

Risk Factors Comparison 2025-02-25 to 2024-02-28 Form: 10-K

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We are exposed to a variety of risks relating to our international sales and operations” of this Annual Report on Form 10-K for further details. ~~Import-export. Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, and import-export. Among other things, these laws restrict, and in some cases can prevent, U. S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in our business dealings with entities in and from foreign countries. In addition to our need to comply with such regulations in connection with our direct activities, we also sell and provide goods, technology and services to agents, representatives and distributors who may export such items to customers and end-users. If we, or the third parties through which we do business, are not in compliance with applicable import, export control or economic sanctions laws and regulations, we may be subject to civil or criminal enforcement action, and varying degrees of liability. Such actions may disrupt or delay sales of our products or services or result in restrictions on our distribution and sales of products or services that may materially impact our business.~~ Environmental Health and Safety. Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. We are subject to country-specific, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We believe that our environmental, health and safety procedures for handling and disposing of these materials comply with the standards prescribed by the controlling laws and regulations. However, risk of accidental releases or injury from these materials is possible. These risks are managed to minimize or eliminate associated business impacts. In the event of this type of accident, we could be held liable for damages and face a liability that could exceed our resources. We could be subject to a regulatory shutdown of a facility that could prevent the distribution and sale of products manufactured there for a significant period of time, and we could suffer a casualty loss that could require a shutdown of the facility in order to repair it, any of which could have a material, adverse effect on our business. Although we continuously strive to maintain full compliance with respect to all applicable global environmental, health and safety laws and regulations, we could incur substantial costs to fully comply with future laws and regulations, and our operations, business or assets may be negatively affected. Furthermore, global environmental, health and safety compliance is an ongoing process. We have compliance procedures in place for compliance with Employee Health & Safety laws, driven by a centrally led organizational structure that ensures proper implementation, which is essential to our overall business objectives. In addition, we are subject to numerous federal, state, foreign and local laws relating to safe working conditions, environmental protection and fire hazard control, among others. We may be required to incur significant costs to comply with these laws and regulations in the future and complying with these laws may result in a material adverse effect upon our business, financial condition and results of operations.

Data Privacy and Cybersecurity Laws and Regulations. As a business with a significant global footprint, compliance with evolving regulations and standards in data privacy and cybersecurity (relating to the confidentiality and security of our information technology systems, products such as medical devices, and other services provided by us) may result in increased costs, lower revenue, new complexities in compliance, new challenges for competition, and the threat of increased regulatory enforcement activity. Our business relies on the secure electronic transmission, storage and hosting of sensitive information, including personal information, financial information, intellectual property, and other sensitive information related to our customers and workforce. For example, in the U. S., the collection, maintenance, protection, use, transmission, disclosure and disposal of certain personal information and the security of medical devices are regulated at the U. S. federal and state, and industry levels. U. S. federal and state laws protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by health care providers. For example, in the U. S. we are obligated to comply with the requirements of the Health Insurance and Portability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, “HIPAA”). Under HIPAA, the HHS has issued regulations, including the HIPAA Privacy, Security and Breach Notification Rules, to protect the privacy and security of protected health information used or disclosed by covered entities including health care providers and their business associates, as well as covered subcontractors. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include significant civil and criminal penalties for each violation. In addition, the FDA has issued guidance advising manufacturers to take cybersecurity risks into account in product design for connected medical devices and systems, to assure that appropriate safeguards are in place to reduce the risk of unauthorized access or modification to medical devices that contain software and reduce the risk of introducing threats into hospital systems that are connected to such devices. The FDA also issued guidance on post market management of cyber security in medical devices. Outside the U. S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. Legal requirements in these countries relating to the collection, storage, handling and transfer of personal data and, potentially, intellectual property continue to evolve with increasingly strict enforcement regimes. In Europe, for example, we are subject to EU General Data Protection Regulation (“GDPR”) which requires member states to impose minimum restrictions on the collection, use and transfer of personal data and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR also requires companies processing personal data of individuals residing in the EU to comply with EU privacy and data protection rules. Please refer to “Item 1A. Risk Factors—Failure to comply with laws relating to the confidentiality of sensitive personal information or standards

related to the transmission of electronic health data, may require us to make significant changes to our products, or incur penalties or other liabilities” of this Annual Report on Form 10-K for additional discussion of the risks accompanying compliance with data privacy and cybersecurity laws and regulations. These laws and regulations impact the ways in which we use and manage personal data, protected health information, and our information technology systems. They also impact our ability to move, store, and access data across geographic boundaries. Compliance with these requirements may require changes in business practices, complicate our operations, and add complexity and additional management and oversight needs. They also may complicate our clinical research activities, as well as product offerings that involve transmission or use of clinical data.

HUMAN CAPITAL Our people are our greatest asset and we view human capital management and the strength of our employees as integral to the long-term success of our business. We understand that we rely on our employees worldwide to propel our organization forward with great ideas, innovations and leadership. **Workforce Demographics** As of December 31, 2023, we had approximately 3,946 regular full and part time employees and 1383 contingent, subcontracted, and outsourced partners. Approximately 70 % of our employees are located in the United States, 21 % in Europe, 2 % in Latin America and Canada and 7 % in Asia-Pacific which includes Australia and New Zealand. **Diversity and Inclusion** A diverse workforce and an inclusive culture and work environment is a business priority and a key to our long-term success. We believe our company is stronger when we build diverse teams and leverage broad perspectives. Diverse teams meet the needs of our shareholders, customers, colleagues and communities we serve. Our commitment to diversity and inclusion starts at the top with our Board of Directors and Chief Executive Officer. At all levels of the Company, we focus on attracting, retaining, and developing our diverse talent. We have implemented initiatives to promote awareness of our corporate commitment to diversity and inclusion and employ trainings and other educational programs to inform and educate our workforce—forming communities of advocates and allies to help advance a culture of inclusion—develop inclusive leadership skills and identify and minimize the impact of unconscious bias. Through our Employee Resource Groups (ERGs), leadership councils and external partnerships, we provide opportunities for colleagues to create a welcoming culture, advance diversity and inclusion in the workplace and to provide feedback to our executive team. In fiscal year 2023, we expanded the number of Integra-sponsored ERGs to seven (7) as we believe our ERGs, which are employee-led groups, provide career and leadership development and networking opportunities for members and strengthen ties between employees of many different backgrounds, cultures, and interests.

Compensation and Benefits Our compensation philosophy is designed to reinforce and align with our mission, business strategy, and financial needs. We invest in the physical, emotional and financial well-being of our employees through our robust compensation and benefit programs. We provide market-competitive compensation and benefits based on benchmarking surveys we conduct regularly for all position levels against relevant peer companies. Our annual and long-term incentive packages are linked directly to business and individual performance, with a balance of short- and long-term financial and strategic objectives. We have an employee stock purchase plan. Eligibility for non-salary benefits such as salary continuance, life insurance, health insurance, and similar benefits, follows local regulations and practices. We are a pay-for-performance company committed to fair pay. All compensation decisions are made without regard to personal characteristics such as, but not limited to, gender, race, color, national or ethnic origin, age, disability, sexual orientation, gender identity or expression, genetic information, religion, or veteran status. As part of our commitment to compensation equity, Integra regularly conducts a pay equity analysis, reviewing how our organization compensates employees against external and internal data in conjunction with the role and scope of each position and making adjustments if necessary.

Talent Development and Retention We have comprehensive and effective human capital development programs in place because we believe that the personal success of our employees is critical to the overall success of our business. To build a diverse and talented organization, we have invested in honing our recruiting and hiring processes to attract top talent and engage new hires from the very beginning of their experience at Integra. We offer a variety of opportunities for our employees to learn and grow. Continued learning and development is a critical component of employee job satisfaction, retention, and career advancement—and ultimately, a driver of business success. We encourage and promote experiential, collaborative, and formal learning programs. Employees are also encouraged to discuss with their managers the skills, training, and experience needed to grow and develop. In addition to several skills-based trainings available (technical, sales, leadership ability) to all employees, managers may recommend external job-specific development programs to employees. These programs are paid for directly by Integra.

Employee Health and Safety: We are committed to providing a safe environment for all employees and visitors. We rely on our environmental, health and safety management systems as well as entrusting our managers to oversee and ensure health and safety at their respective sites and foster a workplace culture to achieve that end. We implement our approach globally by our systems and support at regional and country levels from colleagues that implement proper safety protocols, identify and correct hazards, and remain safety conscious at all times. Managers are expected to enforce health and safety regulations, including compliance with applicable federal, state and local laws. Our Environmental Health and Safety (“EH & S”) organizational structure incorporates both workplace EH & S coordinators and compliance teams. We have developed an Incident Procedure Policy and General Safety Rules that guide our colleagues to improve our workplace environment, improve safety, and reduce risk and costs.

