

## Risk Factors Comparison 2025-02-28 to 2024-02-23 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 **US Securities and Exchange Commission (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** 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 Corporate Sustainability Reporting Directive**, and other emerging corruption, **sustainability**, and data privacy **and cybersecurity** regulations;
- Overlapping, **ambiguous**, 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, **given sensitivity to exchange rates that we experience from our product revenue streams and account balances**;
- Potential **exposure to** adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, including impact felt through our supply chain ~~our~~, **and this** 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~~ **consequences from unexpected global regulatory and trade developments** ~~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~~ **Ultimately, we were** Artivion’s repayment exposure for this period is estimated at approximately € 400,000, which is subject to **change as an immaterial payment obligation following the conclusion of** 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, such as~~ Russia’s **war with** 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. More recently, ~~war has been declared in the Gaza Strip resulting in an~~ **and** 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 ~~instability~~ **to continue to do business in affected regions the Middle East**. 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 wars in Ukraine or **instability in** the Middle East, or increased export controls or additional sanctions imposed on or by impacted countries, their allies, or related entities could adversely affect our financial performance. Although we do not have any direct operations in Russia, Ukraine, Israel, ~~or Gaza,~~ **or Syria**, the NEXUS **family of** and NEXUS DUO (the “NEXUS Products **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 these ~~wars~~ **conflicts** 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, **can change investor focus**, and **can** impact the perceived demand for our products, **which may affect our stock price even if actual demand for our products is unaffected**.

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, ~~ple,~~ Abbott Laboratories, Edwards Lifesciences ~~Corp.~~, C. R. Bard, ~~Inc.~~ (a subsidiary of Becton, Dickinson and Company), Integra Life Sciences ~~Holdings~~,

LifeNet, Corcym, Anteris Technologies, ~~Ine.~~, Elutia (formerly Aziyo Biologics), Cook Medical, Gore & Associates, Terumo, LeMaitre Vascular, ~~Ine.~~, Maquet, ~~Ine.~~, Pfizer, ~~Ine.~~, 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 **global economic downturns** 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 **along with better positioning to minimize the impact of consolidated purchasing and other consolidation within the healthcare industry**; • Lower cost of goods sold or preservation costs; and • Larger direct sales forces and more established distribution networks. **Our established and early-stage competitors may have advantages over us in terms of cost structure, pricing, back-office automation, product development, marketing, supply chain, and sourcing, and if we are unable to compete effectively, our financial results will be adversely affected.** 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 Capitalize on our clinical advantages that we rely on as competitive strengths** 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. In addition, US and foreign governmental authorities have adopted laws and regulations that restrict tissue preservation services **and the avenues available to distribute processed tissues**. Any of these laws or regulations could change, including becoming more restrictive, or our interpretation of them could be challenged by governmental authorities. **As an example of this risk, in January 2025, the Center for Biologics Evaluation and Research (“CBER”) of the FDA issued two “final” guidance documents directed at the reduction of the risk of transmission of tuberculosis (Mtb) in processed human tissue (the “Guidances”), which is already exceedingly low. We believe these Guidances, if implemented as written, could significantly reduce the supply of safe implantable human tissue without simultaneously reducing the risk of Mtb transmission. Although some industry advocates and health care practitioners have expressed strong opposition to these new Guidances, and their implementation has been paused until at least May 2025, if and how they may ultimately be implemented and enforced, and how they may actually impact the availability of our donated tissue, remains to be seen and is difficult to predict.** 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 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 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 **regulatory approval for BioGlue CE Mark expired in China took significantly longer** December 2021. ~~Delays in renewing the CE Mark and challenges securing certain related derogations ultimately impacted the availability of required significant additional investment, at least in part, due to BioGlue in certain European’s animal of origin components. Although we received approval to markets—market and BioGlue in China during other— the third quarter of 2024 markets reliant on the CE Mark, impacting our we do not expect any revenue from BioGlue in until at least those—the second half 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 **2025** 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 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; • **Drive timely adoption of new products in our aortic stent graft portfolio**; • 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; • **Keep up with increasing demand for**

