Risk Factors Comparison 2023-11-21 to 2022-11-15 Form: 10-K

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In evaluating our business, the risks described below, as well as other information contained in this Annual Report and in our other filings with the SEC should be considered carefully. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. The occurrence of any of these events or circumstances could individually or in the aggregate have a material adverse effect on our business, financial condition, cash flow or results of operations. This report contains forward- looking statements; please refer to the cautionary statements made under the heading ~~"~~ **“** Special Note Regarding Forward- Looking Statements ~~"~~ **”** for more information on the qualifications and limitations on forward- looking statements. GLOBAL CHALLENGES, INCLUDING MACROECONOMIC CONDITIONS AND RELATED FINANCIAL RISKS The continuing worldwide macroeconomic and geopolitical uncertainty may adversely affect our business and prospects, both domestically and internationally. Continued concerns about the systemic impact of potential long- term and wide- spread recession and geopolitical issues, including ~~the war~~ **wars** ~~in Ukraine~~ **and 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 **, bank failures** , rising interest rates and availability of capital markets. Uncertainty about global economic conditions, particularly in emerging markets and countries with government- sponsored healthcare systems, 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 **. In addition, continuing social concerns and divisions in the U. S. and throughout the world, could have a material, adverse effect on the economic conditions in markets we serve, and our results of operations, cash flow and financial position** . 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 medical health insurance premiums and procurement activities. Economic uncertainty, an increase in unemployment rates, as well as **an** ~~increasing~~ **increase in** health insurance premiums, co- payments and deductibles may ~~continue to~~ result in cost- conscious consumers making fewer trips to their physicians and specialists, which in turn would 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. Our international sales are often denominated in foreign currencies, including the Euro, UK Pound and ~~Renminbi~~ **Chinese Yuan** . Changes in currency exchange rates, particularly the increase in the value of the dollar against any such foreign currencies, may reduce the reported value of our revenues outside the U. S. and associated cash flows and our ability to compete effectively in foreign markets. In addition, such fluctuations can also result in foreign currency exchange losses. We cannot predict changes in currency exchange rates, the impact of exchange rate changes, nor the degree to which we will be able to manage the impact of currency exchange rate changes. We currently have limited hedging arrangements in place to mitigate some of the impact of negative exchange rates. Our international operations and foreign acquisitions expose us to additional operational challenges that we might not otherwise face. International expansion is a key component of our growth strategy. In fiscal ~~2022~~ **2023** , ~~28~~ **26** . ~~7~~ **0** % of our revenue came from outside of the U. S. As we grow internationally, our future and existing international operations may subject us to a number of additional risks and expenses, any of which could harm our operating results. These risks and expenses include: • political and economic changes and disruptions, export / import controls and tariff regulations; • difficulties in developing staffing and simultaneously managing operations in multiple locations as a result of, among other things, distance, language and cultural differences; • governmental currency controls; • multiple, conflicting and changing government laws and regulations (including, among other things, antitrust and tax requirements); • protectionist laws and business practices that favor local companies; • difficulties in the collection of trade accounts receivable; • difficulties and expenses related to implementing internal controls over financial reporting and disclosure controls and procedures; • expenses associated with customizing products for clients in foreign countries; • possible adverse tax consequences; • the inability to obtain and maintain required regulatory approvals or favorable third- party reimbursement; • operation in parts of the world where strict compliance with anti- bribery laws may conflict with local customs and practices; • the inability to effectively obtain, maintain, protect or enforce intellectual property rights, reduced protection for intellectual property rights in some countries, and the inability to otherwise protect against clone or “ knock off ” products; • the lack of ability to enforce non- compete agreements with former owners of acquired businesses competing with us in China and other foreign countries; and • lower margins on a number of our products sold outside of the U. S. In addition, government policies on international trade and investment such as import quotas, capital controls or tariffs, whether adopted by individual governments or addressed by regional trade blocks, can affect the demand for our products and services, impact the competitive position of our products or prevent us from being able to sell products in certain countries. The implementation of more restrictive trade policies, such as more detailed inspections, higher tariffs or new barriers to entry, could negatively impact our business, results of operations and financial condition. For example, a government' s adoption of ~~"~~ **“** buy national ~~"~~ **”** policies or retaliation by another government against such policies could have a negative impact on our results of operations. Additionally, 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. BUSINESS ~~CONTINUITY~~ **DEVELOPMENT** AND **COMPETITION Our long-term success will depend upon our ability** ~~RELIANCE ON THIRD PARTIES Supply Chain and Manufacturing Supply chain disruptions and constraints and inflationary pressures have had, and may continue~~ to **execute** ~~have, a material adverse effect~~ on **business development activities** ~~our ability to procure raw materials~~ and ~~components~~ **integrate