Employee Engagement and Wellbeing We regularly seek employee feedback and sentiment about our workplace through global engagement surveys conducted on at least a bi-annual basis. After each survey is complete, we share detailed results with senior management and all employees within each department. We are incorporating employee survey results into our corporate strategies—across company, division and function levels—and have further used this employee feedback to modify corporate programs and initiatives. We believe this process enables us to monitor employee engagement and create a continuously improving, satisfying work environment for our employees. We are committed to improving the quality of life of our employees and their families. Our health and wellbeing programs differ by country and typical benefits include comprehensive health insurance, disability coverage, workplace accommodations, parental leave and other leaves of absence based on health or life events (e. g., bereavement), employee assistance programs, fitness reimbursement, and flu shots. We also provide on-demand health advocates to help employees

navigate the health insurance system, access to digital health solutions, a weight management program, smoking cessation assistance, a substance use disorder helpline, a diabetes health program and other similar programs to drive healthy behaviors and awareness.

FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS Financial information about our geographical areas is set forth in our financial statements Note 16, Segment and Geographic Information, to the Notes to Consolidated Financial Statements (Part IV, Item 15 of this Annual Report on Form 10-K).

AVAILABLE INFORMATION We are subject to the informational requirements of the Exchange Act of 1934. In accordance with the Exchange Act, we file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, proxy statements and other information with the Securities and Exchange Commission, ("the SEC"). Our financial information may be viewed, including the information contained in this report, and other reports we file with the SEC, on the Internet, without charge as soon as reasonably practicable after we file them with the SEC, in the "SEC Filings" page of the Investor Relations section of our website at investor.integralife.com. A copy may also be obtained for any of these reports, without charge, from our Investor Relations department, 1100 Campus Road, Princeton, NJ 08540. Alternatively, reports filed may be viewed or obtained through the SEC's website at www.sec.gov. Investors and others should note that we announce material financial information to our investors using our investor relations website (investor.integralife.com), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with the public about our Company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our Company to review the information we post on the social media channels listed on our investor relations website. We have used, and intend to continue to use, our investor relations website as means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Additional corporate governance information, including our certificate of incorporation, bylaws, corporate governance guidelines, board committee charters, and global code of conduct, is also available on our investor relations website under the heading "Corporate Governance." The contents of our websites are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS GLOBAL CHALLENGES AND MACROECONOMIC CONDITIONS The continuing worldwide macroeconomic and geopolitical uncertainty may adversely affect our business and prospects. Geopolitical instability and other macroeconomic factors, including inflation, supply chain disruptions, interest rate and foreign currency rate fluctuations, and volatility in the capital markets could negatively impact our business, financial condition, and results of operations. Global economic disruptions have continued to impact the global supply chain, primarily through constraints on raw materials and electronic components. Additionally, we have observed a reduction in both inbound and outbound transportation capacity as a result of port closures, shipping lane disruptions and delays since the Coronavirus Disease ("COVID-19") pandemic, all of which is causing longer lead times in receiving raw materials, as well as increased freight costs. These highly competitive and constrained supply chain conditions are increasing our cost of sales, which has and may continue to adversely impact our profitability. Continued concerns about the systemic impact of potential long-term and wide-spread recession and geopolitical issues, including wars and acts of terrorism, have contributed to increased market volatility and diminished expectations for economic growth in the world. Our business and results of operations have been and may continue to be adversely impacted by changes in macroeconomic conditions, including inflation, rising interest rates, bank failures and the accessibility of capital markets. Uncertainty about global economic conditions may also cause decreased demand for our products and services and increased competition, which could result in lower sales volume and downward pressure on the prices for our products, longer sales cycles, and slower adoption of new technologies. A weakening of macroeconomic conditions may also adversely affect our suppliers, which could result in interruptions in supply. Market acceptance of our medical products in the U. S. and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient need for our products and procedures and the reimbursement of patients' medical expenses by government healthcare programs and third-party payors. The continuing uncertainty surrounding global economic conditions and financial markets may cause the purchasers of medical equipment to decrease their procurement activities. Economic uncertainty, an increase in unemployment rates, as well as increasing health insurance premiums, co-payments and deductibles may adversely affect demand for our products and procedures. Furthermore, governments and other third-party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could adversely affect sales of our products.

RISKS RELATING TO OUR BUSINESS Our operating results may fluctuate. Our operating results, including components of operating results such as gross margin and operating expenses, may fluctuate from time to time. Our operating results have fluctuated in the past and can be expected to do so from time to time in the future. Some of the factors that may cause these fluctuations include: • economic conditions worldwide, which could affect the ability of hospitals and other customers to purchase our products and could result in a reduction in elective and non-reimbursed operative procedures; • the impact of acquisitions, our ability to integrate acquisitions, and our restructuring activities including portfolio rationalization, and divestitures; • expenditures for major initiatives, including acquired businesses and integrations thereof and restructuring; • the timing of significant customer orders, which tend to increase in the fourth quarter coinciding with the end of budget cycles; • increased competition for a wide range of customers across all our product lines in the markets our products are sold; • market acceptance of our existing products, as well as products in development; • retention of current employees and recruiting of new employees in light of market competition for talent and relevant skills; • the timing of regulatory approvals as well as changes in country-specific regulatory requirements; • changes in the exchange rates between the U. S. dollar and foreign currencies of countries in which we do business; • changes in the variable interest rates of our debt instruments which could impact debt service requirements; • potential backorders, lost sales and expenses incurred in connection with product recalls or field corrective actions; • disruption of our operations and sales resulting from political instability, war, insurrections, extreme weather conditions, the outbreak of

disease, natural disasters, or other events outside our control that damage our manufacturing, distribution, or infrastructure of those facilities, or the suppliers and service providers for those facilities; • our ability to manufacture and ship our products efficiently or in sufficient quantities to meet sales demands; • changes in the cost or decreases in the supply of raw materials and services, including sterilization, energy, steel and honey; • the timing of our research and development expenditures; • reimbursement for our products by third-party payors such as Medicare, Medicaid, private and public health insurers and foreign governmental health systems; • risks related to epidemics or similar widespread health concerns; • the ability to maintain existing distribution rights to and from certain third parties; • the ability to maintain business if or when we opt to convert such business from distributors to a direct sales model; • the ability of our commercial sales representatives to obtain sales targets in a reasonable time frame; • the impact of changes to our sales organization, continued channel expansion, including increased specialization; • peer-reviewed publications discussing the clinical effectiveness of the products we sell; • inspections of our manufacturing facilities for compliance with Quality System Regulations (Good Manufacturing Practices), which could result in Form 483 observations, warning letters, injunctions or other adverse findings from the FDA or from equivalent regulatory bodies, and corrective actions, procedural changes and other actions that we determine are necessary or appropriate to address the results of those inspections, any of which may affect production and our ability to supply our customers with our products; • changes in regulations or guidelines that impact the sales and marketing practices for products that we sell; • the increased regulatory scrutiny of certain of our products, including products which we manufacture for others, could result in removal from the market or involve field corrective actions that could affect the marketability of our products; • enforcement or defense of intellectual property rights; • changes in tax laws, or their interpretations; and • the impact of goodwill and intangible asset impairment charges if future operating results of the acquired businesses are significantly less than the results anticipated at the time of the acquisitions. Fluctuations in our operating results, including any of the above factors, may cause the market price of our common stock to fluctuate. The industry and market segments in which we operate are highly competitive, and we may be unable to compete effectively with other companies. There is intense competition among medical device companies. We compete with established medical technology companies in many of our product areas. Competition also comes from early-stage companies, universities, research institutions and other non-profit entities. In certain cases, our products compete primarily against medical practices that treat a condition without using a device or any particular product, such as the medical practices that use autograft tissue instead of our dermal regeneration products, duraplasty products and nerve repair products, or that use other technologies that cost less than our products. Many of our competitors have access to greater financial, technical, research and development, marketing, manufacturing, sales, distribution, administrative, consulting and other resources than we do. Our competitors may be more effective at developing commercial products or navigating the regulatory approval process in the markets in which we operate. They may be able to gain market share by offering lower-cost products or products that enjoy better reimbursement from third-party payors and foreign governmental health systems. Our competitive position depends on our ability to achieve market acceptance for our products, develop new products, enhance existing products, implement marketing plans, secure regulatory approval for products under development and maintain previously-obtained approvals, demonstrate clinical and economic effectiveness, obtain and maintain reimbursement coverage and funding under third-party payors and foreign governmental health systems, obtain patent protection and produce products consistently in sufficient quantities to meet demand. We may need to develop new applications for our products to remain competitive. Technological advances by one or more of our current or future competitors or their achievement of superior reimbursement from third-party payors and foreign governmental health systems could render our present or future products obsolete or uneconomical. Our future success will depend upon our ability to compete effectively against current technology as well as to respond effectively to technological advances, changes in customers' requirements or in payor or regulatory evidence requirements. Additionally, purchasing decisions of our customers may be based on clinical evidence or comparative effectiveness studies and, because of our vast array of products, we might not be able to fund the studies necessary to gain entry or maintain our position or provide the required information to compete effectively. Other companies may have more resources available to fund such studies. For example, competitors have launched and are developing products to compete with our dural repair products, regenerative skin, neuro-critical care monitors and ultrasonic tissue ablation devices, among others. In the current environment of managed care, consolidation among health care providers, increased competition, and declining reimbursement rates, we have been increasingly required to compete on the basis of price. Competitive pressures could adversely affect our profitability. Given these factors, we cannot guarantee that we will be able to compete effectively or continue our level of success in the areas in which we compete. Changes in the healthcare industry may require us to decrease the selling price for our products, may reduce the size of the market for our products, or may eliminate a market, any of which could have a negative impact on our financial performance. Trends toward managed care, healthcare cost containment and other changes in government and private sector initiatives in the U. S. and other countries in which we do business are placing increased emphasis on the delivery of more cost-effective medical therapies that could adversely affect the sale and/or the prices of our products. For example: • third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid, private and public health insurers and foreign governmental health systems, annually revise their payment methodologies, which can result in stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of reimbursement; • several foreign countries have implemented reforms of their respective healthcare sectors in an effort to reduce healthcare spending, including restricting funding to only those medical technologies and procedures with proven effectiveness, increasing patient co-payments and providing for payback measures. Governmental health systems have revised and continue to consider revisions of healthcare budgets, which could result in stricter standards for implementing certain medical procedures, increased scrutiny of medical devices, and downward pricing pressure; • Medicare, Medicaid, private and public health insurer and foreign governmental outbacks could create downward pricing pressure on our products; • in the U. S., Medicare and Medicaid coverage as well as commercial payor coverage determinations could reduce or eliminate reimbursement or coverage for certain of our wound