**our On- X products globally**; • 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. Continued fluctuation of foreign currencies relative to the US Dollar could materially, adversely affect our business. **Most** The majority of our foreign product revenues are denominated in Euros and, **making them** as such, are sensitive to **exchange rate** changes in exchange rates. **Some** 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 **hold** also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies **affected by**. These foreign currency transactions and balances are sensitive to changes in exchange rates. Additionally, as a result of global **Global** inflationary **inflation** pressures, and in some cases, currency crises **could result in**, 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. . 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. Our charges resulting from acquisitions, **restructurings** **divestitures**, **partnerships**, and **integrations** **other business development activities** 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 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 **earnouts** **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, we fully impaired the value of **a our original** securities purchase option agreement with Endospan (“Endospan Option”) **in the fourth quarter of 2021** and fully wrote-down the value of **our an** agreement for a secured loan from Artivion to Endospan (“Endospan Loan”) **in the second quarter of 2023**, primarily driven by a decrease in forecasted operating results. **This Although the Endospan Option and our loan to Endospan were partially written back up to fair value in the third quarter of 2024, similar impairment impairments**, and other potential risks like those mentioned above, may adversely affect the market value of our common stock. **Public health crises have, may continue.....** 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 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 Aseyrus, 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 **family of Products** **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 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 our 2019** Endospan **Transaction** **transaction** depends on a number of additional factors including Endospan’s ability to: (a) comply with the Endospan Loan and other debt obligations, and avoid an event of default;

(b) successfully commercialize the NEXUS **family of Products-products**, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for the NEXUS **family of Products-products**; (d) meet quality and regulatory requirements for the NEXUS **family of Products-products**; (e) manage any intellectual property risks and uncertainties associated with the NEXUS **family of Products-products**; (f) obtain FDA approval of the NEXUS **family of Products-products**; (g) remain a going concern; and (h) develop the NEXUS **family of Products-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 **ONE** decreased, resulting in an impairment to the carrying value of the Endospa Option, and a full write-down of the value of ~~the our original loan to~~ Endospa ~~Loan~~, reflecting decreased expectations with respect to the anticipated benefits of the Endospa ~~transaction~~. **Similarly, our ability to realize the anticipated benefits of the Baxter Transaction depends on factors beyond our control, including Baxter's performance against Baxter's originally anticipated demand**. 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 or unanticipated delays accessing certain markets or segments due to delays or other issues with regulatory approvals, clinical trials, or other updates arising from or related to 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, personnel data, intellectual property, and, in some instances, patient data **and other personally identifiable information**). Our **business operations rely on critical information technology systems related to systems that power aspects of our Quality System (including our eQMS system) and our global operations (including our ERP systems). We have experienced, and expect to continue to be subject to the risk of, cybersecurity threats and incidents. For example, we experienced a previously-disclosed cyber-attack in the fourth quarter of 2024 that temporarily disrupted our business operations, including our ERP systems, and had an impact on revenue, manufacturing, order processing, shipping, and other corporate operations (the "Cybersecurity Incident"). Our claims for reimbursement with our insurer remain outstanding and we continue to incur expenses in connection with improving our global infrastructure and cybersecurity posture, additionally, we remain subject to other risks and uncertainties as a result of the incident, including those related to scrap, inventory levels, and timely shipping releases, as well as the potential to incur additional expenses. While we have invested, and continue to invest, in our information technology and information security systems and records are potentially vulnerable to employee information security training, there can be no assurance that our efforts will prevent all** security breaches, service interruptions, ~~or data loss-losses~~, or malicious attacks resulting from inadvertent or intentional actions by our employees **particularly in light of rapid improvements in information processing technology accompanying developments in**, among vendors, or other third parties **areas, artificial intelligence platforms**. In addition, as a result ~~portion~~ of our **employees** changes implemented during the COVID-19 pandemic, we now have remote-work **remotely** 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,~~ **or the financial expenses or losses associated with any particular event**, 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. **Our business could be impacted by environmental, social, and governance matters. Governments, investors, customers, employees and other stakeholders are continuing to focus on areas of corporate responsibility, and particularly matters related to environmental, social, and governance ("ESG") factors. Stakeholders are 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 and evolving expectations can be difficult and expensive, and may disrupt our business and divert the attention of our management. We, 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, 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. Legal, Quality, and Regulatory 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, including product recalls, 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 product recalls and / or 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's adopted new regulations governing medical Medical devices— Device Regulation (the MDR), which were was 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. The MDR 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 or rely on CE Marking as a basis for market authorization. Additionally, The transition to the extent the MDR has been fraught 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 significantly impacted the predictability and timelines associated with difficulties and uncertainty the MDR transition. Most recently, the including delays in audits and approvals. The European Parliament has extended the MDR transition period under Regulation (EU) 2023 / 607 but it is still unclear whether this extension will be able to mitigate the transition challenges posed by the transition to the MDR. In order As a result, we face increased risks related to: • Our Custom Devices: Stricter requirements on manufacturers of custom-made devices may delay, impede, or otherwise impact the availability of our E-xtra Design Engineering services and custom-made products; • Our Existing CE Marks: The extended timeline 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 has resulted in certain MDD-based CE Marks expiring prior 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 smaller workforces, and handle the volume completion of the work required to transition tens of thousands of currently-marketed devices from the MDD to the MDR. Our As one such example, our MDD-based CE Mark for BioGlue expired in December 2021, and 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 We have since been able to successfully renew 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 for BioGlue expired in December 2021. Due to delays renewing this CE Mark and Chord- X under the MDR; • Our Notified Bodies: The combination of the increased regulatory framework under the MDR and the UK's exit from the European Union have both had and an transitioning BioGlue to impact on notified bodies. The MDR has significantly increased the workload on existing notified bodies and as a new result, many have elected to leave the space, including our Notified Body in the UK, LRQA our ability to supply certain markets with BioGlue was impacted. Although we were able to mitigate most transition our LRQA- issued certification for BioGlue to a new notified body, DEKRA, we are still in the process of transitioning the LRQA- issue certification for PhotoFix; and • New CE Marks: The increased workload on notified bodies and the other uncertainties around impact by obtaining derogations in the majority of relevant territories, transition to the MDR will likely cause delays in the approval for any new products that we may face similar risks and wish to bring to the EU market disruptions related. While we continue to make progress on the

