to our~~ **or unanticipated delays** ~~day-to-day business operations including disruptions to our ability to receive or our customers' ability to make timely payments;~~ • Disruptions ~~to access~~ **accessing** certain markets or segments due to delays or other issues with regulatory approvals, **clinical trials**, or **other** updates arising from ~~the Corporate Rebrand;~~ • **Unanticipated delays or other impact on our** ~~or related to pending regulatory applications or clinical trials arising from~~ the Corporate Rebrand; • Confusion within the marketplace, particularly with multiple points of contact in our downstream product flow involving purchasing and accounts payable departments and end users; • Intellectual property risks associated with the adoption of a new corporate identity and trade dress; and • Loss of brand equity associated with our legacy brands, including our CryoLife and JOTEC brands that will become less prominent over time. The Corporate Rebrand involved significant financial and resource investment and will continue to do so as we complete our global brand transitions over the coming years. The anticipated benefits of the Corporate Rebrand may not be achieved within the anticipated timeframe, without additional near or long-term investment, or at all. Any of these factors could negatively impact our revenues, earnings per share, decrease or delay the expected accretive effect of the Corporate Rebrand, and negatively impact the price of our common stock. Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business. We rely upon a combination of sophisticated information technology systems as well as 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~~ **personnel** data, intellectual property, and, in some 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~~ **as a result of changes implemented during** the COVID-19 pandemic, we **now** ~~have implemented~~ remote work arrangements for some 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, service interruptions, or data losses, **particularly in light of rapid improvements in information processing technology accompanying developments in, among other areas, artificial intelligence platforms**. We have limited cyber-insurance coverage that may not cover all possible events, and this insurance is subject to deductibles and coverage limitations. Any security breaches, service interruptions, or data losses could adversely affect our business operations or result in the loss of critical or sensitive confidential information or intellectual property, or in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities. **Industry Risks** ~~Our products and tissues are highly regulated and subject to significant quality and regulatory risks.~~ The commercialization of medical devices and processing and distribution of human tissues are highly complex and subject to significant global quality and regulatory risks and as such, we face the following risks: • Our products and tissues allegedly have caused, and may in the future cause, patient injury, which has exposed, and could in the future expose, us to liability claims that could lead to additional regulatory scrutiny; • Our manufacturing and tissue processing operations are subject to regulatory scrutiny, inspections and enforcement actions,

and regulatory agencies could require us to change or modify our operations or take other action, such as issuing product recalls or holds; • Regulatory agencies could reclassify, re-evaluate, or suspend our clearances or approvals, or fail to, or decline to, issue or reissue our clearances or approvals that are necessary to sell our products and distribute tissues; • Regulatory and quality requirements are subject to change, which could adversely affect our ability to sell our products or distribute tissues; and • Adverse publicity associated with our products, processed tissues, or our industry could lead to a decreased use of our products or tissues, increased regulatory scrutiny, or product or tissue processing liability claims. As an example of these risks, on May 25, 2017, the European Union adopted a new **regulations governing medical devices (the MDR)**, which ~~was~~ **were to be** fully implemented on May 26, 2021. The MDR places stricter requirements on manufacturers and European Notified Bodies regarding, among other things, product classifications and pre- and post-market clinical studies for product clearances and approvals which could result in product reclassifications or the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the European Economic Area and other markets that require CE Marking. Additionally, to the extent the MDR places stricter requirements on manufacturers of custom-made devices, those new requirements could delay, impede, or otherwise impact the availability of our **E- xtra Design Engineering services and custom- made** products. COVID- 19 **has significantly** impacted the predictability and timelines associated with the MDR transition. Most recently, the European **Parliament Commission announced an initiative to extend extended** the MDR transition period ~~and amend other related provisions under Regulation (EU) 2023 / 607~~ but it is still unclear ~~if whether~~ **this extension initiative will be adopted legislatively or whether it will be able to mitigate the challenges posed by the transition to the MDR**. **In order for devices to qualify for the extended MDR transition period, manufacturers must submit a formal application to the relevant notified body by May 26, 2024, and the applicant and notified body must enter into a signed written agreement no later than September 26, 2024. If we are unable to obtain agreements covering our products by that time, the presently