matrix, amniotic, surgical reconstruction and advanced wound dressing products as well as other products in most regions, negatively affecting our market for these products, and future determinations could reduce or eliminate reimbursement or coverage for these products in other regions and could reduce or eliminate reimbursement or coverage for other products; • there has been a consolidation among healthcare facilities and purchasers of medical devices in the U. S., some of whom prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices; • in the U. S., we are party to contracts with group purchasing organizations, which negotiate pricing for many member hospitals, require us to discount our prices for certain of our products and limit our ability to raise prices for certain of our products, particularly surgical instruments; • there is economic pressure to contain healthcare costs in domestic and international markets, and, regardless of the consolidation discussed above, providers generally are exploring ways to cut costs by eliminating purchases or driving reductions in the prices that they pay for medical devices, implementing national and provincial tender pricing, as recently implemented in China, or increasing clinical or economic evidence thresholds for product formularies; • there are proposed and existing laws, regulations and industry policies in domestic and international markets regulating the sales and marketing practices and the pricing and profitability of companies in the healthcare industry; • proposed laws or regulations may permit hospitals to provide financial incentives to doctors for reducing hospital costs, will award physician efficiency, and will encourage partnerships with healthcare service and goods providers to reduce prices; and • there have been initiatives by third-party payors and foreign governmental health systems to challenge the prices charged for medical products that could affect our ability to sell products on a competitive basis. Any and all of the above factors could materially and adversely affect our levels of revenue and our profitability. Our current strategy involves growth through acquisitions, which requires us to incur substantial costs and potential liabilities for which we may never realize the anticipated benefits, and also requires us to successfully integrate acquired businesses into our business operations in order to avoid our business being materially and adversely affected. In addition to internally generated growth, our current strategy involves growth through acquisitions. Between January 1, 2021 and December 31, 2023, we have acquired two businesses at a total cost of approximately \$ 358. 4 million which amount includes our acquisition of ACell, Inc. in January 2021 for \$ 306. 9 million and our acquisition of Surgical Innovation Associates, Inc. for \$ 51. 5 million in December 2022. Both of these acquisitions added products to our complex wound management and plastic and reconstructive surgery product portfolios, respectively, and provides additional growth opportunities for our TT segment. In December 2023, we entered into a definitive agreement to acquire Aeclarent from Johnson & Johnson, for \$ 275. 0 million in cash, subject to customary purchase price adjustments, and a cash payment of \$ 5. 0 million upon the achievement of a regulatory milestone. Completion of our pending acquisition of Aeclarent is conditioned upon the receipt of certain regulatory approvals, and we cannot provide assurance that these approvals will be obtained. If any conditions, including with respect to divestitures, or changes to the proposed structure of the acquisition are required to obtain these regulatory approvals, they may have the effect of jeopardizing or delaying completion of the pending acquisition or reducing the anticipated benefits of the pending acquisition. If we are required to agree to any material conditions in order to obtain any approvals required to complete the pending acquisition, the business and results of operations of our company following the closing may be adversely affected. We may be unable to continue to implement our growth strategy and it may ultimately be unsuccessful. A significant portion of our growth in revenues has resulted from, and is expected to continue to result from, the acquisition of businesses or products complementary to our own. We engage in evaluations of potential acquisitions and are in various stages of discussion regarding possible acquisitions, certain of which, if consummated, could be significant to us. Failure to complete the Aeclarent acquisition, on a timely basis or at all, could negatively impact our future business and financial results and those of the acquired business. Any new acquisition could result in material transaction expenses, increased operating, amortization and interest expenses, and possible in-process research and development charges for acquisitions that do not meet the definition of a “business,” any of which could have a material, adverse effect on our operating results. Certain businesses that we acquire may not have adequate financial, disclosure, regulatory, quality or other compliance controls at the time we acquire them and could require significant expenditures to address those controls or subject us to increased risk. As we grow by acquisition, we must manage and integrate the new businesses to bring them into our systems for financial, disclosure, compliance, regulatory and quality control, realize economies of scale, and control costs. Failure to integrate acquired businesses and operations (including acquired employees and systems), retain key customers and suppliers of any acquired business or manage the cost of providing our products or price our products appropriately could preclude realization of the full benefits that we expect from these transactions. Our failure to meet the challenges involved in integrating the business in order to realize the anticipated benefits of the acquisitions could cause an interruption of, or loss of momentum in, our activities and could materially and adversely affect our results of operations. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for the running of our business and the development of our business as well as risks associated with entering markets in which our marketing teams and sales force has limited experience or where experienced distribution alliances are not available. Some acquisitions may include the need for ongoing product development to occur consistent with time sensitive milestones in order for the Company to achieve its commercial projections for the acquisition. Our future profitability will depend in part upon our ability to develop our resources to adapt to these new products or business areas and to identify and enter into or maintain satisfactory distribution networks. As a result of our acquisitions of other healthcare businesses, we may be subject to the risk of unanticipated business uncertainties, regulatory and other compliance matters or legal liabilities relating to those acquired businesses for which the sellers of the acquired businesses may not indemnify us, for which we may not be able to obtain insurance (or adequate insurance), or for which the indemnification may not be sufficient to cover the ultimate liabilities. We may not be able to identify suitable acquisition candidates in the future, obtain acceptable financing or consummate any future acquisitions. Certain potential acquisitions are subject to antitrust and competition laws, which laws could impact our ability to pursue strategic acquisitions and could result in mandated divestitures. If we are unsuccessful in our acquisition strategy, we may be unable to