acquired businesses. As part of our long- term strategy** , **we are engaged in business development activities** including **evaluating** ~~semiconductor chips, and are adversely affecting our ability to meet customer demand for, and increasing our costs to manufacture, warehouse, and transport, certain of our products. Global supply constraints and cost impacts as a result of worldwide economic disruptions, electronic component shortages, fear of~~ future **acquisitions, joint development opportunities, technology licensing arrangements and other opportunities to further expand** ~~or~~ **our presence** ~~ongoing pandemics, inflation, recessionary conditions and geopolitical events, including the war~~ in ~~Ukraine, are impacting our~~ **or diversify into priority growth** ~~ability to procure critical raw materials and components, including semiconductor chips, and are~~ **areas by accessing new** ~~adversely affecting our ability to meet customer demand for, and increasing our costs to manufacture, transport and warehouse a certain subset of our~~ products ~~. Obtaining alternative sources of raw materials~~ and **technologies. We** ~~components could involve significant costs and regulatory challenges and~~ may not be ~~available~~ **able** to ~~us on reasonable~~ **identify appropriate business development activities or acquisition candidates, consummate transactions or obtain agreements with favorable** terms, if at all. ~~In particular, our ability~~ **We may also be subject** to **increasing regulatory scrutiny from competition** ~~manufacture our Breast Health capital equipment products, primarily, but not limited to, our 3D Dimensions systems, Trident specimen radiography systems, Affirm Prone Biopsy systems~~ and **antitrust authorities in connection with acquisitions** ~~Brevera systems, is dependent on the supply of such raw materials and components, including semiconductor chips~~ . If we ~~remain unable~~ **are successful in pursuing future acquisitions, we may face significant competition, be required to expend significant funds, incur additional debt or other obligations, or issue additional securities, which may negatively affect our operating results and financial condition. If we spend significant funds or incur additional debt or obligations, our ability** to obtain **financing** ~~sufficient quantities of raw materials and components on commercially reasonable terms or~~ **for working capital or other purposes could be adversely affected, and we may be more vulnerable to economic downturns and competitive pressures. During fiscal 2021, we made a number of tactical acquisitions which complemented our existing businesses. We continue to integrate those acquisitions. Any inability to successfully integrate new businesses, including our more recent acquisitions, decreases in customer loyalty or product orders, failure to retain or develop the acquired workforce, failure to realize anticipated economic, operational and other benefits and synergies** in a timely manner, **failure to establish and maintain appropriate controls** ~~our~~ **or unknown** ~~ability to manufacture our~~ **or contingent liabilities** ~~capital equipment products, in particular, our Breast Health products, on a timely and cost- competitive basis~~ could ~~materially~~ adversely affect our ~~revenues and results~~ **ability to realize the anticipated benefits** of ~~operations and harm~~ **any new product** ~~our~~ **or acquisition** ~~competitive position and reputation~~ . ~~Our reliance on one~~ **For example, in the** third **quarter of fiscal 2023, we reassessed our short** - **term** ~~party manufacturer for certain of our product lines~~ and ~~a limited number of suppliers for some key raw materials, components and subassemblies for our products exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have sole source third- party manufacturers for each of our Panther and Tigris molecular diagnostics instruments and for our Skeletal Health products. Similarly, we rely on one or a limited number of suppliers for some key components or subassemblies for our products due to cost, quality, expertise or other considerations. We have no firm~~ long- term **commercial plans** ~~volume commitments with certain of our sole source suppliers, including the manufacturers of our Panther or~~ **for the Mobidiag business** ~~Tigris instruments. Similarly~~ , **which** we ~~rely on one or a limited number~~ **acquired in fiscal 2021, and recorded aggregate impairment charges** of ~~suppliers~~ **$ 197. 4 million. The integration of an acquired business, whether** ~~for~~ **or not successful** ~~some key raw materials for our products due to cost~~ , ~~quality, expertise~~ **requires significant efforts which may result in additional expenses and divert the attention of** ~~or~~ **our management and technical personnel from** other ~~considerations~~ **projects. Acquisitions** , **in particular,** ~~and some of these suppliers~~ are **inherently risky** ~~competitors. For example~~ , ~~F. Hoffmann- LaRoche Ltd, a direct competitor of our Diagnostics business, is the parent company of Roche, our current supplier of certain key raw materials for certain of our amplified NAT diagnostic assays. GE Healthcare Bio- Sciences Corp., an~~ **and** ~~affiliate of GE, supplies us with the membranes used in connection with our ThinPrep product line. GE is a direct competitor with our Breast Health and Skeletal Health businesses. Moreover,~~ we **cannot guarantee** ~~use certain components in our products, including semiconductor chips,~~ that ~~have been the subject of global supply chain shortages and disruptions. If~~ any ~~of~~ **past** ~~our~~ **or future transaction will** ~~sole source manufacturers or suppliers, or other third- party manufacturers or suppliers, experiences delays, disruptions, capacity constraints or quality control problems in its development or manufacturing operations or becomes insolvent or otherwise fails to supply us with goods in sufficient quantities, including as a result of disruptions caused by the continued impact of COVID- 19, other epidemics or pandemics, natural disasters, supplier facility shutdowns, or otherwise, then shipments to our customers could~~ be **successful** ~~delayed, which would decrease our revenues and harm our competitive position and reputation~~ . Moreover, the failure of a supplier..... described herein. COMPETITION AND BUSINESS DEVELOPMENT We face intense competition from other companies and may not be able to compete successfully. The markets in which we sell our products are intensely competitive, subject to rapid technological change and may be significantly affected by new product introductions and other market activities of industry participants, and these competitive pressures may reduce the demand and prices for our products. Other companies may develop products that are superior to and / or less expensive than our products. Improvements in existing competitive products or the introduction of new competitive products may reduce our ability to compete for sales, particularly if those competitive products demonstrate better safety or