MDR transition which continues, the transition to be in new notified bodies, and the renewal of expired CE Marks, failure to timely complete any transfers or renewals, or to comply with transition to a newly designated 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, 2028 at the earliest). 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 or further 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 as a whole, may have a material, adverse effect on our ability to supply PhotoFix product in affected certain 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. Beginning in December 2019 and most recently in the fall of 2023-2024, the FDA indicted indicated that it was planning 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 any comment period and subsequent publication of 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 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. Although this proposed rule change has, to our knowledge, remained on the HHS' s unified regulatory agenda since 2019, no final rule has been 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- depend 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. As an 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 BioGlue in China, where the Chinese regulatory body has made additional requests, and expressed several concerns, related to the application. We have obtained an and thromboembolism extension of time until February 2024 in which to file an updated submission for BioGlue in China. If the costs to file an updated submission are prohibitive, or we cannot obtain approval following 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. Finally As an example of this risk, although in September 2022 we recently received regulatory approval halted the PROACT Xa clinical trial based on the recommendation of the trial' s Data and Safety Monitoring Board (“DSMB”) due to market BioGlue in China, it insufficient evidence to support non- inferiority of apixaban to warfarin for valve thrombosis and thromboembolism. The DSMB found that continuing the trial was only after a significantly longer and more expensive regulatory approval process than unlikely-- likely to achieve could reasonably have been anticipated when the program began 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 environmental regulatory regulations enforcement activities and private litigation activity

