

Risk Factors Comparison 2023-05-22 to 2022-05-25 Form: 10-K

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In addition to the other information contained in this Annual Report on Form 10-K and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, cash flows or results of operations could be materially adversely affected by any of these risks. This section contains forward-looking statements. Please refer to the cautionary statements made under the heading “Cautionary Statement Regarding Forward-Looking Information” at the end of Item 1 of this Annual Report on Form 10-K for more information on the qualifications and limitations on forward-looking statements.

Risks Related to the COVID-19 Pandemic The outbreak of communicable diseases could have, and the ongoing COVID-19 pandemic and its related effects are having, a material adverse impact on our business, financial condition, cash flows and results of operations, and we are unable to predict the extent to which COVID-19 and its related impacts will continue to adversely affect our Company and the achievement of our strategic objectives. The COVID-19 outbreak has significantly impacted economic activity and markets around the world and is negatively impacting our business, financial condition, cash flows and results of operations in numerous ways, including, but not limited to, those outlined below. We are unable to predict the extent to which COVID-19 and its related impacts will continue to negatively affect our Company, including the time it will take for vaccines to be broadly distributed and administered worldwide, and the effectiveness of such vaccines in slowing or stopping the spread of COVID-19 and its variants and mitigating the economic effects of the pandemic.

- **Product Demand.** As a result of COVID-19, we have experienced both decreased demand and increased volatility in demand for our products. Lower collection volumes at source plasma collection centers due to COVID-19 factors, including stay-at-home and other government orders designed to slow the spread of COVID-19, donor safety concerns, reduced donor collection capacity due to shutdowns and social distancing requirements, and government economic relief programs that may reduce the propensity of people to be donors, have adversely affected and will likely continue to adversely affect demand for our Plasma disposable products. While elective procedures and hospital capital purchases have increased from initially depressed levels earlier in the pandemic, demand for our Hospital products has been, and in the future may continue to be, negatively impacted by resurgences in COVID-19 and its variants that result in reductions in elective surgeries and trauma cases, restrictions on vendor access at customer sites and the reallocation of hospital resources to address critical intensive care needs. We also have experienced, and may continue to experience, in certain markets rapid and unpredictable changes in demand for some of our Blood Center disposable products both from reductions in donation volumes relating to resurgences in COVID-19 and its variants and as blood collectors seek to replenish their blood product inventories and safety stocks. Such changes could impact our ability to meet demand on a timely basis or could result in potential reductions in demand in future periods, including if safety stock levels in certain markets return to pre-COVID-19 levels or the supply of blood held by our customers significantly exceeds the demand for blood from hospitals due to declines of elective surgeries and trauma cases.
- **Manufacturing, Supply Chain and Distribution System Disruption.** COVID-19 and its associated economic disruptions could have an adverse impact on our manufacturing capacity, supply chains and distribution systems, including impacts associated with preventive and precautionary measures that we, other businesses and governments are taking, such as the recent area-wide lockdowns implemented in China; labor shortages and other financial difficulties experienced by our third-party manufacturers and suppliers; and challenges to our global transportation channels and other aspects of our global supply chain network, including the cost and availability of raw materials and components due to shortages and resulting cost inflation. Although we have not experienced significant manufacturing or supply chain difficulties to date as a result of COVID-19, we may in the future. Delays or disruptions experienced by our suppliers and manufacturers caused by the COVID-19 pandemic and associated economic disruptions may prevent us from obtaining raw materials and component parts for our products in a timely manner. Additionally, China implemented area-wide lockdowns in early 2022 to control the spread of COVID-19, which have disrupted and may continue to disrupt our ability to distribute certain products in China. A protracted reduction or interruption in any of our manufacturing and distribution processes could have a material adverse effect on our business.
- **Potential Liquidity and Credit Impacts.** While we have significant sources of cash and liquidity and access to committed credit lines, we may be adversely impacted by delays in payments of outstanding receivables if our customers experience financial difficulties or are unable to borrow money to fund their operations, which may adversely impact their ability to pay for our products on a timely basis, if at all, which in turn would adversely affect our financial condition. As these and other impacts of COVID-19 continue to adversely affect our Company, they may also have the effect of heightening many of the other risks described in the Risk Factors section of this Annual Report on Form 10-K. We believe the magnitude of the adverse impact of these factors on our business, financial condition, cash flows and results of operations in the future will be primarily driven by: the severity and duration of the COVID-19 pandemic (including the extent of future surges, variants and the efficacy of vaccinations); global vaccine distribution and acceptance; the timing, scope and effectiveness of governmental responses to the COVID-19 pandemic and associated economic disruptions; general confidence about personal health and safety; and the COVID-19 pandemic’s impact on U. S. and international healthcare systems, the U. S. economy and the worldwide economy.

Risks Related to our Business and Industry If our business strategy does not yield the expected results or we fail to implement the necessary changes to our operations, we could see material adverse effects on our business, financial condition or results of operations. We view our operations and manage our business in three principal reporting segments: Plasma, Blood Center and Hospital. We believe that Plasma and Hospital have growth potential, while Blood Center competes in challenging markets that require us to manage the business differently, including reducing costs, shrinking the scope of the current product line and evaluating opportunities to