effectiveness, clinical results, ease of use or lower costs. Organizational changes we have made or may make to streamline and improve customer experience may not have the intended effect and may instead harm our competitive position and reputation. **.** In addition,some companies may have significant competitive advantages over us,which may make them more attractive to hospitals,clinics,radiology clients,group purchasing organizations,laboratories,and physicians,including:• greater brand recognition;• larger or more established distribution networks and customer bases;• a broader product portfolio,resulting in the ability to offer rebates or bundle products to offer discounts or incentives to gain a competitive advantage;• higher levels of automation and greater installed bases of such equipment;• more extensive research,development,sales,marketing,and manufacturing capabilities and greater financial resources;and • greater technical resources positioning them to continue to improve their technology in order to compete in an evolving industry ~~.~~ We also developed assays to detect COVID- 19. ~~While we have seen significant~~ **Considerable uncertainty remains as to the** demand **for ongoing COVID- 19 testing, and thus,** for our COVID- 19 assays **. In addition** , other companies ~~are working to produce or~~ have produced tests for COVID- 19 (including so- called high throughput nucleic acid tests, rapid antigen tests and at- home testing solutions) which may lead to the diversion of customers away from us and toward other companies. ~~Moreover, considerable uncertainty remains as to the demand for ongoing COVID- 19 testing, and thus, for our COVID- 19 assays. There is no guarantee that current or anticipated demand will continue, or if demand does continue or increases, that we will be able to produce in quantities to meet the demand.~~ As COVID- 19 testing declines, customers may also consolidate their molecular testing menu to high throughput, high automation platforms which may further increase the competition our Panther and Panther Fusion instruments face. **Continued** ~~A significant~~ decline in demand for our COVID- 19 assays or a reduction in the reimbursement rates for our COVID- 19 assays without a corresponding increase in our other businesses could have a material, adverse effect on our results of operations, cash flow and financial position . In addition, some companies may..... order to compete in an evolving industry . Challenges in the development of our products could materially impact our long- term success. Our growth depends in large part on our ability to identify and develop new products or new indications for or enhancements of existing products. The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate and develop new products, complete clinical trials, obtain regulatory clearances and approvals and reimbursement in the U. S. and abroad, manufacture products in a cost- effective manner, obtain, maintain, protect and enforce appropriate intellectual property protection for our products, gain and maintain market approval of our products and access capital. If we are not able to successfully enhance existing products or develop new products, our products may be rendered obsolete or uncompetitive by changing technology or new industry standards. We cannot assure that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval or gain market acceptance, and we may be unable to recover all or a meaningful part of our investment in such products and technologies. The markets for our newly developed products and newly introduced enhancements to our existing products may not develop as expected. The successful commercialization of our newly developed products and newly introduced enhancements to our existing products are subject to numerous risks, both known and unknown, including: • uncertainty of the development of a market for such product; • trends relating to, or the introduction or existence of, competing products or technologies that may be more effective, safer or easier to use than our products or technologies; • the perception of our products as compared to other products; • recommendation and support for the use of our products by influential customers, such as highly regarded hospitals, physicians and treatment centers; • the availability and extent of data demonstrating the clinical efficacy of our products or treatments; • competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and • other technological developments. Often, the development of a significant market for a product will depend upon the establishment of a reimbursement code or an advantageous reimbursement level for use of the product. Moreover, even if addressed, such reimbursement codes or levels frequently are not established until after a product is developed and commercially introduced, which can delay the successful commercialization of a product. If we are unable to successfully commercialize and create a significant market for our newly developed products and newly introduced enhancements to our existing products our business and prospects could be harmed. If we cannot maintain our current corporate collaborations and enter into new corporate collaborations, our product development could be delayed and our revenue could be adversely impacted. We have relied and / or expect to rely on corporate collaborators for funding development, marketing, distribution, and the commercialization of certain products. If any of our corporate collaborators were to breach, terminate, fail to renew our agreements or otherwise fail to properly conduct its obligations in a timely manner, the