meet our financial targets and our financial performance could be materially and adversely affected. In addition, dispositions of certain key products, technologies and other rights, including pursuant to conditions imposed on us to obtain regulatory approvals, may affect our business operations. These risks may be heightened in cases where a substantial portion of an acquired businesses' operations, employees or customers are located outside the U. S. Any one or all of these factors could complicate the integration of acquired employees and operations, increase operating costs or lower anticipated financial performance. Many of these factors are also outside of our control. For example, following the anticipated consummation of the Aeclarent acquisition, the ongoing conflict in Israel, including any escalation or expansion thereof, and the measures enacted by the Israeli and other governments in response may make it more difficult for us to both integrate Aeclarent and realize the anticipated benefits of the acquisition. Even if the operations of the businesses are integrated successfully, we may not realize the full benefits of the acquisition, including the synergies, cost savings or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all. Additional unanticipated costs could be incurred in the integration of the businesses. All of these factors could cause a reduction to our earnings per share, decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock. Our global business exposes us to operational and economic risks. A significant portion of our current operations are conducted and located outside the United States, and our growth strategy involves expanding our existing foreign operations and entering into new foreign jurisdictions. We have significant manufacturing and distribution sites in North America and Europe. Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries, the U. S. Foreign Corrupt Practices Act and local anti-bribery and other laws regarding interactions with healthcare professionals, and product registration requirements. Among other things, these laws restrict, and in some cases prevent, U. S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. As we seek to continue to expand and strengthen our international operations, we may experience difficulty in growing our sales in certain new markets and other international markets in which we are attempting to increase our presence due to, among other things, customer acceptance, undeveloped and/or unfamiliar distribution channels, regulatory restrictions and changes, and business knowledge of these markets. From time to time, proposals are made to significantly change existing trade agreements and relationships between the U. S. and other countries. In recent years, the U. S. government has implemented substantial changes to U. S. trade policies, including import restrictions, increased import tariffs and changes in U. S. participation in multilateral trade agreements, such as the United States-Mexico-Canada Agreement to replace the former North American Free Trade Agreement. The ongoing global economic competition and trade tensions between the U. S. and China has resulted in the U. S. government assessing supplemental tariffs on certain goods imported from China and China's assessment of retaliatory tariffs on certain imports of U. S. goods into China. In addition, the United States has assessed or proposed supplemental tariffs and quantitative restrictions on U. S. imports of certain products from other countries as well. Owing to the complex relationships between the U. S. and such other countries, political, diplomatic, military, or other events could result in business disruptions, including increased regulatory enforcement against companies, tariffs, trade embargoes, **capital controls**, export restrictions and the termination or modification of existing trade agreements. The imposition of such restrictions could increase the cost of the Company's products and the components and raw materials that go into making them, require the Company to change its operations and the products it offers and negatively impact consumer confidence and spending, all of which, both individually and in the aggregate, could materially and adversely affect our business, results of operations and financial condition. ~~The Russia-Ukraine conflict and resulting sanctions and export restrictions are creating barriers to doing business in Russia and adversely impacting global supply chains. While we have no manufacturing, distribution or direct material suppliers in the region, we are closely monitoring the potential raw material or supplier impact in both Russia and Ukraine. Materials like palladium and neon, which are both dependent on Russian supply, are part of broader semiconductor shortages in industry. Additional sanctions, export restrictions, and potential countermeasures within Russia may lead to greater uncertainty and geopolitical shifts in Asia that could cause additional adverse impacts on global supply chains and our business, results of operations, financial condition and cash flows.~~ Exchange rate fluctuations and foreign currency hedges could adversely affect our financial results. We generate significant revenues outside the U. S. in multiple foreign currencies, and in U. S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U. S. dollar. For those foreign customers who purchase our products in U. S. dollars, currency fluctuations between the U. S. dollar and the currencies in which those customers do business may have a negative impact on the demand for our products in foreign countries where the U. S. dollar has increased in value compared to the local currency. Since we have operations based outside the U. S. and we generate revenues and incur operating expenses in multiple foreign currencies, we experience currency exchange risk with respect to those foreign currency-denominated revenues and expenses. Our most significant currency exchange risk relates to transactions conducted in Australian dollars, British pounds, Canadian dollars, Chinese yuan, Euros, Japanese yen, and Swiss francs. We cannot predict the consolidated effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. Although we address currency risk management through regular operating and financing activities, and, on a limited basis, through the use of derivative financial instruments, those actions may not prove to be fully effective. For a description of our use of derivative financial instruments, see Note 6 ~~7~~. Derivative Instruments to the Notes to Consolidated Financial Statements (Part IV, Item 15 of this Annual Report on Form 10-K). Our future financial results could be adversely affected by impairments or other charges. We are required to test both goodwill and indefinite-lived intangible assets for impairment on an annual basis based upon a fair value approach, rather than amortizing them over time. We are also required to test goodwill and indefinite-lived intangible assets for impairment between annual tests if an event occurs such as a significant decline in revenues or cash flows for certain products, or the discount rates

used in the calculations of discounted cash flows change significantly, or circumstances change that would more likely than not reduce our enterprise fair value below its book value. If such a decline, rate change or circumstance were to materialize, we may record an impairment of these intangible assets that could be material to the financial statements. See Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations- Critical Accounting Estimates” of this Annual Report on Form 10-K, and Note 7, “Goodwill and Other Intangible Assets” to the Notes to Consolidated Financial Statements (Part IV, Item 15 of this Annual Report on Form 10-K). 24 The guidance on long-lived assets requires that we assess the impairment of our long-lived assets, including finite-lived intangible assets, whenever events or changes in circumstances indicate that the carrying value may not be recoverable as measured by the sum of the expected future undiscounted cash flows. Also, Company decisions and other economic factors relating to our trade names may occur over time. For instance, we may discontinue certain products in the future as we continue to assess the profitability of our product lines. As a result, we may need to record impairment charges or accelerate amortization on certain trade names or technology-related intangible assets in the future. The value of a medical device business is often volatile, and the assumptions underlying our estimates made in connection with our assessments under the guidance may change as a result of that volatility or other factors outside our control and may result in impairment charges. The amount of any such impairment charges could be significant and have a material, adverse effect on our reported financial results for the period in which the charge is taken and could have an adverse effect on the market price of our securities, including the notes and the common stock into which they may be converted. Lack of market acceptance for our products or market preference for technologies that compete with our products could reduce our revenues and profitability. Market acceptance of our products depends on many factors, including our ability to convince prospective customers that our technology is an attractive alternative to other technologies, to manufacture products in sufficient quantities and at acceptable costs, and to supply and service sufficient quantities of our products directly or through our distribution alliances. For example, the use of autograft tissue is a well-established means for repairing the dermis, and it competes for acceptance in the market with our collagen-based wound care products. In addition, unfavorable payment amounts or adverse coverage determinations of third-party payors, including Medicare, Medicaid, private and public health insurers, such as Medicare and Medicaid, and foreign governmental health systems, regarding our products or third-party determinations that favor a competitor’s product over ours, could harm acceptance or continued use of our products. For example, greater market acceptance of our wound graft products may ultimately depend on our ability to demonstrate that coverage and reimbursement are available and favorable, or because they are an attractive, cost-effective alternative to other treatment options. If there are negative events in the healthcare industry, whether real or perceived, there could be a negative impact on the industry as a whole. The industry is subject to rapid and continuous change arising from, among other things, consolidation, technological improvements, the pressure on governments, third-party payors and providers to reduce healthcare costs, and healthcare reform legislation and initiatives domestically and internationally. In addition, our future success depends, in part, on our ability to license and develop additional products. Even if we determine that a product candidate has medical benefits, the cost of commercializing, either through internal development or payments associated with licensing arrangements, could be too high to justify development and we could ultimately face competitors with more effective products and better reimbursement status that cost less and are ready for commercial introduction before our products. If we are unable to develop additional commercially viable products, our future prospects could be materially and adversely affected. One or more of these factors could vary unpredictably, and such variations could have a material, adverse effect on our competitive position. We may not be able to adjust our contemplated plan of development to meet changing market demands. It could be difficult to replace some of our suppliers. Outside vendors, some of whom are sole-source suppliers, provide key components and raw materials used in the manufacture of our products. Although we believe that alternative sources for many of these components and raw materials are available, any interruption in supply of a limited or sole-source component or raw material could harm our ability to manufacture our products until a new or alternative source of supply is identified and qualified. In addition, an uncorrected defect or supplier’s variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired. We believe that these factors are most likely to affect the following products that we sell: • our collagen-based products and bovine-based products, such as the Integra Dermal Regeneration Template and wound matrix products, the DuraGen® family of products, our Absorbable Collagen Sponges, PriMatrix® and SurgiMend products; • our products made from silicone, such as our neurosurgical shunts and drainage systems and hemodynamic shunts; • products which use many different specialty parts, electrical components, or chemicals from numerous suppliers, such as our intracranial monitors, shunts, catheters, tissue ablation, and headlights; • our biosynthetic products, including the DuraSeal sealant system and DuraSorb biosynthetic mesh scaffold; • products which are amniotic tissue-based • products which are porcine tissue-based; • products that use medical grade leptospermum honey, such as our Medihoney products; and 25 • our TCC-EZ® total contact cast system products. The availability of amniotic tissue-based products depends upon, among other factors, the availability of tissue from human donors. Access to donated amniotic tissue could also be adversely impacted by regulatory changes or evolving public perceptions of the donor process. Additionally, many of our products require sterilization by third-party suppliers. To the extent these suppliers are unable to provide sterilization services, whether due to lack of capacity, regulatory requirements, environmental concerns such as those relating to ethylene oxide or otherwise, we may be unable to transition sterilization to other suppliers in a timely or cost-effective manner, or at all, which could have an adverse impact on our operating results. For example, there is increased focus on the use and emission of ethylene oxide by the EPA and state environmental regulatory agencies. Additional regulatory requirements associated with the use and emission of ethylene oxide for sterilization may be imposed in the future, both domestically and outside the U. S. This increased regulation has required certain of the sterilization suppliers we use to temporarily suspend operations and it is possible that additional