exit unfavorable customer contracts. If we have not correctly identified the product categories with greatest growth potential, we will not allocate our resources appropriately which could have a material adverse effect on our business, financial condition or results of operations. Material reductions in purchasing from or loss of a significant customer could adversely affect our business. In fiscal 2022-2023, our largest Plasma customer, CSL, accounted for more than 10% of our net revenues and our ten largest customers accounted for approximately 45-48% of our net revenues. **As previously disclosed, our largest Plasma customer, CSL, informed us in April 2021, CSL informed us of its intent not to renew its supply agreement for the use of PCS2 plasma collection system devices and the purchase of disposable plasmapheresis kits in the U. S. following the expiration of the then current term of its contract, which was subsequently amended in fiscal 2022 to extend extended on a non-exclusive basis through December 2023-2025. Any non-renewal** In addition to the anticipated financial impact of the expiration of the CSL supply agreement in December 2023, we **termination or material reduction in purchasing by any of our largest customers for any reason, including material decreases in demand for plasma or development of alternative processes, could experience an have a material** adverse effect on our business, results of operations or financial condition if any of our **or results** other largest customers materially reduce their purchases from us or terminate their relationship with us for **or operations** any reason, including material decreases in demand for plasma or development of alternative processes. We face intense competition, and if we are unable to successfully expand our product lines through internal research and new product development or keep pace with rapid technological changes in the healthcare industry, our business may be materially and adversely affected. A significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. The medical device markets in which we participate, however, are highly competitive. We encounter significant competition across our product lines and in each market in which our products are sold from various medical device companies, some of whom have greater financial and marketing resources than we do. In addition, the medical device markets in which we participate and healthcare industry generally are characterized by extensive research and development and rapid technological change. New product development requires significant investment in research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate and develop new products and technologies, successfully complete clinical trials, obtain regulatory approvals in the United States and abroad, manufacture products in a cost-effective manner, obtain appropriate intellectual property protection for our products, and gain and maintain market acceptance of our products. In addition, patents attained by others could preclude or delay our commercialization of a product. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we fail to develop new products or enhance existing products, or if competitive technologies or therapeutic alternatives to plasma-derived pharmaceuticals in development, such as FcRn-targeted therapies, emerge and gain market acceptance, such events could have a material adverse effect on our business, financial condition or results of operations. In addition, a delay in the timing of the launch of next-generation products and the overall performance of, and continued customer confidence in, those products may result in declines in our market share and have an adverse impact on our business, financial condition or results of operations. Defects or quality issues associated with our products could adversely affect the results of operations. Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or as required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs and lost sales and customers, enforcement actions and / or investigations by state and federal governments or other enforcement bodies, as well as negative publicity and damage to our reputation that could reduce future demand for our products. Personal injuries relating to the use of our products can also result in significant product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements. ~~Our success depends on our ability to attract and retain key personnel needed to successfully operate the business and to plan for future executive transitions. Our ability to compete effectively depends on our ability to attract and retain key employees, including people in senior management, sales, marketing and R & D positions, and to facilitate seamless leadership transitions for key positions. Our ability to recruit and retain key talent will depend on a number of factors, including hiring practices of our competitors, compensation and benefits, work location, work environment, COVID-19 related health and safety protocols (including vaccine mandates) and industry economic conditions. In December 2019, we relocated our corporate headquarters to a leased office space in Boston, Massachusetts and in response to the COVID-19 pandemic, we instituted remote working practices for many of our employees. Although we believe our move to Boston and the steps we have taken to build a collaborative, performance driven culture and to maintain employee well-being during COVID-19 will help us to attract and retain key talent, we face intense competition for talent in our industry, particularly as employees are increasingly able to work remotely. Vaccine mandates applicable to our employees may also lead to employee attrition, challenges securing future labor needs, inefficiencies connected to employee turnover and costs associated with implementation and on-going compliance. If we fail to attract and retain key personnel in senior management and other positions, or if our succession planning efforts are not effective, it could have a material adverse effect on our business, financial condition and results of operations.~~ We are increasingly dependent on information technology systems and subject to privacy and security laws and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations. We increasingly rely on information technology systems, including cloud-based computing, to process, transmit and store electronic information for our day-to-day operations and for our customers, including sensitive personal information and proprietary or confidential information. Additionally, certain of our products collect data regarding patients and donors and connect to our

systems for maintenance and other purposes or are actively managed by Haemonetics on behalf of specific customers. Similar to other large multi-national companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. We also outsource certain elements of our information technology systems to third parties that, as a result of this outsourcing, could have access to certain confidential information and whose systems may also be vulnerable to these types of attacks or disruptions. Security threats, including cyber and other attacks are becoming increasingly sophisticated, frequent, and adaptive and, like other large multi-national companies, we have experienced cyber incidents in the past and may experience them in the future. Accordingly, our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information and changing customer patterns. Although prior cyber incidents have not had a material effect on our business and we have invested and continue to invest in the protection of personal information and proprietary or confidential information, there can be no assurance that our efforts will prevent cyber-attacks, intrusions, breakdowns or other incidents or ensure compliance with all applicable securities and privacy laws, regulations, standard standards. In addition, third parties may attempt to hack into our products to obtain data relating to patients with our products or our proprietary information. Any failure by us or third parties we work with to maintain or protect our respective information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Any of these events, in turn, may cause us to lose existing customers, have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other healthcare professionals, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations. Additionally, the legal and regulatory environment surrounding information security and privacy is increasingly demanding, with the imposition of new and changing requirements across businesses. We are required to comply with increasingly complex and changing legal and regulatory requirements that govern the collection, use, storage, security, transfer, disclosure and other processing of personal data in the United States and in other countries, including, but not limited to, HIPAA, HITECH, the California Consumer Privacy Act, or CCPA, the California Privacy Rights Act, ~~effective January 1, 2023,~~ and the EU's General Data Protection Regulation, or GDPR. The GDPR imposes stringent EU data protection requirements and provides for significant penalties for noncompliance. HIPAA also imposes stringent data privacy and security requirements and the regulatory authority has imposed significant fines and penalties on organizations found to be out of compliance. CCPA provides consumers with a private right of action against companies who have a security breach due to lack of appropriate security measures, and several other U. S. states have introduced or proposed similar privacy laws **which may apply to us directly or indirectly through our customers, manufacturers, suppliers or other third-party partners**. In addition, new information security and privacy laws have also come into effect in China and other countries where ~~we the Company conducts~~ **conduct** business. We or our third-party providers and business partners may also be subjected to audits or investigations by one or more domestic or foreign government agencies relating to compliance with information security and privacy laws and regulations, and noncompliance with the laws and regulations could result in material fines or litigation. We outsource certain aspects of our business to a single third-party vendor that subjects us to risks, including disruptions in business and increased costs. Currently, we rely on a single vendor to support several of our business processes, including customer service and support and elements of enterprise technology, procurement, accounting and human resources. We make diligent efforts to ensure that the provider of these outsourced services is observing proper internal control practices. However, there are no guarantees that failures will not occur. Accordingly, we are subject to the risks associated with the vendor's ability to successfully provide the necessary services to meet our needs. If our vendor is unable to adequately protect our data or information is lost, if our ability to deliver our services is interrupted (including as a result of significant outbreaks of disease, ~~including the ongoing COVID-19 pandemic,~~ natural disasters, **extreme weather and other conditions caused by or related to climate change**, strikes, terrorism attacks or other adverse events in the countries in which the vendor operates), if our vendor's fees are higher than expected, if our vendor makes mistakes in the execution of operations support, or if the vendor terminates our relationship, then our business and operating results may be negatively affected. A significant portion of our revenue derives from the sale of blood collection supplies. Declines in the number of blood collection procedures have adversely impacted our business and future declines may have an adverse effect on our business, financial condition and results of operations. The demand for whole blood disposable products in the U. S. ~~continued~~ **continues** to decrease ~~in fiscal 2022~~ due to sustained declines in transfusion rates caused by hospitals' ~~improved blood management techniques and protocols~~ **prefer single source vendors** **are primarily focused on obtaining the lowest average selling prices** for their whole blood collection products ~~and are primarily focused on obtaining the lowest average selling prices~~. We expect to see continued declines in transfusion rates and the market to remain price-focused and highly competitive for the foreseeable future. Continued declines in this market could have a material adverse effect on our liquidity and results of operations. Consolidation of healthcare providers and blood collectors, healthcare cost containment pressures, government payment and delivery system reforms and changes in private payer policies could decrease demand for our products, the prices which customers are willing to pay for those products and / or the number of procedures performed using our devices, which could have an adverse effect on our business, financial condition and results of operations. Political, economic and policy influences are causing the healthcare and blood collection industries to make substantial structural and financial changes that affect our results of operations. Government and private sector initiatives limiting the growth of healthcare costs are causing structural reforms in healthcare delivery,