applicable extensions will expire and impact our ability to market those devices**. Since the implementation of the MDR, Notified Bodies must review any proposed changes to determine if they require evaluation under the MDR or if they can still be evaluated under ~~the~~ currently held **Medical Device Directive (“MDD”)** certifications. Our inability to obtain certifications for changes under the transitional provisions of the MDR’s Article 120 or successfully submit proposed changes requiring MDR evaluation will delay implementation of those changes which could adversely impact our ability to obtain or renew certifications, clearances, or approvals for our products. Additionally, as MDD-based CE Marks expire, recertification must be obtained under the MDR. Industry- wide, companies are experiencing delays in obtaining new and updated certifications under the MDR as Notified Bodies struggle to recover from COVID- 19, deal with ~~depleted- smaller~~ workforces, and handle the volume of work required to transition tens of thousands of currently- marketed devices from the MDD to the MDR. As one such example, our MDD- based CE Mark for Chord- X expired in September 2022, which will impact our ability to supply certain territories once our saleable inventory is depleted. If Notified Bodies continue to struggle to meet demand and timely process submissions and recertifications, we may face additional disruptions associated with the MDR transition. As another example of this risk, our CE ~~mark~~ **Mark** for BioGlue expired in December 2021. Due to delays renewing this CE ~~mark~~ **Mark** and transitioning BioGlue to a new Notified Body, our ability to supply certain markets with BioGlue was impacted. Although we were able to mitigate most of the impact by obtaining derogations in the majority of relevant territories, we may face similar risks and market disruptions ~~relating- related~~ to the MDR transition which continues to be in a state of change. Finally, we anticipate additional regulatory impact as a result of Brexit. The UK Medicines and Healthcare Products Regulatory Agency has announced that CE Marking will continue to be recognized in the UK and certificates issued by EU- recognized Notified Bodies will continue to be valid in the UK market until **the certificates expire or the applicable transition period expires (currently June 30, 2023- 2028 at the earliest)**. ~~Thereafter~~ **Upon expiration**, all devices marketed in the UK will require UK Conformity Assessed Marks certified by a UK Approved Body (the re- designation of the UK Notified Body). In 2019 our Notified Body in the UK, LRQA, informed us that it would no longer provide Notified Body services for medical devices effective September 2019. The governing German competent authority, the Regierungspraesidium- Tubingen, granted us an extended grace period until December 31, 2021 to transfer LRQA- issued certifications for BioGlue and PhotoFix to a new Notified Body. Although our BioGlue CE Mark has been successfully transferred to our new Notified Body, DEKRA, we are still in the process of transferring PhotoFix to DEKRA. While progress has been made, failure to timely complete the transfer or any other delays in the MDR transition, may have a material, adverse effect on our ability to supply PhotoFix in affected jurisdictions, have a material, adverse impact on our business, and may also impact our **Medical Device Single Audit Program (“MDSAP”)** certifications. Failure to timely obtain new MDSAP certifications following their expiration may impact our ability to distribute covered products in Australia, Brazil, Canada, and Japan. Reclassification by the FDA of CryoValve SG pulmonary heart valve (“CryoValve SGPV”) may make it commercially infeasible to continue processing the CryoValve SGPV. **In Beginning in** December 2019 ~~we learned~~ **and most recently in the fall 2023, the FDA indicted that it was planning the FDA is preparing to issue a proposed rule for reclassification of more than minimally manipulated (“MMM”)** allograft heart valves to Class III medical devices, which could include our CryoValve SGPV. Following ~~a any~~ comment period and subsequent publication of ~~any a~~ final rule, should the CryoValve SGPV be determined to be MMM **or classified as a Class III device**, we **currently** expect to have approximately thirty months to submit ~~a an~~ **FDA- PMA application**, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during **its** review of the PMA application. ~~To date, the FDA~~ **Although this proposed rule change has, to our knowledge, remained on the HHS’ s unified regulatory agenda since 2019, not- no issued such a proposed- final rule has published at this time**. If the FDA ultimately classifies our CryoValve SGPV as a Class III medical device, and if there are delays in obtaining the PMA, if we are unsuccessful in obtaining the PMA, or if the costs associated with these activities are significant, we could decide that the requirements for continued processing of the CryoValve SGPV are too onerous, leading us to discontinue distribution of these tissues. We may not be successful in obtaining clinical results or