sterilization suppliers we use might also have to suspend operations, install additional emissions control technology, limit the use of ethylene oxide or take other actions, which would impact or further reduce the available capacity to sterilize medical devices and healthcare products. Although Integra has business continuity plans in place to mitigate the impact of any such disruptions, these plans may not be able to fully offset the full impact of such regulations. Our supply chain and our cost of goods also may be negatively impacted by unanticipated price increases due to factors such as global economic disruptions, electronic component shortages, ~~trade wars~~ **fear of future or ongoing pandemics**, inflation, including wage inflation, recessionary conditions and geopolitical events, including the ~~Wars~~ **war** in Ukraine ~~and~~, **the conflicts in the Middle East involving Israel** ~~and fear of future or ongoing pandemics~~, all of which are beyond our control or the control of our suppliers. While it is our policy to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials. We may experience difficulties, delays, performance impact or unexpected costs from consolidation of facilities and transfer of manufacturing facilities. In recent years, we consolidated several facilities or transferred manufacturing operations from third parties to our existing internal manufacturing facilities and may further undertake similar consolidations or transfers in the future in order to improve our cost structure, achieve increased operating efficiencies, and improve our competitive standing or results of operations and / or to address unfavorable economic conditions. **For example, in the second quarter of 2024, the Company announced its plans to operationalize its Braintree, Massachusetts manufacturing facility (the “ Braintree facility ”) by the first half of 2026 and to transition the restart of the manufacture of PriMatrix and SurgiMend to the Braintree facility rather than attempt to restart the manufacture of these products at the Company’ s Boston, Massachusetts manufacturing facility (the “ Boston facility ”).** As part of these initiatives, we may also lose favorable tax incentives or not be able to renew leases on acceptable terms. We may further reduce staff, make changes to certain capital projects, close certain production operations and abandon leases for certain facilities that will not be used in our operations. In conjunction with any actions, we will continue to make significant investments and build the framework for our future growth. We may not realize, in full or in part, the anticipated benefits and savings from these efforts because of unforeseen difficulties, delays, implementation issues or unexpected costs. If we are unable to achieve or maintain all of the resulting savings or benefits to our business or other unforeseen events occur, our business and results of operations may be adversely affected. If any of our facilities or those of our suppliers were damaged and / or our manufacturing or business processes interrupted, we could experience lost revenues and our business could be seriously harmed. Damage to our manufacturing, distribution, development and / or research facilities because of fire, extreme weather conditions, natural disaster, power loss, communications failure, geopolitical disruption, unauthorized entry or other events, such as a flu or other health epidemic, could significantly disrupt our operations, the operations of suppliers and critical infrastructure and delay or prevent product manufacture and shipment during the time required to repair, rebuild or replace the damaged facilities. Certain of our manufacturing facilities are located in Puerto Rico, which in the past has experienced both severe hurricanes and other natural disasters. Climate change may increase both the frequency and severity of extreme weather conditions and natural disasters and, consequently, risks to our operations and growth. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs. Global supply constraints have and may continue to adversely affect our ability to meet customer demand, and increase our costs to manufacture, transport and warehouse a certain subset of our products. In addition, global supply constraints have **26** resulted in increases to the costs of production of certain of our products that we may not be able to pass on to our customers. We expect these factors will continue to impact us in the future and obtaining alternative sources of raw materials and components could involve significant costs and regulatory challenges and may not be available to us on commercially reasonable terms, if at all. We may have significant product liability exposure and our insurance may not cover all potential claims. We are exposed to product liability and other claims if our technologies or products are alleged to have caused harm. We may not be able to obtain insurance for the potential liability on acceptable terms with adequate coverage or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Our insurance may not be renewed at a cost and level of coverage comparable to that then in effect. Economic and political instability around the world could adversely affect the ability of hospitals, other customers, suppliers and distributors to access funds or otherwise have available liquidity, which could reduce orders for our products or interrupt our production or distribution or result in a reduction in elective and non- reimbursed operative procedures. Economic and political instability around the world could adversely affect the ability of hospitals and other customers to access funds to enable them to fund their operating and capital budgets. As a result, hospitals and other customers could reduce budgets or put all or part of their budgets on hold or close their operations, which could have a negative effect on our sales, particularly the sales of capital equipment such as our ultrasonic surgical aspirators, neuro monitors and cranial stabilization products, or result in a reduction in elective and non- reimbursed procedures. The occurrence of those economic conditions could make it more difficult for us to accurately forecast and plan our future business activities and depending on their severity, could have a material, adverse effect on our business, financial condition and results of operations. Our private label product lines depend significantly on key relationships with third parties, which we could be unable to establish and maintain. Our private label business depends in part on entering into and maintaining long- term supply agreements with third parties. The third parties with whom we have entered into agreements might terminate these agreements for a variety of reasons, including developing other sources for the products that we supply. **In addition, the voluntary global recall of all products manufactured in our Boston, Massachusetts facility (“ the Boston recall ”) and manufacturing stoppage impacted certain of our private label products and, following the anticipated resumption of the commercialization of products manufactured at the Boston facility, we are unable to**

predict the effect that the Boston recall will have on our relationships for such private label products. The diminution or termination of our most important relationships could adversely affect our expectations for the growth of private label products.

RISKS RELATED TO OUR REGULATORY ENVIRONMENT We are subject to stringent domestic and foreign medical device regulations and oversight and any adverse action may adversely affect our ability to compete in the marketplace and our financial condition and business operations. Our medical devices and technologies, development activities and manufacturing processes are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies, as discussed in “ Part 1, Item 1. Business – Government Regulation ” of this Annual Report on Form 10- K. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our medical devices. We are also subject to regulations that may apply to certain of our products that are Drug / Device Combination products or are considered to be subject to pharmaceutical regulations outside the U. S. 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 FD & C Act, a grant of a request for de novo classification, or a PMA from the FDA, unless an exemption applies. The process of obtaining marketing approval or clearance from the FDA and comparable foreign regulatory agencies for new products, or for enhancements or modifications to existing products could be costly, time consuming and burdensome, **lead to may be impacted by** failed clinical trials or weakened clinical evidence, involve modifications, repairs or replacements of our products and result in limitations on the indicated use of our products, which may negatively impact our ability to market our products and services, result in delays or prevent full commercial realization of future products or service. Furthermore, failure to obtain timely approvals, **certifications** or renewals may result in **significant** penalties and fines. Additional regulations govern the approval, initiation, conduct, monitoring, documentation and reporting of clinical studies to regulatory agencies in the countries or regions in which they are conducted. Failure to comply, could subject us to significant enforcement actions and sanctions, including halting the study, rejection of data generated in the study, seizure of investigational devices or data, sanctions against investigators, civil or criminal penalties, and other actions. In addition, without the data from one or more clinical studies, it may not be possible for us to secure the data necessary to support certain regulatory submissions, to secure reimbursement or demonstrate other requirements. We cannot assure that access to clinical investigators, sites and subjects, documentation and data will be available on the terms and timeframes necessary. **We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Further, changes or shortages in FDA staffing resulting from the change in the federal administration could result in delays in the FDA’s responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all, which could negatively impact our business.** 27 We are subject to extensive complex regulatory requirements by domestic and foreign government agencies and any failure to comply with our ongoing responsibilities under their applicable laws and regulations could result in a material adverse impact on our business. Failure to comply with applicable regulations could result in future product recalls, injunctions preventing the shipment of products or other enforcement actions that could have a material adverse effect on our business. In addition, the FDA has taken the position that device manufacturers are prohibited from promoting their products other than for the uses and indications set forth in the **cleared or** approved product labeling, and any failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, and / or other potential penalties from, and / or agreements with, the federal government. **Similar restrictions exist in many other countries where we do business, included EEA.** We also are subject to the **EU European Medical Device Regulation (“MDR”)**, which was adopted by the **European Union (“EU”)** as a common legal framework for all EU **member Member states States (and also applies to Norway, Iceland and Liechtenstein)**. The **EU MDR became applicable implementation for Class I products occurred on May 26, 2021 and, repealing the EU MDD. The EU MDR sets out certain transitional provisions that allow for medical devices covered by the repealed EU MDD (called “ legacy devices ”) to still be marketed in the EEA for a certain period of time. Most Class I medical devices had to comply with the EU MDR from May 26, 2021. However, the European Commission has recently extended the implementation transition period-periods to the end of December 31, 2027, for high- risk legacy devices (all Class III devices, and Class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) and to the end of December 31, 2028 for medium and low - risk devices (other Class IIb devices, Class IIa devices, and Class I devices placed on the market in sterile condition or having a measuring function)**. Under the EU MDR, companies that wish to manufacture and distribute medical devices in **EEA EU member states** must meet certain quality system, **performance** and safety requirements as well as ongoing product monitoring responsibilities. Companies must also **obtain affix a “ CE ” marking to (i. e., a mandatory conformity marking for certain products sold within the European Economic Area) for their products. The right to affix the “ CE ” marking requires that the manufacturer has previously undergone a conformity assessment procedure for the relevant medical devices, in most cases involving a Notified Body (an organization accredited by the competent authority of an EEA country to conduct conformity assessments)**. Complying with the requirements of these regulations may require us to incur significant expenditures. Expenditures for EU MDR compliance activities amounted to \$ **46-44. 6 million** for the year ended December 31, **2023-2024** and we anticipate incurring additional expenditures in connection with our on- going efforts to obtain certification for our products under the **EU MDR European Medical Device Regulation**. Various penalties exist for non- compliance with the **requirements of the EU MDR and the related laws of EEA countries implementing the European Medical Device Regulations** which, if incurred, could have a material adverse impact on our business, results of operations and cash flows. Further, the regulatory environment in China continues to evolve, and officials in the Chinese government exercise broad discretion in deciding how to interpret and apply regulations. It is possible that the Chinese government’s current or future interpretation and application of existing or new regulations will negatively impact our China