including the reduction in blood use and reduced payments for care. These trends have placed greater pricing pressure on suppliers and, in some cases, decreased average selling prices and increased the number of sole source relationships. This pressure impacts our Hospital and Blood Center businesses. Our Vascular Closure devices, for example, are often perceived as physician preference devices with a relatively higher price point compared to certain vascular closure alternatives such as sutures or manual compression, and purchases are commonly made by a hospital only after approval by its value analysis committee. If a hospital value analysis committee does not approve or revokes prior approval for any of the reasons set forth above, the demand for our vascular closure devices may decrease and we could experience an adverse effect on our results of operations or financial condition. **Additionally, while Hospital capital purchase patterns have increased from initially depressed levels earlier in the COVID-19 pandemic, it is difficult to predict the long-term impact of the pandemic on hospital spending patterns.** The influence of integrated delivery networks, group purchasing organizations and large single accounts has the potential to put price pressure on our Hospital business. It also puts price pressure on our U. S. Blood Center customers who are also facing reduced demand for red cells. Our Blood Center customers have responded to this pressure by creating their own group purchasing organizations and resorting to single source tenders to create incentives for suppliers, including us, to significantly reduce prices. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors. This may exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations. An interruption in our ability to manufacture our products, obtain key components or raw materials, or the failure of a sole source supplier or sterilization service provider may adversely affect our business. We have a complex global supply chain that involves integrating key suppliers and our manufacturing capacity into a global movement of components and finished goods. We manufacture certain key disposables and devices at single locations with limited alternate facilities. If natural disasters, **extreme weather and other conditions caused by or related to climate change,** strikes, terrorism attacks or other adverse events occur that result in the closure of or damage to one or more of these facilities, we may be unable to supply the relevant products at previous levels or at all for some period. Additionally, for reasons of quality assurance or cost effectiveness, we purchase certain finished goods, components and raw materials from sole suppliers who have their own complex supply chains. We ~~also use~~ **have experienced increased levels of unpredictability in the supply of certain raw materials and components in our products,** including semiconductor chips, **used in the manufacturing of our products. While we continue to believe we will have access to the raw materials and components that we need, any** have been the subject of recent global supply chain shortages and disruptions. Any disruption to one or more of our suppliers' production or delivery of sufficient volumes of **raw materials and** components conforming to our specifications, ~~including as a result of disruptions caused by the COVID-19 pandemic (as described above) or otherwise,~~ could disrupt or delay our ability to deliver finished products to our customers. For example, we purchase components in Asia for use in manufacturing in the U. S. and Mexico. We source all of our apheresis equipment from Asia and regularly ship finished goods from the U. S. and Mexico to the rest of the world. ~~Some~~ **Many** of our products **also** require sterilization prior to sale or distribution, and we utilize ~~third-party facilities~~ **a mix of internal resources and contract sterilizers to perform this service. To the extent we or our contract sterilizers are unable to sterilize our products, whether due to capacity, availability of materials for this process. If sterilization, regulatory or other constraints, including federal and state regulations** event occurs that results in damage to or closure, whether temporarily or permanent, of one ~~on~~ or more of these ~~the facilities use of ethylene oxide,~~ we may be unable to ~~manufacture~~ **transition to alternative internal or sterilize the relevant products at prior levels external resources or methods in a timely or cost effective manner,** or at all, ~~and which could have a material impact~~ **third-party may not be available on our results of operations and financial condition** a timely basis (if at all) to replace sterilization capacity. In addition, we manufacture our vascular closure devices under a shelter plan service agreement with Offshore International Incorporated (d/b/a Tetakawi), ~~or Tetakawi,~~ pursuant to which we lease our manufacturing facility in Guaymas, Mexico ~~and~~ Tetakawi is responsible for a number of ongoing services related to the facility, including provision of external security and maintenance, manufacturing personnel related human resource matters, recruiting support, government compliance, workforce transportation and cross-border shipping of raw components. We are reliant on Tetakawi to provide these services and any disruption in these services or our failure to maintain our contractual relationship with Tetakawi could significantly harm our ability to manufacture our vascular closure devices and maintain sufficient quality standards, which would negatively impact our business and results of operations. Due to the high standards and stringent requirements of the FDA and other similar non-U. S. regulatory agencies applicable to manufacturing our products, such as the FDA's QSR and cGMP regulations, we also may not be able to quickly establish additional or replacement sources for certain raw materials, components or finished goods. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials, components or finished goods on commercially reasonable terms or in a timely manner, could compromise our ability to manufacture our products on a timely and cost-competitive basis, which may have a material adverse effect on our business, financial condition and results of operations. ~~Plastics and other petroleum-based products are the principal components of our disposables, which are the main source of our revenues. Changes in the cost, composition or availability of the plastics and resins we purchase, or~~ **of cost volatility associated with** other raw materials and components used in our products, could adversely affect our business, financial condition and results of operations. We face risks related to ~~the~~ **price, composition and availability of the plastic raw materials used in our business disposable products, which represent a substantial portion of our revenues.** Material or sustained increases in the price of petroleum or petroleum derivatives could have an adverse impact on the costs to procure plastic raw materials. ~~Our~~ **Additionally, our** results of operations could be negatively impacted by volatility in the cost **or availability** of these and other raw materials and components used in our products **that,** including associated freight and energy **in turn, increase the** costs that, in turn, increase the costs of producing and distributing our products. Recently **In recent years,** we have experienced