regulatory clearances / approvals for new and existing products and services, and our approved products and services may not achieve market acceptance. Our growth and profitability depends in part upon our ability to develop, and successfully introduce, new products and services, or expand upon existing indications, clearances, and approvals, requiring that we invest significant time and resources to obtain new regulatory clearances / approvals, including investment into pre- and post- market clinical studies. Although we believe certain products and services in our portfolio or under development may be effective in a particular application, we cannot be certain until we successfully execute on relevant clinical trials, and the results we obtain from pre- and post- market clinical studies may be insufficient for us to obtain or maintain any required regulatory approvals or clearances. We are currently seeking regulatory approval for BioGlue in China, where the Chinese regulatory body has made additional requests, and expressed several concerns, related to the application. We have obtained an extension of time until February 2024 in which to ~~secure approval~~ **file an updated submission** for BioGlue in China. If **the costs to file an updated submission are prohibitive, or** we cannot obtain approval ~~by following then~~ **the review of the updated submission** or the costs to do so are prohibitive, we ultimately may be unable to sell BioGlue in China. **Similarly, in November 2023 we announced that we were no longer pursuing a labeling change for our On- X mitral valve in connection with our PROACT Mitral trial due to additional investments that would be required to do so.** As another example of this risk, we obtained a CE Mark for E- nya in the fourth quarter of 2019 and ~~an~~ **began limited distribution of E- nya in the second quarter of 2020. In the fourth quarter of 2021 we suspended the limited release to evaluate modifications in response to customer feedback. We ultimately concluded the E- nya device would not achieve our market acceptance targets without additional design changes and ended the limited market release.** As a further example of this risk, in September 2022 we halted the PROACT Xa clinical trial based on the recommendation of the trial' s Data and Safety Monitoring Board (" DSMB ") due to insufficient evidence to support non-inferiority of apixaban to warfarin for valve thrombosis and thromboembolism. The DSMB found that continuing the trial was unlikely to achieve the primary endpoint while possibly exposing patients to increased risk. Each of our trials, studies, and approvals is subject to the risks outlined herein. We cannot give assurance that regulatory agencies will clear or approve these products and services or indications, or any new products and services or new indications, on a timely basis, if ever, or that the products and services or new indications will adequately meet the requirements of the market or achieve market acceptance. Pre- and post- market clinical studies may also be delayed or halted due to many factors beyond our control. If we are unable to successfully complete the development of a product, service, or application, or if we determine for any reason not to complete development or obtain regulatory approval or clearance of any product, service, or application, particularly in instances when we have expended significant capital, this could materially, adversely affect our financial performance. Research and development efforts are time consuming and expensive, and we cannot be certain that these efforts will lead to commercially successful products or services. Halting R & D efforts and clinical trials prematurely may lead to accelerated or unanticipated wind down costs. Even the successful commercialization of a new product or service in the medical industry can be characterized by slow growth and high costs associated with marketing, under- utilized production capacity, and continuing research and development and education costs, among other things. The introduction of new products or services may require significant physician training or years of clinical evidence in order to gain acceptance in the medical community. **Increased Regulatory regulatory** enforcement activities ~~or and~~ private litigation **activity relating to processes and materials** regarding the use of ethylene oxide (" EtO "), which is used ~~in to sterilize some of our~~ **industry products and components**, could have a material, adverse impact on us. Some of our products, including ~~our certain~~ **On- X products**, are sterilized using EtO. Although we have a small- scale EtO facility in Austin, Texas, we rely primarily on **third- party** large- scale EtO facilities to sterilize our products. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to increased activism and lobbying as well as various regulatory enforcement activities against EtO facilities, including closures and temporary closures, lawsuits against EtO service providers, and proposals increasing regulations related to EtO **, including any required reduction in EtO concentration levels**. The number of EtO facilities in the US is limited, and any permanent or temporary closures or disruption to their operations for any reason could delay, impede, or prevent our ability to commercialize our products. **The per- and polyfluoroalkyl substances (" PFAS ") are used in a wide variety of consumer and industrial products, including medical devices and product packaging. In October 2023, the Environmental Protection Agency (the " EPA ") released final rules requiring companies to report the manufacture or import of PFAS- containing products. In addition, numerous states have instituted bans on PFAS- containing products and reporting obligations. These requirements impose a high compliance burden, and further regulation of PFAS- containing products is expected. Although we have yet to experience any material impact from this activity or identify any of our products materially impacted by PFAS- related regulation, the ultimate impact and associated cost of current and future rulemaking cannot be predicted at this time. In addition, any litigation,** regulatory enforcement ~~, activities against us for~~ **or our government regulation regarding