operations, result in regulatory investigations or lead to fines or penalties. Should we delay or fail to comply with one or more of the regulatory requirements we could have reduced sales, increased costs, delays to new product introductions, enhancements or our strategic plans, or harm to our reputation or competitiveness, which could have a material adverse effect on our business and financial results. In addition, maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our manufacturing processes. Our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other regulatory agencies, and these facilities are subject to the FDA's Quality System Regulation and Good Manufacturing Practices. Please refer to "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – FDA Matters" (Part II, Item 7 of this Annual Report on Form 10-K) for more information relating to the warning letter we received from the FDA related to inspection observations of the quality systems at our Boston, Massachusetts manufacturing facility and our remediation efforts and expectations regarding the ~~resumption of commercial distribution at the Boston facility~~ **operationalization of our Braintree facility and the transition of products manufactured at activities from the Boston facility to the Braintree facility and the warning letter we received from the FDA in December 2024 (the "December 2024 Warning Letter") related to quality system issues identified during FDA inspections at three of the Company's facilities located in Mansfield, Massachusetts, Plainsboro, New Jersey, and Princeton, New Jersey**. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products. **Further, there can be no assurance that the Company will build and operationalize the Braintree facility, transition manufacturing activities to the Braintree facility or realize the anticipated benefits of the Company's consolidation of its efforts at Braintree on the planned timeline, or at all, which could have a material adverse effect on our business and financial results**. Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims. We are subject to laws and regulations that govern the means by which companies in the healthcare industry may market their products to healthcare professionals and may compete by discounting the prices of their products, including for example, the federal ~~AKS Anti-Kickback Statute~~, the federal False Claims Act, ~~the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA")~~, state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, in some instances civil and criminal penalties, damages, fines, **restitution** and exclusion from **28** participation in federal and state healthcare programs, including Medicare and Medicaid. **For a more detailed discussion of these laws, see "Item 1. Business — Government Regulation and Compliance — Other Regulations — Healthcare Fraud and Abuse Laws."** Our international operations are subject to the provisions of the U. S. ~~FCPA Foreign Corrupt Practices Act of 1977, as amended ("FCPA")~~, which prohibits U. S. companies and their representatives from offering or making improper payments to foreign officials for the purpose of obtaining or retaining business. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. Our international operations are also subject to various other international anti-bribery laws such as the UK Anti-Bribery Act. ~~In addition, the Chinese government recently launched a campaign to combat corruption in healthcare with a focus on pharmaceutical and medical device companies covering production, supply, sales, usage, and reimbursement. The target of the campaign is kickbacks to hospitals and healthcare professionals with a focus on transfers of value to healthcare professionals in the form of grants, donations, event sponsorships, honoraria, and consulting fees.~~ Despite meaningful measures that we undertake to facilitate lawful conduct, which include training and compliance programs and internal policies and procedures, we may not always prevent unauthorized, reckless or criminal acts by our employees or agents, or employees or agents of businesses or operations we may acquire. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction and have a material adverse effect on our business, financial condition and results of operations. We also could be subject to adverse publicity, severe penalties, including criminal and civil penalties, disgorgement, further changes or enhancements to our procedures, policies and controls, personnel changes and other remedial actions. Moreover, our failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, and withdrawal of an approved product from the market. ~~We have in place policies and procedures for compliance that we believe are at least as stringent as those set forth in the AdvaMed Code of Ethics which was developed by AdvaMed, a trade association that represents the medical device industry, and which is intended to represent best practices with respect to medical device companies' interactions with healthcare providers. We regularly train our sales and marketing personnel on our policies regarding sales and marketing practices. Pursuant to the AdvaMed Code, we have certified our adoption of the AdvaMed Code.~~ The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. Various hospital organizations, medical societies and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies or ban or restrict certain marketing and sales practices such as gifts and business meals. Since these laws, regulations and ultimate enforcement continue to evolve, we cannot predict with certainty, what, if any, impact, changes to them may have on our business or our customers. Our medical device products are subject to reporting requirements and recalls, even after receiving regulatory clearance, approval or certification, which could harm our reputation, business and financial results. Both before and after a device is placed on the market, numerous regulatory requirements apply, which require manufacturers to follow, among other things, design, testing, production, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and medical device reporting regulations that require us to report to FDA or similar governmental bodies in other countries if our products are ineffective or may have caused or contributed to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental bodies in other countries have the authority to require the recall,

repair, replacement, or refund of such products, refuse to grant pending pre- market approval applications or require certificates of non- U. S. governments for exports, and / or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, and in certain rare circumstances, ban medical devices. We may **voluntarily**, under our own initiative, recall a product if a reasonable possibility of serious injury or any material deficiency in a device is found, or withdraw a product to improve device performance or for other reasons. For example, in May 2023, after consultation with the FDA, we initiated a voluntary global recall of all products manufactured in our Boston, Massachusetts facility distributed between March 1, 2018 and May 22, 2023. **Additionally, in response to Form 483s issued to the Company by the FDA at the conclusion of the FDA's inspection of three of the Company's facilities located in Mansfield, Massachusetts, Plainsboro, New Jersey, and Princeton, New Jersey during June and August of 2024, the Company took a number of voluntary actions including the initiation of shipping holds for several products and a voluntary recall of certain disposable cottonoid patties and strips. In July 2024, we announced plans to implement an enterprise- wide CMP, a systematic and holistic approach to improving our quality management system across our manufacturing and supply network. We currently cannot predict with certainty whether we will be able to effectively implement the CMP and realize the benefits contemplated thereby within the anticipated timeframe, or at all.** For more information concerning the Boston recall, including our remediation efforts, **including the implementation of the CMP, and our expectations regarding the resumption of commercial distribution of products- Company's plans to build and operationalize the Braintree manufactured manufacturing at facility and to transition manufacturing activities from the Boston facility to the Braintree facility and respond to the December 2024 Warning Letter**, please see" Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations- FDA Matters" in this Annual Report on Form 10- K. Recalls of any of our products may divert managerial and financial resources and have an adverse effect on our financial condition and results of operations and cash flows. A recall could harm our reputation with customers and consumers which could reduce the sales of our products. In addition, the FDA or other foreign governmental agencies may implement enforcement actions Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre- market clearances or approvals, and could result in a substantial modification to our business practices and operations. The adoption of healthcare reform in the U. S. and initiatives sponsored by other governments may adversely affect our business, results of operations and / or financial condition. **29** Our operations may be substantially affected by potential fundamental changes in the global political, economic and regulatory landscape of the healthcare industry. Government and private sector initiatives to limit the growth of healthcare costs are continuing in the U. S., and in many other countries in which we do business, causing the marketplace to put increased emphasis on the delivery of more cost- effective treatments. These initiatives include price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed- care arrangements. For example, Congress also drafts and introduces, from time to time, legislation that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. ~~For example, over the last several years, the FDA has proposed reforms to its 510 (k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510 (k) clearance process for their products.~~ The adoption of some or all of these initiatives could have a material, adverse effect on our financial condition and results of operations. We cannot predict what impact ongoing uncertainty regarding federal and state health reform proposals, instability of the insurance markets, changes in the U. S. administration, **laws and policy policies**, an expansion in government's role in and / or additional proposals and / or changes to the U. S. health care system ~~or its legislation~~ will have on our customer's purchasing decisions and / or reimbursement which could have a material adverse effect on our business. We expect that additional state and federal and foreign health care reform measures will be adopted in the future, including those initiatives affecting coverage and reimbursement for our products, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could adversely affect the growth of the market for our products or demand for our products, or result in additional pricing pressures. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or **policies or** the impact ~~of potential legislation~~ on us. We continue to monitor the implementation of such legislation and, to the extent new market or industry trends or new governmental programs evolve, we will consider implementing or implement programs in response. Certain of our products contain materials derived from animal sources and may become subject to additional regulation. Certain of our products are derived from bovine or porcine tissue sources. As a result, we may experience difficulties in processing and producing our bovine and porcine tissue products at scale, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures and availability of skilled personnel. With respect to bovine, among other products, our dermal regeneration products, duraplasty products, wound care products, bone void fillers, nerve and tendon repair products and certain other products, contain material derived from bovine tissue. In ~~2023-2024~~, **43-25**, **4-67** % of our revenues derived from products containing material derived from bovine tissue. Products that contain materials derived from animal sources, including food, pharmaceuticals and medical devices, are subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans via those materials. This public scrutiny has been particularly acute in Japan and Western Europe with respect to products derived from animal sources, because of concern that materials infected with the agent that causes bovine spongiform encephalopathy, otherwise known as BSE or mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt- Jakob Disease, an ultimately fatal disease with no known cure. The World Organization for Animal Health recognizes the U. S. as having a negligible risk for BSE, which is the highest status available. We take care to provide that our products are safe and free of agents that can