inflationary pressures that have **significantly** increased ~~significantly~~ the cost of raw materials, transportation, construction, services, and energy necessary for the production and distribution of our products, ~~which we expect will continue~~ **Continued throughout fiscal 2023 uncertainty around inflationary pressures, rising interest rates and macroeconomic conditions have increased the risk of creating new, or exacerbating existing, economic challenges we face**. While we have implemented cost containment measures, selective price increases and taken other actions to offset these inflationary pressures in our global supply chain, we may not be able to completely offset all the increases in our operational costs. Additionally, climate change (including laws or regulations passed in response thereto) could increase our **supply costs, including in particular our costs of supply, energy and transportation / freight - related expenses, or reduce the availability of raw materials**. The composition of the plastic we purchase is also important. Today, we purchase plastics that contain **DEHP and other** phthalates, which are used to make plastic malleable. Due to regulatory changes and evolving customer expectations, we may be required to remove materials such as phthalates from our devices, find alternative materials which then need to be validated or obtain regulatory approvals from the regulatory authorities for a number of products. While we have not experienced significant shortages in the past, any interruption in the supply for certain plastics could have a material impact on our business by limiting our ability to manufacture and sell the products that represent a significant portion of our revenues. These outcomes may in turn result in customers transitioning to available competitive products, loss of market share, negative publicity, reputational damage, loss of customer confidence or other negative consequences (including a decline in stock price). We may not realize the benefits we expect from our Operational Excellence Program. In July 2019, our Board of Directors approved a new Operational Excellence Program, also referred to in this report as the 2020 Program, and delegated authority to management to determine the detail of the initiatives that will comprise the program. ~~During the first quarter of fiscal 2022, the Company revised the program to improve product and service quality, reduce cost principally in our manufacturing and supply chain operations and ensure sustainability while helping to offset impacts from the expiration of CSL's U. S. Supply Agreement in December 2023, rising inflationary pressures and effects of the COVID-19 pandemic.~~ While cost savings from the 2020 Program to date have been consistent with our expectations, it is possible that events and circumstances, such as **rising interest rates, macroeconomic uncertainty and the aforementioned related impacts on us, our customer customers loss, labor shortages, sustained inflationary pressures and suppliers other financial or strategic difficulties, delays and unexpected costs, including as a direct or indirect result of the COVID-19 pandemic,** could result in our not realizing all of the anticipated benefits or our not realizing the anticipated benefits on our expected timetable. **Additionally, any material reduction in purchases by significant customers and any actions we take in response to such anticipated reduction could result in a decrease in benefits we realize under the 2020 Program**. Our inability to realize all of the anticipated benefits from the 2020 Program could have a material adverse effect on our business, results of operations, cash flows and financial condition. If our business development activities are unsuccessful, we may not realize the intended benefits. We have sought and in the future may seek to supplement our organic growth through strategic acquisitions, investments and alliances. We have also sought and in the future may seek to divest certain assets deemed non-core to our long-term strategic objectives. Such transactions are inherently risky and require significant effort and management attention. The success of any acquisition, investment or alliance, or of any ~~divestiture~~ **divestiture**, may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity or to successfully integrate any business we may acquire into our existing business. ~~For example, we anticipate that a material factor in achieving the anticipated benefits of our March 2021 acquisition of Cardiva will be our ability to effectively integrate and profitably market and sell the vascular closure devices acquired from Cardiva. Also as a result of the Cardiva acquisition, we have entered into a new line of business. Unlike our other products, the VASCADE and VASCADE MVP vascular closure devices are designated as Class III medical devices, which are subject to additional and complex regulatory requirements. Complying with these regulations will be costly, time-consuming and complex. Furthermore, any new business line and / or new product or service could have an adverse impact on the effectiveness of our system of internal controls.~~ Promising partnerships and acquisitions may also not be completed for reasons such as competition among prospective partners or buyers, the inability to reach satisfactory terms, the need for regulatory approvals or the existence of economic conditions affecting our access to capital for acquisitions and other capital investments. If our business development activities are unsuccessful, we may not realize the intended benefits of such activities, including that acquisition and integration costs may be greater than expected or the possibility that expected return on investment synergies and accretion, or on new growth opportunities funded in whole or part by divestitures, will not be realized or will not be realized within the expected timeframe. Risks Related to Government Regulation As a medical device and drug manufacturer, we operate in a highly regulated industry, and non-compliance with applicable laws or regulations could adversely affect our financial condition and results of operations. The manufacture, distribution and marketing of our products are subject to extensive regulation by the FDA and other state and non-U. S. regulatory bodies. Our operations are also subject to review and monitoring by the FDA and other regulatory authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things, the product's development, testing, premarket clearance and approval, manufacture, marketing, labeling, post-market surveillance, reporting, and imports and exports. Before a new medical device, or a new use of an existing product can be marketed in the United States, it must first receive either premarket clearance under Section 510 (k) of the U. S. Federal Food, Drug, and Cosmetic Act, or FDCA, a grant of a request for de novo classification or a Premarket Approval, or PMA, from the FDA, unless an exemption applies. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. Many of our currently commercialized products have received 510 (k) clearance. In the future, the FDA may determine that our products will require more costly, lengthy and uncertain de novo or PMA processes. Modifications to Class III devices, like ~~the our~~ **the our** Vascular Closure products ~~we acquired from Cardiva in March 2021,~~ may require additional clinical studies or supplemental PMA submissions. If the FDA requires us to go through a lengthier, more rigorous process for