the** use of EtO could result in financial, legal, business, and reputational harm to us. We may be subject to fines, penalties, and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off- label, uses. Our business and future growth depend on the continued use of our products for approved uses. Generally, regulators contend that, unless our products are approved or cleared by a regulatory body for alternative uses, we may not make claims about the safety or effectiveness of our products or promote them for such uses. Such limitations present a risk that law enforcement could allege that the nature and scope of our sales, marketing, or support activities, though designed to comply with all regulatory requirements, constitute unlawful promotion of our products for an unapproved use. We also face the risk that such authorities might pursue enforcement based on past activities that we discontinued or changed. Investigations concerning the promotion of unapproved uses and related issues are typically expensive, disruptive, and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant, and educational activities. In addition, we or our officers could be excluded from participation in government

healthcare programs such as Medicare and Medicaid. Healthcare policy changes may have a material, adverse effect on us. In response to perceived increases in healthcare costs in recent years, there have been, and continue to be, proposals by the governmental authorities, third- party payors, and elected office holders and candidates to impact public health, control healthcare costs and, more generally, to reform the healthcare systems. Additional uncertainty is anticipated as debates about healthcare ~~-vaccines-~~ and public health continue in light of the COVID- 19 pandemic which may have an impact on US law relating to the healthcare industry. Many US healthcare laws, such as the Affordable Care Act, are complex, subject to change, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. The application of these laws to us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately any changes to, or the repeal or invalidation of all or part of the Affordable Care Act and similar or future laws and regulations, or our failure to comply with them, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition. Further, the growth of our business, results of operations and financial condition rely, in part, on customers in the healthcare industry that receive substantial revenues from governmental and other third- party payer programs. A reduction or less than expected increase in government funding for these programs or a change in reimbursement or allocation methodologies, or a change in reimbursement related to products designated as “ breakthrough devices ” by the FDA, could negatively affect our customers’ businesses and, in turn, negatively impact our business, results of operations and financial condition. Any changes that lower reimbursement for our products or reduce medical procedure volumes, could adversely affect our business and profitability.

Legal, Quality, and Regulatory Risks

As a medical device manufacturer and tissue services provider we are exposed to risk of product liability claims and our existing insurance coverage may be insufficient, or we may be unable to obtain insurance in the future, to cover any resulting liability. Our products and processed tissues allegedly have caused, and may in the future cause, injury or result in other serious complications that may result in product or other liability claims from our customers or their patients. If our products are defectively designed, manufactured, or labeled, or contain inadequate warnings, defective components, or are misused, or are used contrary to our warnings, instructions, and approved indications, we may become subject to costly litigation that can have unpredictable and sometimes extreme outcomes. We maintain claims- made insurance policies to mitigate our financial exposure to product and tissue processing liability and securities, claims, among others, that are reported to the insurance carrier while the policy is in effect. These policies do not include coverage for punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, if we are unsuccessful in arranging cost- effective acceptable resolutions of claims, it is possible that our insurance program may not be adequate to cover any or all possible claims or losses, including losses arising out of natural disasters or catastrophic circumstances. Any significant claim could result in an increase in our insurance rates or jeopardize our ability to secure coverage on reasonable terms, if at all. Any securities or product liability / tissue processing claim, even a meritless or unsuccessful one, could be costly to defend, and result in diversion of our management’ s attention from our business, adverse publicity, withdrawal of clinical trial participants, injury to our reputation, or loss of revenue. We are subject to various US and international bribery, anti- kickback, false claims, privacy, transparency, and similar laws, any breach of which could cause a material, adverse effect on our business, financial condition, and profitability. Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various US and international bribery, anti- kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as “ healthcare compliance laws. ” Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to change and changing interpretations. The ongoing **war wars** in Ukraine **and Gaza**, and the current and future sanctions imposed on Russia and others as a result may exacerbate these risks. See also Part I, Item 1A, “ Risk Factors – Business and Economic Risks- We are subject to a variety of risks due to our international operations and continued global expansion. ” Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws. We have entered into consulting and product development agreements with healthcare professionals and healthcare organizations, including some who may order our products or make decisions to use them. We have also adopted the AdvaMed Code of Conduct, the MedTech Europe Code of Ethical Business Practice, and the APACMed Code of Ethical Conduct which govern our relationships with healthcare professionals to bolster our compliance with healthcare compliance laws. While our relationships with healthcare professionals and organizations are structured to comply with such laws and we conduct training sessions on these laws and codes, it is possible that enforcement authorities may view our relationships as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties or debarment. In any event, any enforcement review of or action against us as a result of such review, regardless of outcome, could be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going- forward basis only. The proliferation of new and expanded data privacy laws, including the General Data Protection Regulation in the European Union, could adversely affect our business. An increasing number of federal, state, and foreign data privacy laws and regulations, which can be enforced by private parties or governmental entities, have been or are being promulgated and are constantly evolving. These laws and regulations may include new requirements for companies that receive or process an individual’ s personal data (including employees), which increases our operating costs and requires significant management time and energy. Many of these laws and regulations, including the European Union’ s General Data Protection Regulation (“ GDPR ”) also include significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR and other data privacy laws and regulations, there can be no assurance that regulatory or enforcement authorities will view our arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Any privacy related government enforcement activities may be costly, result in negative publicity, or subject us to significant penalties. Some of our products and technologies are subject to significant intellectual

property risks and uncertainty. We own trade secrets, patents, patent applications, and licenses relating to our technologies and trademarks and goodwill related to our products and services, which we believe provide us with important competitive advantages. We cannot be certain that we will be able to maintain our trade secrets, that our pending patent applications will issue as patents, or that no one will challenge the validity or enforceability of any intellectual property that we adopt, own, or license. Competitors may independently develop our proprietary technologies or design non-infringing alternatives to patented inventions. We do not control the maintenance, prosecution, enforcement, or strategy for in-licensed intellectual property and as such are dependent in part on the owners of these rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies. Additionally, our technologies, products, or services could infringe intellectual property rights owned by others, or others could infringe our intellectual property rights. If we become involved in intellectual property disputes, the costs could be expensive, and if we were to lose or decide to settle, the amounts or effects of the settlement or award by a tribunal could be costly. Risks Relating to Our Indebtedness The agreements governing our indebtedness contain restrictions that limit our flexibility in operating our business. The agreements **currently** governing our indebtedness contain, and any instruments governing future indebtedness of ours may contain, covenants that impose significant operating and financial restrictions on us and certain of our subsidiaries, including (subject in each case to certain exceptions) restrictions or prohibitions on our and certain of our subsidiaries' ability to, among other things: • Incur or guarantee additional debt or create liens on certain assets; • Pay dividends on or make distributions of our share capital, including repurchasing or redeeming capital stock, or make other restricted payments, including restricted junior payments; • Enter into agreements that restrict our subsidiaries' ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries; • Enter into certain transactions with our affiliates including any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary; • Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement; • Amend, supplement, waive, or otherwise modify our or our subsidiaries' organizational documents in a manner that would be materially adverse to the interests of the ~~lenders~~ **lender**, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the ~~lenders~~ **lender**; • Make changes to our and our subsidiaries' fiscal year without notice to the administrative agent; • Enter into agreements which restrict our ability to incur liens; • Engage in any line of business substantially different from that in which we are currently engaged; and • Make certain investments, including strategic acquisitions or joint ventures. Our indebtedness could adversely affect our ability to raise additional capital to fund operations and limit our ability to react to changes in the economy or our industry. Our current and future levels of indebtedness could adversely affect our ability to raise additional capital, limit our operational flexibility, and hinder our ability to react to changes in the economy or our industry. It may also limit our ability to borrow money, require us to dedicate