development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. Further, we would be required to devote additional resources to product development or marketing, to terminate some development programs or to seek alternative corporate collaborations with certain partners or companies that could make it more difficult for us to enter into advantageous business transactions or relationships with others. Any of the foregoing risks could harm our business and prospects. Our long- term success will depend..... key employees, could be harmed. CYBERSECURITY AND DATA PRIVACY Increased cybersecurity requirements, vulnerabilities, threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, products, solutions, services and data. Increased global cybersecurity vulnerabilities, threats, computer viruses, ransomware and phishing attacks and more sophisticated and targeted cyber- related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of Hologic and its customers, business partners' and suppliers' products, systems and networks and the confidentiality, availability and integrity of data on these products, systems and networks. As the perpetrators of such attacks become more capable, as cybercrime becomes commoditized, and as critical infrastructure is increasingly becoming digitized, the risks in this area continue to grow. While we attempt to mitigate these risks by employing ~~a number of~~ **certain physical, administrative, and technical** measures, including **, but not limited to,**

employee training **, logical access controls** , monitoring and testing, and maintenance of protective systems and contingency plans, we remain potentially vulnerable to additional known or unknown threats, and we cannot assure that the impact from such threats will not be material. In addition to existing risks, flexible work arrangements, the adoption of new technologies and acquisitions of new businesses may also increase our exposure to cybersecurity breaches and failures. We **regularly assess external and internal cybersecurity- related risks and identify potential improvements to our cybersecurity program (including its staffing, processes, and technology). When potential improvements are identified, we weigh the costs and benefits of such improvements (including against other potential improvements) and, if selected, the improvements are added to a roadmap for possible implementation. Additionally, we have incurred and expect to continue to incur significant costs implementing additional security measures to protect against existing and emerging cybersecurity threats. We** also have access to sensitive, confidential or personal data or information that is subject to privacy and security laws, regulations or customer- imposed controls. Despite our implementation of **certain** controls to protect our systems and sensitive, confidential or personal data or information, we may be vulnerable to material security breaches, theft, misplaced, lost or corrupted data, employee errors and / or malfeasance (including misappropriation by departing employees) 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 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. **While we carry cyber liability insurance, such insurance may not cover us with respect to any or all claims or costs associated with such a breach.** Although we have experienced occasional ~~actual~~ **cybersecurity incidents and /** or attempted breaches of our computer systems, to date we do not believe any of these breaches ~~has~~ **have** had a material effect on our business, operations or reputation. 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 the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, regulate the confidentiality of 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 breaches. 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, establish standards regarding 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 the unauthorized disclosure or exfiltration of confidential and personal information which are continuously being enacted and proposed** . Outside the U. S., we are impacted by privacy and data security requirements at the international, national and regional level, and on an industry specific basis. More privacy and security laws and regulations are being adopted, and more are being enforced, with 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) 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. The GDPR also requires companies processing personal data of individuals residing in the EU to comply with EU privacy and data protection rules. Failure to maintain the confidentiality of sensitive personal information in accordance with the applicable regulatory requirements, or to abide by electronic health data transmission standards, could expose us to breach of contract claims, fines and penalties, costs for remediation and harm to our reputation. THIRD- PARTY REIMBURSEMENT AND GUIDELINES Healthcare cost containment legislation and the failure of third- party payors to provide appropriate levels of coverage and reimbursement for the use of products and treatments facilitated by our products could harm our business and prospects. Sales and market acceptance of our diagnostics, breast and skeletal health and surgical products and the treatments facilitated by these products are dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. These policies affect which products customers purchase and the prices they are willing to pay. Reimbursement varies by country and can significantly impact the acceptance of new products and technologies. Even if we develop a promising new product, we may find limited demand for the product unless appropriate reimbursement approval is obtained from private and governmental third- party payors. Further legislative or administrative reforms to the reimbursement systems in the U. S. and other countries in a manner that significantly reduces reimbursement for procedures using our diagnostics, breast and skeletal health and surgical products or denies coverage for those procedures facilitated by our products, including price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed- care arrangements, could have a material adverse effect on our business, financial condition or results of operations. Guidelines, recommendations and studies published by various organizations may reduce the use of our products. Professional societies, government agencies, practice management groups, private health / science foundations, and organizations involved in healthcare issues may publish guidelines, recommendations or studies to the healthcare and patient communities. Organizations like these have in the past made recommendations about our products and those of our competitors. If followed by healthcare providers and insurers, such publications could result in decreased use of our products. For example, in November 2012, the American Congress of Obstetrics and Gynecologists, known as the ACOG, released updates in which it recommended less