future products or modifications to existing products, our product introductions or modifications could be delayed or canceled, which could adversely affect our revenue. **In particular, the FDA has recently placed increased scrutiny on cybersecurity for medical devices which may necessitate additional time and cost for product development, submission and approval or clearance.** In addition, even if we do obtain clearance or approval, the FDA may not approve or clear these products for the indications that we requested. Any delay in, or failure to receive or maintain, clearances or approvals for our products under development could prevent us from generating revenue from these products. Failure to substantially comply with applicable regulations could subject our products to recall or seizure of our products by government authorities, or an order to suspend manufacturing and distribution activities. If our products were determined to have design or manufacturing flaws, this could also result in their recall or seizure. Either of these situations could also result in the imposition of fines, administrative actions like untitled or warning letters, and other penalties or sanctions. Our products are also subject to approval and regulation by foreign regulatory and safety agencies. For example, the EU has adopted the EU Medical Device Regulation, or EU MDR, and EU In Vitro Diagnostic Regulation, or EU IVDR, each of which impose stricter requirements for the marketing and sale of medical devices beyond those of the current medical device directives they replace, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. ~~The EU MDR became fully applicable as of May 26, 2021 and the EU IVDR is fully applicable as of May 26, 2022. There is a transition period for devices with a notified body certificate with an expiry date after the date of full application, provided that there are no significant changes to the design or intended use. However, a new EU certificate under the applicable regulations must be obtained before that expiry date if there is to be no interruption in manufacturing and supply of devices to the market.~~ Complying with the requirements of these regulations may require us to incur significant expenditures **and we may experience delays that negatively impact the ability to sell our full suite of products in certain jurisdictions.** Similarly, the separation of states from participation in the EU, such as through the cessation of the UK's membership in the EU (commonly known as "Brexit") and the separation of the Swiss and EU medical product markets with the adoption of the EU MDR (commonly referred to as "Swexit"), may result in further regulatory risk and complexity as the former EU member or participant state establishes separate laws and regulations governing medical products. **More stringent regulations have also been introduced in many countries outside of Europe that previously did not have medical device regulations, had minimal regulations or relied on reciprocal recognition of approval in other markets.** Failure to meet these requirements could adversely impact our business in the EU and other applicable regions. If we or our suppliers fail to comply with laws and regulations governing the manufacture and production of our products, our products could be subject to restrictions or withdrawal from the market. Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspection (both routine and unannounced) by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers must comply with the FDA's QSR or cGMP requirements (depending on the products at issue), which address, among other things, the methods of documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Any future failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA or other regulatory authority could result in administrative actions, field actions, or civil or criminal enforcement actions. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. Any sanctions by the FDA or other regulatory authority could have a material adverse effect on our reputation, business, results of operations and financial condition. We are also subject to environmental laws, which are becoming more stringent throughout the world. For example, the U. S. Environmental Protection Agency regulates the use of ethylene oxide for sterilization of medical devices, and is increasingly focused on reducing emissions from the ethylene oxide sterilization process, which could increase our costs of operations and necessitate changes to our manufacturing plants and processes. Other environmental laws may have similar consequences to us or our suppliers, or result in liability to us. ~~The~~ **Additionally, increased environmental regulation, including the** enactment of ~~additional~~ **environmental laws in the future and regulations to address climate change,** may increase our compliance costs or ~~otherwise~~ **adversely impact** ~~restrict certain aspects of~~ **our operations-activities.** If our products cause or contribute to a death or serious injury, or malfunction in certain ways, we will be subject to medical device reporting requirements. Under the FDA's medical device reporting regulations, medical device manufacturers are required to report to the FDA information of which they become aware that a device has or may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or one of our similar devices were to recur. Similar reporting requirements exist in some of the other jurisdictions in which we operate. Failure to report these events to the FDA or other applicable regulatory authorities within the required timeframes, or at all, could lead to enforcement actions, fines and criminal sanctions against us. ~~Class III medical devices are those that pose the highest risk to patients. As a result of the acquisition of our Vascular Closure products from Cardiva in March 2021, we may receive a greater number of complaints requiring investigation and potentially need to file a greater number of medical device reports with FDA, which may require additional time and resources.~~ Our relationships with customers and third-party payers are subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion, contractual damages, reputational harm and diminished profits and future earnings. We are subject to fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute our products. In addition, we are subject to transparency laws and patient privacy regulation by U. S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or

pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance, or anti-bribery laws such as the Foreign Corrupt Practices Act of 1977, or equivalent laws in other jurisdictions. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business. Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our financial condition, results of operations and / or liquidity. We are subject to income taxes, non-income based taxes and tax audits in both the U. S. and various foreign jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision and have established contingency reserves for material, known tax exposures. However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many jurisdictions, as well as interpretations as to the legality under various rules in certain jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of these disputes or other tax audits or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves and the actual outcomes of these disputes and other tax audits could have a material impact on our results of operations or financial condition. **The Changes in tax regimes laws and regulations, or their interpretation and application, in the jurisdictions where we are subject to tax could materially impact our or effective tax rate operate under are unsettled and may be subject to significant change**. For example, **in August 2022, the U. S. Congress has recently been debating changes to U. S. United States enacted the Inflation Reduction Act that imposes a 15 % minimum tax for large corporate corporations on global adjusted financial statement income for tax laws years beginning after December 31, including provisions 2022, and a 1 % excise tax on certain share repurchases occurring after December 31, 2022. We do not currently expect that may alter the U. S. taxation of the profits of foreign subsidiary corporations. If ultimately enacted, these -- the changes could Inflation Reduction Act will have a material impact on our income tax liability, but we will continue to monitor this change in future periods. We are unable to predict what changes to the tax laws of the U. S. and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. Any significant increase in our future effective tax rate could have a material adverse impact**. Additionally, the U. S. Congress, government agencies in non-on -U. S. jurisdictions where we and our affiliates do business and, financial condition, results of operations, or cash flows. There is also a high level of uncertainty in the current tax environment stemming from both global initiatives put forth by the Organization for Economic Co- operation and Development, or (the “OECD”, have recently focused”) and unilateral measures being implemented by various countries due to a lack of consensus on issues related to the these global initiatives. Further, unilateral measures in response to such measures are creating additional uncertainty. As we expand the scale of our international business activities, any changes in the U. S. or foreign taxation of such activities may increase our worldwide effective multinational corporations. The OECD has released its comprehensive plan to create an agreed set of international rules for fighting base erosion and profit shifting. In addition, the OECD, the European Commission and individual countries are examining changes to how taxing rights should be allocated among countries in light of the digital economy. As a result, the tax rate laws in the U. S. and harm other countries in which we and our affiliates do business could change on a prospective or retroactive basis and any such changes could materially adversely affect our business, results of operations or financial condition and results of operations. Such changes may also apply retroactively to our historical operations and result in taxes greater than the amounts estimated and recorded in our financial statements. Risks Related to our Financial Obligations and Indebtedness We have a significant amount of debt that may decrease our business flexibility, access to capital, and / or increase our borrowing costs, and we may still incur additional debt in the future, which may adversely affect our operations and financial results. **In July 2022, the Company entered into an amended and restated credit agreement with certain lenders to refinance the existing term loan and revolving loan and extend their maturity date through June 2025. The amended and restated credit agreement provides for a \$ 280. 0 million term loan and access to a \$ 420. 0 million revolving loan (together, the “ Revised Credit Facilities ”). As of April 2-1, 2022-2023, we had in addition to our \$ 500. 0 million aggregate principal amount of indebtedness under our convertible senior notes due 2026 (the “ 2026 Notes ”) as well as a \$ 350. 0 million term loan (the “ Term Loan ”) and access to a \$ 350. 0 million revolving loan (the “ Revolving Credit Facility ” and together with the Term Loan, the Company “ Credit Facilities ”). As of April 2, 2022, we had \$ 284-274. 47 million of debt outstanding under the Term Loan-loan and no borrowings were outstanding under the Revolving revolving Credit credit Facility-facility. Our Revised Credit Facilities contain financial covenants that require us to maintain specified financial ratios that may limit our ability to borrow additional funds and that require us to make interest and principal payments. As of April 2-1, 2022-2023, we were in compliance with the covenants pursuant to our Revised Credit Facilities, and we currently forecast that we will be in compliance with these our Credit Facility-covenants through the period ending March April 1, 2023. Additionally, our Credit Facilities mature on June 15, 2023 and the Company will be required to pay the scheduled remaining balance of the Term Loan over the four calendar quarters preceding the expiration of the Credit Facilities in payments of \$ 70. 0 million per quarter commencing September 30, 2022-2024, along with any amounts outstanding under the Revolving Credit Facility as of the**

~~maturity date~~. The conditional conversion feature of the 2026 Notes, if triggered, may adversely affect our financial condition and operating results. Under certain circumstances, the noteholders may convert their 2026 Notes at their option prior to the scheduled maturities. If one or more noteholders elect to convert their 2026 Notes, we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, holders of our 2026 Notes will have the right to require us to repurchase their 2026 Notes upon the occurrence of a fundamental change (as defined in the indenture, dated as of March 5, 2021, between U. S. Bank National Association, as trustee (the “ Trustee ”) and us (the “ Indenture ”)), at a repurchase price equal to the principal amount of the 2026 Notes to be repurchased, plus accrued and unpaid special interest, if any, to but not including, the fundamental change repurchase date. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2026 Notes or pay the cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the 2026 Notes or pay the cash amounts due upon conversion. Our failure to repurchase the 2026 Notes or to pay the cash amounts due upon conversion when required will constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, including our **Revised** Credit Facilities, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Notes. Even if holders do not elect to convert their 2026 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2026 Notes as a current rather than long- term liability, which would result in a material reduction of our net working capital. The Capped Call Transactions may affect the value of the 2026 Notes and our common stock. In connection with the 2026 Notes issuance, we entered into privately negotiated capped call transactions (the “ Capped Call Transactions ”) with certain financial institutions (the “ Option Counterparties ”). The Capped Call Transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the 2026 Notes and / or offset any potential cash payments we are required to make in excess of the principal amount of converted Notes, as the case may be, with such reduction and / or offset subject to a cap. From time to time, the Option Counterparties and / or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the 2026 Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2026 Notes. We are subject to counterparty risk with respect to the Capped Call Transactions. The Option Counterparties are financial institutions, and we are subject to the risk that one or more of the Option Counterparties may default or otherwise fail to perform, or may exercise certain rights to terminate, their obligations under the Capped Call Transactions. Our exposure to the credit risk of the option counterparties is not secured by any collateral. Past global economic conditions have from time to time resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an Option Counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at the time under such transactions with such Option Counterparty. Our exposure depends on many factors, but our exposure will generally increase if the market price or the volatility of our common stock increases. In addition, upon default by an Option Counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the Option Counterparties. In addition, the Capped Call Transactions are complex, and they may not operate as planned. For example, the terms of the Capped Call Transactions may be subject to adjustment, modification or, in some cases, renegotiation if certain corporate or other transactions occur. Accordingly, these transactions may not operate as we intend if we are required to adjust their terms as a result of transactions in the future or upon unanticipated developments that may adversely affect the functioning of the Capped Call Transactions. Provisions in the Indenture could delay or prevent an otherwise beneficial takeover of us. Certain provisions in the 2026 Notes and the Indenture could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their 2026 Notes for cash. In addition, if a takeover constitutes a make- whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the 2026 Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of our common stock may view as favorable. Conversion of the 2026 Notes may dilute the ownership interest of existing stockholders. The conversion of some or all of the Notes will dilute the ownership interests of existing stockholders to the extent we deliver shares of our common stock upon conversion of any of the 2026 Notes. Any sales in the public market of the common stock issuable upon such conversion could adversely affect our common stock’ s prevailing market prices. In addition, the existence of the 2026 Notes may encourage short selling by market participants because the conversion of the 2026 Notes could be used to satisfy short positions, or anticipated conversion of the 2026 Notes into shares of our common stock could depress the price of our common stock. Risks Related to Operating Internationally As a substantial amount of our revenue comes from outside the U. S., we are subject to geopolitical events, economic volatility, violations of anti- corruption laws, export and import restrictions and tariffs, decisions by local regulatory authorities and the laws and medical practices in foreign jurisdictions. We do business in over 90 countries and have distributors in approximately 80 of these countries. This exposes us to currency fluctuation, geopolitical risk, economic volatility, anti- corruption laws, export and import restrictions, local regulatory authorities and the laws and medical practices in foreign jurisdictions. U. S. legislation aimed at boosting competitiveness of U. S. businesses may have unintended effects on our business. Tariffs and other protectionist measures directed at China and other markets, as well as prolonged uncertainty regarding such measures as administrations change, may have adverse effects on our ability to source, manufacture and distribute products, or receive payments, in a timely and cost effective manner, thereby adversely affecting our business. Additionally, the military conflict between Russia and Ukraine has resulted in the implementation of sanctions by the U. S. and other governments against Russia and has caused