substantial portions of our cash flow to repayment, and restrict our ability to invest in business opportunities. Because most of our borrowings are at a variable rate of interest, we are exposed to interest rate fluctuations. We have pledged substantially all of our US assets as collateral under our existing Credit Agreement. If we default on the terms of such credit agreements and the holders of our indebtedness accelerate the repayment of such indebtedness, there can be no assurance that we will have sufficient assets to repay our indebtedness. A failure to comply with the covenants in our existing Credit Agreement could result in an event of default, which, if not cured or waived, could have a material, adverse effect on our business, financial condition, and profitability. In the event of any such default, the holders of our indebtedness: • Will not be required to lend any additional amounts to us; and • Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable. If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against their secured collateral to seek repayment out of proceeds from the sale or liquidation of our assets. If our indebtedness were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full. Risks ~~Related~~ **Relating** to Ownership of our Common Stock Our business could be negatively impacted as a result of shareholder activism. In recent years, shareholder activists have become involved in the governance, strategic direction, and operations of companies. Such involvement with us may disrupt our business and divert the attention of our management, and any perceived uncertainties as to our future direction resulting from such involvement could result in the loss of business opportunities, be exploited by our competitors, cause concern for our current or potential customers, cause significant fluctuations in stock price, or make it more difficult to attract and retain qualified personnel and business partners. Our business could be impacted by increased shareholder emphasis on environmental, social, and governance matters **or efforts by certain governmental authorities to reduce such emphasis**. Investors and other key stakeholders are increasingly focusing on areas of corporate responsibility, and particularly matters related to environmental, social, and governance ("ESG") factors. Institutional investors have expressed expectations with respect to ESG matters that they use to guide their investment strategies and may, in some cases, choose not to invest in us if they believe our ESG policies are lagging or inadequate. Other stakeholders also have expectations regarding ESG factors, such as employees or potential employees who desire to work for a company that reflects their personal values. These areas of focus are continuing to evolve, as are the criteria that investors assess companies' performance in these areas. Investors are increasingly looking to companies that demonstrate strong ESG and sustainability practices as an indicator of long-term resilience, especially in light of events such as the COVID-19 pandemic. **Additionally, some governmental entities, regulators, and industry activist groups, particularly in Europe, are placing an increased emphasis on sustainability including through initiatives like the German Sustainability Code (the ("Deutscher Nachhaltigkeitskodex")), the Global Reporting Initiative, and guidance from agencies like the European Federation of**

Financial Analyst Societies. Conversely, certain governmental authorities are challenging investors' reliance on ESG factors as, among other things, inconsistent with certain fiduciary duties. Keeping up with and meeting these expectations, **sometimes contradictory,** may disrupt our business and divert the attention of our management, and we may be unable to make the investments in ESG programs that our competitors with greater financial resources are able to make **or we may be challenged by governmental authorities if we choose to make such investments.** Failure to meet the expectations of investors **and,** other stakeholders, **, or certain governmental authorities** in these areas may damage our reputation, impact employee retention, impact the willingness of our customers to do business with us, or otherwise impact our financial results and stock price. We do not anticipate paying any dividends on our common stock for the foreseeable future. In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our shareholders may receive a return on their investment in our common stock only through appreciation of shares of our common stock that they own. In addition, restrictions in our credit facility limit our ability to pay future dividends. Provisions of Delaware law and anti- takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to shareholders, which could affect our share price adversely and prevent attempts by shareholders to remove current management. Effective January 1, 2022 we reincorporated in Delaware. Our status as a Delaware corporation and the anti- takeover provisions of the Delaware General Corporation Law may discourage, delay, or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, the organizational documents adopted in connection with our reincorporation contain provisions that restrict persons who may call shareholder meetings, allow the issuance of blank- check preferred stock without the vote of shareholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Delaware law and our articles of incorporation and bylaws could prevent attempts by shareholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders. The effects of reincorporation in Delaware are detailed in our 2021 Special Proxy Statement and Notice of Special Meeting filed with the SEC on October 7, 2021.