frequent cervical cancer screening similar to guidelines released in March 2012 by the U. S. ~~Preventative -~~ **Preventive** Services Task Force, or the USPSTF, and the American Cancer Society. We believe that these recommendations and guidelines may have contributed to increased screening intervals for cervical cancer, which we believe has and may continue to adversely affect our ThinPrep revenues. Our **cervical cancer screening revenues, primarily from** ThinPrep ~~revenues~~ **sales,** may also be adversely affected by the July 2020 American Cancer Society cervical cancer screening ~~recommendation for~~ **guidelines, which recommended the use of** a ~~primary~~ human papillomavirus (HPV) test **for primary screening** rather than **co- testing (the use of an HPV test with** a **Pap test) or a standalone** Pap test. In addition, on October 20, 2015, the American Cancer Society issued guidelines recommending that women start annual mammograms at age 45 instead of 40 and have a mammogram every two years instead of annually. We believe that this recommendation **Moreover** ,the failure of a supplier to provide sufficient quantities,acceptable quality and timely delivery of goods at an acceptable price,or an interruption in the delivery of goods from such a supplier could adversely affect our business and results of operations.Obtaining alternative sources of supply of products,components,subassemblies or raw materials could involve significant delays and other costs and regulatory challenges and may not be available to us on reasonable terms,if at all.We may in the future need to find new contract manufacturers or suppliers to replace existing manufacturers or suppliers,increase our volumes or reduce our costs.We may not be able to find contract manufacturers or suppliers that meet our needs,including regulatory requirements,and even if we do,the process of qualifying such alternative manufacturers and suppliers is often expensive and time consuming.As a result,we may lose revenues and our customer relationships may suffer.Business Continuity Interruptions,delays,shutdowns or damage at our manufacturing or laboratory facilities ~~,or the facilities of third parties on which we depend,~~ could harm our business.In most cases,the manufacturing and warehousing of each of our products is concentrated in one or a few locations.In addition,we rely on a single laboratory facility to process each of our Biotheranostics gene expression tests for breast cancer.An interruption in manufacturing,testing capabilities or warehousing at any of these facilities,as a result of equipment failure,transportation interruptions,disruptions caused by ~~strikes or~~ **the continued impact of COVID- 19,** other ~~labor unrest,~~ epidemics or pandemics,natural disaster,environmental factors or property damage could reduce,delay or prevent the production and distribution of our products.Our facilities and those of our contract manufacturers ~~,~~ **or** suppliers ~~,customers or third parties on which we depend~~ are also subject to the risk of catastrophic loss due to unanticipated events,such as fires,earthquakes,explosions,floods or weather conditions ~~,or other events outside of our control~~ .Our facilities may experience plant shutdowns,strikes or other labor disruptions,or periods of reduced production as a result of equipment failures,loss of power,gray outs,delays in deliveries or extensive damage,which could harm our business and prospects.Some of our manufacturing operations are located outside the U.S.,including in Costa Rica and the **United Kingdom.Those manufacturing operations are also subject to additional challenges and risks associated with international operations described herein.COMPETITION AND BUSINESS DEVELOPMENT** could result in ~~a decrease~~ **lower revenues than previously received from the distributor** in ~~use~~ **that territory. TALENT AND EMPLOYEE RETENTION Our success depends on our ability to attract, motivate** and ~~purchases~~ **retain key personnel and plan for future executive transitions. The loss** of **any of our key personnel, particularly executive management** ~~our -~~ **or** ~~mammography systems~~ **key** research and development personnel,could harm our business and prospects and could impede the achievement of our research and development,operational or strategic objectives.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 ~~the ongoing impacts of COVID- 19,~~ macroeconomic uncertainties,including inflation,and other factors,may adversely impact job performance and employee retention.Additionally,in our industry,there is substantial competition for key personnel in the regions in which we operate.We face intense competition for employees,particularly as employees are increasingly able to work remotely.Also,facilitating seamless leadership transitions for key positions is a critical factor in sustaining the success of our organization.If our succession planning efforts are not effective,it could adversely impact our business.We continue to assess the key personnel that we believe are essential to our long- term success.Future organizational changes could also cause our employee attrition rate to increase.