significant volatility and disruptions to the global markets. It is not possible to predict the short- and long- term implications of this conflict, which could include but are not limited to further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber- attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets. We are continuing to monitor the situation in Ukraine and globally as well as assess its potential impact on our business. Although our business in Russia accounted for only about 2-1% of fiscal 2022-2023 net revenue revenues, a significant escalation or further expansion of the conflict's current scope or related disruptions to the global markets could have a material adverse effect on our results of operations. Our international operations are governed by the U. S. Foreign Corrupt Practices Act, or FCPA, and other similar anti- corruption laws in other countries. Generally, these laws prohibit companies and their business partners or other intermediaries from making improper payments to foreign governments and government officials in order to obtain or retain business. Global enforcement of such anti- corruption laws has increased in recent years, including aggressive investigations and enforcement proceedings. While we have an active compliance program and various other safeguards to discourage impermissible practices, we have distributors in approximately 80 countries, several of which are considered high risk for corruption. As a result, our global operations carry some risk of unauthorized impermissible activity on the part of one of our distributors, employees, agents or consultants. Any alleged or actual violation could subject us to government scrutiny, severe criminal or civil fines, or sanctions on our ability to export product outside the U. S., which could adversely affect our reputation and financial condition. Export of U. S. technology or goods manufactured in the U. S. to some jurisdictions requires special U. S. export authorization or local market controls that may be influenced by factors, including political dynamics, outside our control. Finally, any other significant changes in the competitive, legal, regulatory, reimbursement or economic environments of the jurisdictions in which we conduct our international business could have a material impact on our business. We sell our products in certain emerging economies which exposes us to less mature regulatory systems, more volatile markets for our products and greater credit risks. A loss of funding for our products or changes to the regulatory regime could lead to lost revenue or account receivables. There are risks with doing business in emerging economies, such as Brazil, Russia, India and China. These economies tend to have less mature product regulatory systems and more volatile financial markets. In addition, the government controlled healthcare system's ability to invest in our products and systems may abruptly shift due to changing government priorities, geopolitical events or funding capacity. Our ability to sell products in these economies is dependent upon, among other factors, our ability to hire qualified employees or agents to represent our products locally and our ability to obtain and maintain the necessary regulatory approvals in a less mature regulatory environment. If we are unable to retain qualified representatives or maintain the necessary regulatory approvals, we will not be able to continue to sell products in these markets. We are also exposed to a higher degree of financial risk if we extend credit to customers in these economies. In many of the international markets in which we do business, including certain parts of Europe, South America, the Middle East and Asia, our employees, agents or distributors offer to sell our products in response to public tenders issued by various governmental agencies. There is additional risk in selling our products through agents or distributors, particularly in public tenders. If they misrepresent our products, do not provide appropriate service and delivery, or commit a violation of local or U. S. law, our reputation could be harmed and we could be subject to fines, sanctions or both. We are exposed to fluctuations in currency exchange rates, which could adversely affect our cash flows and results of operations. International revenues and expenses account for a substantial portion of our operations. In fiscal 2022-2023, our international revenues accounted for 35-27. 6-9% of our total revenues. The exposure to fluctuations in currency exchange rates takes different forms. Reported revenues, as well as manufacturing and operational costs denominated in foreign currencies by our international businesses, fluctuate due to exchange rate movement when translated into U. S. dollars for financial reporting purposes. Fluctuations in exchange rates could adversely affect our profitability in U. S. dollars of products and services sold by us into international markets, where payment for our products and services and related manufacturing and operational costs is made in local currencies. Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued. We are subject to taxation in numerous countries, states and other jurisdictions. In preparing our financial statements, we record the amount of tax payable in each of the jurisdictions in which we operate. Our future effective tax rate, however, may be lower or higher than prior years due to numerous factors, including a change in our geographic earnings mix, changes in the measurement of our deferred taxes and recently enacted and future tax law changes in jurisdictions in which we operate. Changes in our operations, including headcount in Switzerland or Malaysia, could adversely affect our tax rate due to favorable tax rulings in these jurisdictions. We are also subject to tax audits in various jurisdictions and tax authorities may disagree with certain positions we have taken and assess additional taxes. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could adversely affect our business, results of operations and cash flows.

Risks Related to Intellectual Property and Litigation There is a risk that our intellectual property may be subject to misappropriation in some countries. Certain countries, particularly China and Russia, do not enforce compliance with laws that protect intellectual property rights with the same degree of vigor as is available under the U. S. and European systems of justice. Further, certain of our intellectual property rights are not registered in China, or if they were, have since expired. This may permit others to produce copies of products in China that are not covered by currently valid patent registrations. There is also a risk that such products may be exported from China to other countries. In order to aggressively protect our intellectual property throughout the world, we have a program of patent disclosures and filings in markets where we conduct significant business. While we believe this program is reasonable and adequate, the risk of loss is inherent in litigation as different legal systems offer different levels of protection to intellectual property and it is still possible that even patented technologies may not be protected absolutely from infringement. Pending and future intellectual property litigation could be costly and disruptive to us. We operate in an industry that is susceptible to significant intellectual property litigation. This type of litigation is expensive, complex and lengthy and its outcome is difficult to predict. Patent litigation may result in adverse outcomes and could significantly divert the