cause disease. In particular, we qualified a source of collagen from a country outside the U. S. that is considered BSE / TSE-free. The World Health Organization classifies different types of bovine tissue for relative risk of BSE transmission. Deep flexor tendon and bovine fetal skin, which are used in our products, are in the lowest- risk categories for BSE transmission and are therefore considered to have a negligible risk of containing the agent that causes BSE (an improperly folded protein known as a prion). Nevertheless, products that contain materials derived from animals, including our products, could become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of prions. Significant new regulations, or a ban of our products, could have a material, adverse effect on our current business or our ability to expand our business. Certain countries, such as Japan, China, Taiwan and Argentina, have issued regulations that require our collagen products be sourced from countries where no cases of BSE have occurred, and the EU has requested that our dural replacement products and other products that are used in neurological tissue be sourced from a country where no cases of BSE have occurred. Currently, we source bovine fetal hides from the U. S. and purchase tendon from the U. S. and New Zealand. New Zealand has never had a case of BSE. We received approval in the U. S., the EU, Japan, Taiwan, China, Argentina as well as other countries for the use of New Zealand- sourced tendon in the manufacturing of our products. If we cannot continue to use or qualify a source of tendon from New Zealand or another country that has never had a case of BSE, we could be prohibited from selling our collagen products in certain countries. We are subject to current and potential future requirements relating to protection of the environment, such as hazardous materials regulations, which may impose significant compliance or other costs on us. **30** Certain of our processes in manufacturing and research and development involve the controlled use of certain hazardous materials. In addition, we own and / or lease a number of facilities at which hazardous materials have been used in the past. Finally, we have acquired various companies that historically have used certain hazardous materials and that have owned and / or leased facilities at which hazardous materials have been used. For all of these reasons, we are subject to federal, state, foreign, and local laws and regulations governing the use, manufacture, storage, transportation, handling, treatment, remediation, and disposal of hazardous materials and certain waste products (“ Environmental, Health, Safety and Transportation Laws ”). Although we believe that our procedures for handling, transporting, and disposing of hazardous materials comply with the Environmental, Health, Safety and Transportation Laws, such laws may be amended in ways that increase our cost of compliance, perhaps materially. Furthermore, the potential risk of accidental contamination or injury from these materials cannot be eliminated, and there is also a risk that such contamination previously has occurred in connection with one of our facilities or in connection with one of the companies we have purchased. In the event of such an accident or contamination, we could be held liable for any damages that result and any related liability could exceed the limits or fall outside the coverage of our insurance and could exceed our resources and could have a material impact on our operations and cash flows. We may not be able to maintain insurance on acceptable terms or at all. Our business and operations are subject to risks related to climate change. The long- term effects of global climate change present both physical risks (from the increased frequency of extreme weather conditions or natural disasters) and transition risks (from regulatory requirements or technology changes). Such extreme weather conditions could pose physical risks to our facilities and disrupt operation of our supply chain and may impact operational costs. Concern over global climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the regulatory obligations and such measures may interrupt our operations or the operations of our suppliers, potentially leading to higher costs, and therefore negatively impact our results of operations. Environmental, social and corporate governance (ESG) issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation. There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies’ ESG practices continue to grow. While we may create and publish voluntary disclosures regarding ESG matters from time to time, many of the statements in those voluntary disclosures are based on hypothetical expectations and assumptions that may or may not be representative of current or actual risks or events or forecasts of expected risks or events, including the costs associated therewith. Such expectations and assumptions are necessarily uncertain and may be prone to error or subject to misinterpretation given the long timelines involved and the lack of an established single approach to identifying, measuring and reporting on many ESG matters. **In addition, collecting, measuring and reporting environmental data is subject to evolving reporting standards, including the SEC’ s climate- related reporting requirements, if such reporting requirements survive pending judicial review, California’ s disclosure requirements and similar regulations established by other international regulatory bodies, such as the Corporate Sustainability Reporting Directive in the European Union. In addition, a number of our customers who are payors or distributors have adopted, or may adopt, procurement policies that include environmental provisions applicable to us.** If we do not adapt to or comply with new regulations, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, **we may incur increased compliance costs,** investors may reconsider their capital investment in our Company, and customers may choose to stop purchasing our products, which could have a material adverse effect on our reputation, business or financial condition. If we do not retain our key personnel and attract and retain other highly skilled employees, our business could suffer. If we fail to recruit, develop and retain the necessary personnel, our business and our ability to obtain new customers, develop new products **and,** provide acceptable levels of customer service **and achieve our research and development, operational or strategic or business objectives** could suffer. The success of our business is heavily dependent on the leadership of our key management personnel. Our success also depends on our ability to recruit, develop and retain and motivate highly skilled sales, marketing, manufacturing, **quality, regulatory** and scientific personnel. Competition for these persons in our industry is intense, and we may not be able to successfully recruit, train or retain qualified personnel. In addition, we recognize that attracting, retaining and developing a diverse workforce is a critical success factor for our business. In that regard, we are continuously facing significant

competition in our markets and at all levels in the workforce. We also continue to face the challenges of maintaining employee well-being, recognizing that the continued additional financial, family and health burdens that many employees may be experiencing due to macroeconomic uncertainties, including inflation, and other factors, may adversely impact job performance, employee engagement and employee retention. Additionally, in our industry, there is substantial competition for key personnel in the regions in which we operate **and plan to expand our business**. Labor shortages and competition for qualified personnel, particularly as employees are increasingly able to work remotely, could cause disruptions in our business operations. **Also, facilitating seamless leadership transitions for key positions is a critical factor in sustaining the success of our organization**. If we fail to effectively manage any organizational and / or strategic changes, our financial condition, results of operations, and reputation, as well as our ability to successfully attract, motivate and retain key employees, could be harmed.

RISKS RELATED TO TAX AND DEBT We may have additional tax liabilities. We are subject to income taxes in the U. S. and many foreign jurisdictions and are commonly audited by various tax authorities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. Significant judgment is required in determining our worldwide provision for income taxes. Although we believe that our tax estimates are reasonable, tax authorities may disagree with certain positions we have taken, and the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. In addition, economic and political pressures to increase tax revenue in various jurisdictions may make resolving tax disputes favorably more difficult. The results of an audit or litigation could have a material, adverse effect on our financial statements in the period or periods for which that determination is made and could result in the imposition of fines and penalties. Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results. We are subject to income taxes, as well as taxes that are not income-based, in both the U. S. and many foreign jurisdictions. Taxes could significantly increase due to changes in tax laws or changes in our interpretation of those laws. For example, **several countries, including the United States and other members of the Organization for Economic Co-operation and Development (“ OECD ”) have reached agreement on a global policy forum, released model rules related to a new 15 % global minimum tax regime initiative (“ Pillar Two ”)**. Several of the Other jurisdictions that **OECD countries are also actively considering changes to existing tax laws or have proposed new laws to align with the recommendations and guidelines proposed by the OECD, including Pillar Two. Enactment of such tax laws could increase our tax obligations in countries where we do business or cause us to change the way we operate our business. Beginning in have already adopted 2024, Pillar Two is in effect in some of the jurisdictions in which we operate. The Pillar Two impact on 2024 was immaterial. However, we cannot provide any assurance that there will not be a material impact to our effective tax rate because of these developments and evolving rules, which could impact the amount of taxes -- tax that we pay legislation in 2025 and beyond**. Taxes could also significantly increase due to changes in accounting guidance. Our future effective tax rate could be unfavorably affected by numerous factors including a change in, or the interpretation of, tax rules and regulations in the jurisdictions in which we operate (including changes in legislation currently being considered), the expiration of or disputes about certain tax agreements in a particular jurisdiction, a change in our geographic earnings mix, and / or to the jurisdictions in which we operate, or a change in the measurement of our deferred taxes. Our leverage and debt service obligations could adversely affect our business. Our leverage and debt service obligations could adversely affect our business. As of December 31, **2023-2024**, our total consolidated external debt was approximately \$ **1. 4-8** billion (See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 5, Debt, to the Notes to Consolidated Financial Statements (Part IV, Item 15 of this Annual Report on Form 10- K) for a discussion of our consolidated external debt). We may also incur additional indebtedness in the future. Our substantial indebtedness could have material, adverse consequences, including: • making it more difficult for us to satisfy our financial obligations; • increasing our vulnerability to adverse economic, regulatory and industry conditions, and placing us at a disadvantage compared to our competitors that are less leveraged; • limiting our ability to compete and our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; ~~and~~ • limiting our ability to borrow additional funds for working capital, capital expenditures, acquisitions and general corporate or other purposes; **and • result in greater interest rate risk and volatility**. Our debt service obligations will require us to use a portion of our operating cash flow to pay interest and principal on indebtedness instead of for other corporate purposes, including funding future expansion of our business, acquisitions, and ongoing capital expenditures, which could impede our growth. In addition, **the Convertible Senior Notes due 2025 (the “ 2025 Notes ”) will mature in August 2025, unless earlier converted, redeemed, or repurchased. Our** ability to comply with, renegotiate or extend the Company's debt obligations will depend on **various factors, including the accessibility of the capital markets and** our operating and financial performance, which, in turn, is subject to prevailing economic conditions and financial, business and other factors beyond our control. Any disruptions in our operations, the financial markets, or the overall economy, may adversely affect the availability and cost of credit to us and / or our ability to comply with our existing obligations.