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** . REGULATORY AND LEGAL We operate in a highly regulated industry, and changes in healthcare laws and regulations or our inability to obtain in a timely manner or at all U. S. or foreign regulatory clearances or approvals for our current and newly developed products and services or product or service enhancements, could adversely affect our business and prospects. We operate in a highly regulated industry. As a result, governmental actions may adversely affect our business, operations or financial condition, including: • new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, method of delivery and payment for healthcare products and services; • changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity; • changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products; and • new laws, regulations and judicial decisions affecting pricing or marketing practices. Given the high level of regulatory oversight to which our products are subject, the process of obtaining clearances and approvals can be costly and time consuming. In addition, there is a risk that any approvals or clearances, once obtained, may be withdrawn. Most medical devices cannot be marketed in the U. S. without 510 (k) clearance or pre- market approval by the FDA. Any modifications to a device that has received a pre- market approval that affect the safety or effectiveness of the device require a pre- market approval supplement or possibly a separate pre- market approval, either of which is likely to be time consuming, expensive and uncertain to obtain. If the FDA requires us to seek one or more pre- market approval supplements or new pre- market approvals for any modification to a previously approved device, we may be required

to cease marketing or to recall the modified device until we obtain approval, and we may be subject to significant criminal and / or civil sanctions, including, but not limited to, regulatory fines or penalties. States may also regulate the manufacture, sale and use of medical devices, particularly those that employ x- ray technology. Our products are also subject to approval and regulation by foreign regulatory and safety agencies. For example, the EU has adopted the EU Medical Device Regulation (the " EU MDR ") and the In Vitro Diagnostic Regulation (the " EU IVDR "), each of which impose stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Implementation of the compliance requirements of these regulations requires us to incur significant expenditures and utilize resources. Failure to continue to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements. We anticipate that governmental authorities will continue to scrutinize the healthcare industry closely and that changes in laws, regulations or policies by governmental authorities may cause increased uncertainties and compliance costs, exposure to litigation and other adverse effects to our business and operations. Delays in receipt of, or failure to obtain or maintain, clearances or approvals for future products could delay or preclude realization of product revenues from new or existing products or result in substantial additional costs which could decrease our profitability. 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. 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. 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 the provisions of a federal law commonly known as the anti- kickback statute, and several similar state laws, which prohibit payments intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs that may be used with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Similarly, the Patient Protection and Affordable Care Act also includes stringent reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals. Specifically, under one provision of the law, which is commonly referred to as the Physician Payment Sunshine Act, we are required to collect data on and annually report to CMS certain payments or other transfers of value to physicians and teaching hospitals and annually report certain ownership and investment interests held by physicians or their immediate family members. Anti- kickback and false claims laws and the Physician Payment Sunshine Act prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. Similarly, our international operations are subject to the provisions of the U. S. 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. 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 are subject to the risk of product liability claims relating to our products for which we may not have adequate insurance. Our business involves the risk of product liability and other claims inherent to the medical device business. If even one of our products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. We maintain product liability insurance subject to deductibles and exclusions. There is a risk that the insurance coverage will not be sufficient to protect us from product and other liability claims, or that product liability insurance will not be available to us at a reasonable cost, if at all. An under- insured or uninsured claim could harm our business and prospects. In addition, claims could adversely affect the reputation of the related product, which could damage that product' s competitive position in the market. The sale and use of our diagnostic products could also lead to product liability claims if someone were to allege that one of our products contained a design or manufacturing defect that resulted in inaccurate test results or the failure to detect a disorder for which it was being used to screen, or caused injuries to a patient **. We are currently the subject of product liability litigation proceedings described in more detail under Note 15 to our consolidated financial statements entitled " Litigation and Related Matters ". The outcome of litigation is difficult to assess or quantify** . Any product liability claim brought against us, with or without merit, could result in an increase in our product liability insurance rates or the inability to secure additional coverage in the future. Also, even a meritless or unsuccessful product liability claim could be time consuming and expensive to defend. This could result in a diversion of management' s attention from our business and adversely affect the perceived safety and efficacy of our products, which could harm our business and prospects. We are subject to environmental, health and safety laws and regulations, including related to