attention of our technical and management personnel. Our products may be determined to infringe another party's patent, which could lead to financial losses or adversely affect our ability to market our products. There is a risk that one or more of our products may be determined to infringe a patent held by another party. If this were to occur, we may be subject to an injunction or to payment of royalties, or both, which may adversely affect our ability to market the affected product or otherwise have an adverse effect on our results of operations. In addition, competitors may patent technological advances that may give them a competitive advantage or create barriers to entry. In order to guard against the risk of infringement of intellectual property rights held by third parties we conduct freedom to operate studies through qualified counsel on all newly developed or acquired technologies. While we believe this practice is reasonable and adequate, there is risk that third party patents or trademarks were not identified in such studies or that litigation outcomes regarding infringement or validity may be contrary to our understanding of the facts or the established law. We operate in an industry susceptible to significant product liability claims. Pending and future product liability claims and other litigation may adversely affect our financial condition and results of operations or liquidity, and they also have the potential to damage our reputation, impair our ability to market our products and impact our ability to maintain applicable insurance coverage on reasonable terms or at all. Our products are relied upon by medical personnel in connection with the treatment of patients and the collection of blood or blood components from donors. In the event that patients or donors sustain injury or death in connection with their condition or treatment, we, along with others, may be sued and whether or not we are ultimately determined to be liable, we may incur significant legal expenses. These claims may be brought by individuals seeking relief on their own behalf or purporting to represent a class. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians and healthcare providers to properly and correctly use our products on patients. If these physicians or healthcare providers are not properly trained, are negligent in using our products or use our products "off-label," the capabilities of our products may be diminished or the patient may suffer critical injury. We cannot prevent a physician from using our products for off-label applications. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Any such complications or adverse safety outcomes following use of VASCADE or VASCADE MVP may result in higher payments to our customers under a Performance Guarantee program applicable to those products, which would harm our business and results of operations. In addition, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. If we cannot successfully defend ourselves against pending or future product liability claims and other litigation (including class actions and stockholder derivative actions), we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defenses require significant financial and management resources. Regardless of the merits or eventual outcome, such litigation could have a material adverse effect on our financial condition, results of operations or liquidity and further could damage our reputation and, therefore, impair our ability to market our products and make applicable insurance coverage more costly or difficult to obtain. While we believe that our current product liability insurance coverage is sufficient, there is no assurance that such coverage will be adequate to cover incurred liabilities or that we will be able to obtain acceptable product and professional liability coverage in the future. Additionally, we do not maintain third-party insurance coverage for all categories of potential liability, which increases our exposure to unanticipated claims and adverse decisions and these losses could have a material adverse effect on our financial condition, results of operations or liquidity.

General Risk Factors **Actual or threatened public health emergencies could harm our business. Our business and operations could be adversely affected by health epidemics that impact the markets and communities in which we, our partners and our clients operate. The COVID-19 pandemic caused significant disruption to the business and financial markets. We continue to monitor the potential effects of future health epidemics on our business and operations. While the spread and impact of COVID-19 has stabilized, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, which could have the effect of decreasing demand and / or increasing volatility in demand for our products. Our success depends on our ability to attract and retain key personnel needed to successfully operate the business and to plan for future executive transitions. Our ability to compete effectively depends on our ability to attract and retain key employees, including people in senior management, sales, marketing and R & D positions, and to facilitate seamless leadership transitions for key positions. Our ability to recruit and retain key talent will depend on a number of factors, including hiring practices of our competitors, compensation and benefits, work location, work environment, hybrid work environment policies and industry economic conditions. If we fail to attract and retain key personnel in senior management and other positions, or if our succession planning efforts are not effective, it could have a material adverse effect on our business, financial condition and results of operations.** Our share price has been volatile and may fluctuate, and accordingly, the value of an investment in our common stock may also fluctuate. Stock markets in general and our common stock in particular have experienced significant price and trading volume volatility over recent years. The market price and trading volume of our common stock may continue to be subject to significant fluctuations due to factors described under this Item 1A. Risk Factors, as well as economic and geopolitical conditions in general and to variability in the prevailing sentiment regarding our operations or business prospects, as well as, among other things, changing investment priorities of our shareholders. Because the market price of our common stock fluctuates significantly, shareholders may not be able to sell their shares at attractive prices. Share repurchase programs, **including under our existing share repurchase authorization,** could affect the price of our common stock and increase volatility and may be suspended or terminated at any time, which may result in a decrease in the trading price of our common stock. ~~We may in the future request~~ **In August 2022, we announced that the our Board of Directors authorize one or more had approved a new three-year share repurchase programs- program authorizing the repurchase of up to \$ 300.0 million of outstanding shares of our common stock through August 2025.** Under ~~such the~~ share repurchase ~~programs- program~~, we are generally authorized to repurchase,

from time to time, outstanding shares of common stock in accordance with applicable laws both on the open market, including under trading plans established pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended and in privately negotiated transactions. The actual timing, number and value of shares repurchased is determined by us and depends on a number of factors, including market conditions, applicable legal requirements and compliance with the terms of loan covenants. ~~Such~~ **The** share repurchase ~~programs-~~ **program** may be suspended, modified or discontinued at any time and we have no obligation to repurchase any amount of our common stock under the programs. Repurchases pursuant to ~~a-~~ **our** share repurchase program could affect our stock price and increase its volatility. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our common stock. There can be no assurance that any share repurchases ~~would~~ **will** enhance shareholder value because the market price of our common stock may decline below the levels at which we repurchased our common stock. Although our share repurchase ~~programs-~~ **program** ~~are~~ **is** intended to enhance long- term shareholder value, short- term stock price fluctuations could reduce ~~a-~~ **the** program' s effectiveness. **Refer to Note 7, Earnings per Share, to the Consolidated Financial Statements in Item 8 of this Annual Report on Form 10- K for additional information. Our business could be negatively impacted by corporate responsibility matters. There has been increased focus from certain regulatory bodies, investors, customers, employees and other stakeholders concerning corporate responsibility matters, including topics identified under the framework of Environmental, Social and Governance (“ ESG ”). For example, customer preferences or requirements may be influenced by company progress across various ESG topics related to, among other things, human capital and environmental impact matters. From time to time, we may announce certain initiatives, including goals, regarding corporate responsibility focus areas for our company. We may not achieve, or may be perceived as not achieving, against such initiatives, including as a result of changes in our business. Moreover, the standards by which corporate responsibility efforts and related matters are measured are developing and evolving, and certain areas are subject to assumptions that could change over time. Any failure, or perceived failure, to achieve against our corporate responsibility initiatives or to establish goals that align with stakeholder expectations could result in declines in our market share and have an adverse impact on our business, financial condition or results of operations.**