~~GLOBAL PUBLIC HEALTH CONCERNS~~ Public health crises, such as the COVID-19 pandemic, have had, and could in the future have, a negative effect on our business. Our global operations and interactions with healthcare systems, providers and patients around the world expose us to risks associated with public health crises, including epidemics and pandemics. Such pandemics or disease outbreaks, such as the COVID-19 pandemic, have created and may continue to create significant volatility, uncertainty and economic disruption in the markets in which we sell our products and in which we operate. In response to the COVID-19 pandemic, governments around the world imposed measures designed to reduce the transmission of COVID-19 and individuals responded to the fear of contracting COVID-19. Additionally, the impact of the COVID-19 pandemic and its aftermath on general macroeconomic conditions has led to disruptions in the global supply chain, primarily through a lack of availability of raw materials and electronic components. We have experienced challenges associated with material and component availability for certain product lines, longer shipping and delivery times for raw materials and components, constrained logistics capacity related to the movement of our products,

availability of skilled labor and increased costs of raw materials, components, labor, and freight and courier services. The direct and indirect disruptions caused by the pandemic and the responses of both governments and individuals could negatively impact the number of surgical and medical intervention procedures performed and have a material adverse effect on our business, financial condition, results of operations, or cash flows. The extent to which fear of exposure to or actual effects of COVID-19, new variants, disease outbreak, epidemic or a similar widespread health concern impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the speed and extent of geographic spread of the disease, the duration of the outbreak, travel restrictions, the efficacy of vaccination and treatment; impact on the U. S. and international healthcare systems, the U. S. economy and worldwide economy; the timing, scope and effectiveness of U. S. and international governmental response; and the impact on the health, well-being and productivity of our employees.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY **32** Our intellectual property rights may not provide meaningful commercial protection for our products, potentially enabling third parties to use our technology or very similar technology and could reduce our ability to compete in the market. To compete effectively, we depend, in part, on our ability to maintain the proprietary nature of our technologies and manufacturing processes, which includes the ability to obtain, protect and enforce patents on our technology and to protect our trade secrets. We own or have licensed patents that cover aspects of some of our product lines. Our patents, however, may not provide us with any significant competitive advantage. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. Competitors may develop products similar to ours that our patents do not cover. In addition, the approval or rejection of patent applications may take several years and our current and future patent applications may not result in the issuance of patents in the U. S. or foreign countries. Our competitive position depends, in part, upon unpatented trade secrets, which we may be unable to protect. Our competitive position also depends upon unpatented trade secrets, which are difficult to protect. We cannot assure that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, that our trade secrets will not be disclosed or that we can effectively protect our rights to unpatented trade secrets. In an effort to protect our trade secrets, we require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements provide that, except in specified circumstances, all confidential information developed or made known to the individual during the course of their relationships with us must be kept confidential. We cannot assure, however, that these agreements will provide meaningful protection for our trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information. Our success will depend partly on our ability to operate without infringing or misappropriating the proprietary rights of others. We may be sued for infringing the intellectual property rights of others. In addition, we may find it necessary, if threatened, to initiate a lawsuit seeking a declaration from a court that we do not infringe the proprietary rights of others or that their rights are invalid or unenforceable. If we do not prevail in any litigation, in addition to any damages we might have to pay, we would be required to stop the infringing activity (which could include a cessation of selling the products in question) or obtain a license for the proprietary rights involved. Any required license may be unavailable to us on acceptable terms, if at all. In addition, some licenses may be nonexclusive and allow our competitors to access the same technology we license. If we fail to obtain a required license or are unable to design our products so as not to infringe on the proprietary rights of others, we may be unable to sell some of our products, and this potential inability could have a material, adverse effect on our revenues and profitability and cash flows. We may be involved in lawsuits relating to our intellectual property rights and promotional practices, which may be expensive. The medical device industry is characterized by extensive intellectual property litigation and to protect or enforce our intellectual property rights, we may have to initiate or defend legal proceedings, such as infringement suits or opposition proceedings, against or by third parties. In addition, we may have to institute proceedings regarding our competitors' promotional practices or defend proceedings regarding our promotional practices. Legal proceedings are costly, and, even if we prevail, the cost of the legal proceedings could affect our profitability and cash flows. In addition, litigation is time-consuming and could divert management's attention and resources away from our business. Moreover, in response to our claims against other parties, those parties could assert counterclaims against us.

RISKS RELATED TO CYBERSECURITY AND DATA PRIVACY **Cybersecurity incidents** **Cyber-attacks** or other disruptions to our information technology systems could adversely affect our business. We are increasingly dependent on sophisticated information technology for our infrastructure and to support business decisions. 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** **expectations regarding** **protect** **protection of** patient and, customer, **and employee** information, and changing customer patterns. An experienced third party maintains the enterprise business system used to support our transaction processing, accounting and financial reporting, and supply chain and manufacturing processes. Any significant breakdown, intrusion, interruption, corruption, or destruction of these systems, as well as any **data breaches** **other cybersecurity incident**, could have a material, adverse effect on our business. Third parties may attempt to **breach** **compromise** our systems and may obtain data relating to patients, proprietary or **other** sensitive information. We may face increased cybersecurity risks due to our reliance on internet technology and the number of our **33** employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. If we, or third parties on whom we rely, fail to maintain or protect our information systems and data integrity effectively, we could lose existing customers, have difficulty attracting new customers, suffer backlash from negative public relations, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy **breach** **incident (including from class action settlements or awards)**, or suffer other adverse consequences. We have programs, processes (including ongoing improvements) and technologies in place to prevent, detect, contain, respond to and mitigate security related threats and potential incidents. Because the techniques used to obtain unauthorized access or interrupt services change frequently and can be difficult to detect, anticipating, identifying or preventing

these threats or mitigating them if and when they occur, may be challenging. We are also dependent on third party vendors to supply and / or support certain aspects of our information technology systems which may contain defects in design or manufacture or other problems that could result in system disruption or unexpectedly compromise the information security of our own systems. In addition, as we grow in part through new acquisitions we may face risks due to implementation, modification, or remediation of controls, procedures, and policies relating to data privacy and cybersecurity at the acquired business **that may or may not have been identified as part of due diligence or encounter issues as part of integration**. We continue to consolidate and integrate the number of systems we operate, and to upgrade and expand our information system capabilities for stable and secure business operations. Despite our implementation of controls to protect our systems and ~~sensitive, confidential or personal data or~~ information, we ~~remain~~ may be vulnerable to ~~material security~~ **cybersecurity breaches, incidents such as** theft, misplaced, lost or corrupted data, employee errors and / or malfeasance (including misappropriation by departing employees), **ransomware, and evolving attacks such as with the assistance of the use of AI tools or involving open source software vulnerabilities**, that could potentially lead to the compromising of sensitive, confidential or personal data or information, improper use of our systems, software solutions or networks, unauthorized access, use, disclosure, modification or destruction of information, defective products, production downtimes and operational disruptions. In addition, a **cybersecurity incident** ~~cyber-related attack~~ could result in other negative consequences, including damage to our reputation or competitiveness, remediation or increased protection costs, litigation or regulatory action. Failure to comply with laws relating to the confidentiality of sensitive personal information or standards related to the transmission of electronic health data, may require us to make significant changes to our products, or incur penalties or other liabilities. State, federal and foreign laws, such as HIPAA, **Section 5 of the FTC Act**, or the California Consumer Privacy Act of 2018, **as amended by the CCPA, and other similar state laws** regulate the confidentiality of **personal information, including** sensitive ~~personal~~ information and the circumstances under which such information may be released. These measures may govern the disclosure and use of personal and patient medical record information and may require users of such information to implement specified security measures, and to notify individuals in the event of privacy and ~~security~~ **cybersecurity breaches incidents**. Evolving laws and regulations in this area could restrict the ability of our customers to obtain, use or disseminate patient information, or could require us to incur ~~significant~~ additional costs to re- design our products in a timely manner, either of which could have an adverse impact on our results of operations. Other health information standards, such as regulations under HIPAA **and FDA guidance and requirements**, establish standards regarding **device security**, electronic health data transmissions and transaction code set rules for specified electronic transactions, for example transactions involving submission of claims to third- party payors. These standards also continue to evolve and are often unclear and difficult to apply. We have incurred and expect that we will continue to incur ~~significant~~ costs implementing additional security measures to protect against new or enhanced data security or privacy threats, or to comply with current and new federal, state and international laws governing **data privacy** ~~the unauthorized disclosure or exfiltration of confidential and~~ **cybersecurity** ~~personal information~~ which are continuously being enacted and proposed. **Moreover, as a result of the broad scale release and availability of AI technologies such as generative AI, there is a global trend towards more regulation (e. g., the EU AI Act and AI laws passed in U. S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.** Outside the U. S., we are **also** impacted by privacy and data security requirements at the international, national and regional level, and on an industry specific basis. More privacy and ~~security~~ **cybersecurity** laws and regulations are being adopted, and more are being enforced, with **the** potential for ~~significant~~ financial penalties. ~~In the EU, increasingly stringent data protection and privacy rules have been enacted. The EU General Data Protection Regulation (GDPR),~~ **including as implemented in the UK**, applies ~~uniformly~~ across the EU and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances **as well as requirements prior to transferring personal data to other jurisdictions**. The GDPR also requires companies processing personal data of individuals ~~residing~~ in the EU to comply with EU ~~privacy and~~ data protection rules. **The GDPR, and its United Kingdom equivalent, is also influential for a growing number of jurisdictions who have adopted, or contemplated adoption, of similar data protection laws.** Failure to maintain the confidentiality of ~~sensitive~~ ~~personal information~~ ~~data~~ in accordance with the applicable regulatory requirements, or to abide by electronic health data transmission standards, could expose us to breach of contract claims, **regulatory** fines and penalties, **litigation expenses**, costs for remediation and harm to our reputation.