relating to processes and materials used in our industry could have a material, adverse impact on us. Some of our products, including certain On- X products, are sterilized using EtO. ~~Although we have a small-scale EtO facility in Austin, Texas, we rely primarily on by~~ 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. **In addition, any litigation, regulatory enforcement, or government regulation regarding the use of EtO could result in financial, legal, business, and reputational harm to us.** 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 PFAS have been subject to increasing regulations, and in some cases bans, by** the Environmental Protection Agency **and** (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, or 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..... 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 government officials, healthcare providers, and others** 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, **counterintuitive**, complex, and subject to change and changing interpretations. ~~The~~ **Our global expansion into higher-risk regions and Russia's ongoing wars- war in with Ukraine and Gaza- the instability of the Middle East**, 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, **government officials,** 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. **United States policy changes may have a material, adverse effect on us.** The ~~proliferation of~~ **transition to a new presidential administration in the US brings several potential risks that could impact our business operations and financial performance. Changes in policy regarding international trade, including import and export regulation and international trade agreements, could negatively impact our business. The US has imposed tariffs and export controls on certain goods and products imported from abroad, which has resulted in retaliatory tariffs. Additional tariffs imposed by the US on a broader range of imports, or further retaliatory trade measures taken by other countries in response, could result in** ~~and- an expanded~~ **Healthcare policy** ~~and mandated return-to-office policies, could impact the capabilities of regulatory agencies which could affect the timeliness and efficiency of regulatory reviews and approvals that are critical to our operations. Regulatory focus, particularly with respect to sustainability matters, may change~~ **changes may have a material, adverse effect on** reducing or changing regulations relating to ethylene oxide (EtO), per- and polyfluoroalkyl substances (PFAs), or other sustainability initiatives, potentially requiring us to make additional expenditures to comply with new regulations, or abandon programs we have already invested in. 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. **These changes. Additional uncertainty is anticipated as debates about healthcare and public health continue in light of the COVID-19 pandemic which may have an impact on US law relating costs and reimbursement, as well as potential changes to the regulatory environment and healthcare generally industry.** Many US healthcare laws, including **such as** the Affordable Care Act and the Federal Food, Drug, and Cosmetics Act, are complex, subject to change particularly during a change in administrations, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. Changes in federal funding or staffing at administrative agencies like the FDA may impact, for example, the speed at which we are able to obtain regulatory approvals, and changes in the focus of those administrative agencies may result in the repeal of applicable regulations or guidance or impact us in other ways we can not anticipate. The **impact application** of this uncertainty on **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 **these 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** changes to legal and regulatory frameworks, 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. **Failure to comply with data privacy and security laws, including the General Data Protection Regulation in the European Union, could have a material adverse effect on our business. An We are subject to an increasing number of federal, state, and foreign laws and regulations to address topics relating to data privacy laws, sustainability, and artificial intelligence. These regulations, some of which can be enforced by private parties or governmental entities, have been or are being promulgated and are constantly evolving and becoming increasingly complex and rigorous.** These laws and regulations may include new **compliance or disclosure requirements for companies that receive or process an individual’s personal data (including employees)**, which increases our operating costs and requires significant management **investment 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 **relevant 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 aspects of our compliance programs**. Any **resulting privacy-related** government enforcement activities may be costly, result in negative publicity, or subject us to significant penalties. **Some of our products and technologies..... 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 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 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 **execute our strategic plan, and** limit our ability to react to changes in the economy or our industry. **We may need to seek additional debt or equity financing to execute our strategic plan. However, we may be unable to obtain any desired additional financing on terms favorable to us, if at all.** 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 Relating to Ownership of our Common Stock** Our business could be negatively impacted as a result of **shareholder-stockholder** activism. In recent years, **shareholder-stockholder** 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..... 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 stockholders** 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 stockholders**, which could affect our share price adversely and prevent attempts by **shareholders stockholders** 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-stockholder** meetings, allow the issuance of blank- check preferred stock without the vote of **shareholders stockholders**, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Delaware law and our **articles-Certificate of incorporation-Incorporation and bylaws-Bylaws** could prevent attempts by **shareholders stockholders** 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 stockholders**. **37** 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.