our use and recycling of hazardous materials and the composition of our products. Our research and development and manufacturing processes involve the controlled use of hazardous materials, such as toxic and carcinogenic chemicals and various radioactive compounds, and the risk of contamination or injury from these materials cannot be eliminated. In such event, we could be held liable for any resulting damages, and any such liability could be extensive. From time to time new regulations are enacted, and it is difficult to anticipate how such regulations will be implemented and enforced. We continue to evaluate the necessary steps for compliance with regulations as they are enacted. These regulations include, for example, regulations enacted in the EU such as the Registration, Evaluation, Authorization and Restriction of Chemical Substances, or REACH, which requires the registration of and regulates use of certain chemicals, the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive, or RoHS, which regulates the use of certain hazardous substances in certain products we manufacture, and the Waste Electrical and Electronic Equipment Directive, or WEEE, which requires the collection, reuse and recycling of waste from certain products we manufacture. These and similar legislation that has been or is in the process of being enacted in Japan, China and various states of the U. S. may require us to re- design our products to ensure compliance with the applicable standards, for example by requiring the use of different types of materials. These redesigns or the use of alternative materials may detrimentally impact the performance of our products, add greater testing lead times for product introductions, result in additional costs or have other similar effects. In addition, changes in environmental laws and regulations, in particular relating to climate change and greenhouse gas (“ GHG ”) emissions, could require us, or our contract manufacturers or suppliers, to install additional equipment, or alter operations to incorporate new technologies or processes, which may result in additional expenses and adversely affect our operating results. We may also incur significant costs and utilize additional resources to comply with future regulations related to climate- related disclosures. We are also subject to other substantial regulation relating to environmental, health and safety matters, including occupational health and safety, environmental protection, hazardous substance control, and waste management and disposal. The failure to comply with such regulations could subject us to, among other things, fines and criminal liability. We may also be required to incur significant costs to comply with these and future regulations, which may result in a material adverse effect upon our business, financial condition and results of ~~operation~~ **operations** . 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 jurisdictions outside of the U. S. 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), 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. We are also subject to ongoing tax audits in various jurisdictions, and tax authorities may disagree with certain positions we have taken and assess additional taxes. **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.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 we sell our products into and operate in,primarily the U.S.,Europe,and Asia- Pacific and may negatively impact business and healthcare activity globally.In response to the COVID- 19 pandemic,governments around the world ~~have~~ imposed measures designed to reduce the transmission of COVID- 19 and individuals ~~continue to respond~~ **responded** to the fear of contracting COVID- 19.In particular,elective procedures and exams were delayed or cancelled,there has been a significant reduction in physician office visits,and hospitals postponed or canceled capital purchases as well as limited or eliminated services.While elective procedures and exams and capital purchases have increased from initially depressed levels, ~~the~~ **a** reduction in elective procedures,exams and capital purchases has had,and we believe may continue to have,a negative impact on the sales of most of our products (other than our COVID- 19 assays and related systems and ancillaries).Additionally,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 further adversely affect sales of our products.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. INTELLECTUAL PROPERTY Our business is dependent on technologies we license, and if we fail to maintain these licenses or license new technologies and rights to particular nucleic acid sequences for targeted diseases in the future, we may be limited in our ability to develop new products. Our business is dependent on licenses from third parties for some of our key technologies. For example, our patented TMA technology is based on technology we licensed from Stanford University. We anticipate that we will enter into new licensing arrangements in the ordinary course of business to expand our product portfolio and access new technologies to enhance our products and develop new products. Many of these licenses will provide us with exclusive rights to the subject technology or disease marker. If our license with respect to any of these technologies or markers is terminated for any reason, we may not be able to sell products that incorporate that technology. Similarly, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license. Our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Our ability to design products that target these diseases may depend on our ability to obtain the necessary rights from the third parties that make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT diagnostic assays may be economically viable. If we are unable to access new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products. Our products and

manufacturing processes may require access to technologies and materials that may be subject to patents or other intellectual property rights held by third parties. Our business could be adversely affected if we are unable to obtain the additional intellectual property rights necessary to commercialize our products. Our business could be harmed if we are unable to protect our proprietary technology. We have relied primarily on a combination of trade secrets, patents, copyrights, trademarks and confidentiality procedures to protect our products and technology. Despite these precautions, unauthorized third parties may infringe, misappropriate or otherwise violate our intellectual property, or copy or reverse engineer portions of our technology. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. We do not know if current or future patent applications will be issued with the full scope of the claims sought, if at all, or whether any patents that are issued will be challenged or invalidated. The patents that we own or license could also be subjected to invalidation proceedings or similar disputes, and an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to the technology from the prevailing party. There is also a risk that intellectual property laws outside of the U. S. will not protect our intellectual property rights to the same extent as intellectual property laws in the U. S. Even if our proprietary information is protected by patents or otherwise, the initiation of actions to protect our proprietary information could be costly and divert the efforts and attention of our management and technical personnel, and the outcome of such litigation is often uncertain. As a result of these uncertainties, we could also elect to forego such litigation or settle such litigation without fully enforcing our proprietary rights. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology. Additionally, rights provided by a patent are finite in time. Over the coming years, certain patents relating to current products will expire in the U. S. and abroad thus allowing third parties to utilize certain of our technologies. Our business could be harmed if we infringe upon the intellectual property rights of others. There has been substantial litigation regarding patent and other intellectual property rights in the medical device, diagnostic products and related industries. We are and have been involved in patent litigation and may in the future be subject to further claims of infringement of intellectual property rights possessed by third parties. In connection with claims of patent infringement, we may seek to enter into settlement and / or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide to litigate such claims or to design around the technology. These actions could be costly and would divert the efforts and attention of our management and technical personnel. As a result, any infringement claims by third parties or claims for indemnification by customers resulting from infringement claims, whether or not proven to be true, may harm our business and prospects. INDEBTEDNESS We have a significant amount of indebtedness outstanding, which limits our operating flexibility, and could adversely affect our operations and financial results and prevent us from fulfilling our obligations. As of September ~~24~~ **30**, ~~2022~~ **2023**, we had approximately $ 2. ~~85~~ **84** billion aggregate principal of indebtedness outstanding (exclusive of additional funds that would be available to draw under our revolver). We also have other contractual obligations and deferred tax liabilities, which as of September ~~24~~ **30**, ~~2022~~ **2023**, are described under " Notes to Consolidated Financial Statements — Income Taxes, and Non- cancelable Purchase Commitments. " This significant level of indebtedness and our other obligations may: • make it more difficult for us to satisfy our obligations with respect to our outstanding indebtedness; • increase our vulnerability to general adverse economic and industry conditions, including increases in interest rates; • require us to dedicate a substantial portion of our cash flow from operations to interest and principal payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, expansion efforts, strategic transactions and other general corporate purposes; • limit our flexibility in planning for, or reacting to, changes in our business and the markets in which we participate; • place us at a competitive disadvantage compared to our competitors that have less debt; and • limit our ability to borrow additional funds for working capital, capital expenditures, expansion efforts, strategic transactions or other general corporate purposes. In addition, the terms of our financing obligations contain certain covenants that restrict our ability, and that of our subsidiaries, to engage in certain transactions and may impair our ability to respond to changing business and economic conditions, including, among other things, limitations on our ability to: • incur indebtedness or issue certain preferred equity; • pay dividends, repurchase our common stock, or make other distributions or restricted payments; • make certain investments; • agree to payment restrictions affecting the restricted subsidiaries; • sell or otherwise transfer or dispose of assets, including equity interests of our subsidiaries; • enter into transactions with our affiliates; • create liens; • designate our subsidiaries as unrestricted subsidiaries; • consolidate, merge or sell substantially all of our assets; and • use the proceeds of permitted sales of our assets. Our credit facilities also require us to satisfy certain financial covenants. Our ability to comply with these provisions may be affected by general economic conditions, political decisions, industry conditions and other events beyond our control. Our failure to comply with the covenants contained in our credit facilities, including financial covenants, could result in an event of default, which could materially and adversely affect our results of operations and financial condition. If there were an event of default under one of our debt instruments or a change of control, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and may be cross- defaulted to other debt, including our outstanding notes. Our assets or cash flow may not be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default or a change of control, and there is no guarantee that we would be able to repay, refinance or restructure the payments on such debt. See " Management' s Discussion and Analysis of Financial Condition and Results of Operations- Liquidity and Capital Resources. " We may not be able to generate sufficient cash flow to service all of our indebtedness and other obligations. Our ability to make payments on and to refinance our indebtedness and to fund planned capital expenditures, strategic transactions and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. Our business may not be able to generate sufficient cash flow from operations, and we cannot assure that future borrowings will be available to us in amounts sufficient to enable us to pay our indebtedness as such indebtedness matures and to fund our other liquidity needs. If

this occurs, we will need to refinance all or a portion of our indebtedness on or before maturity, and there can be no assurance that we will be able to refinance any of our indebtedness on commercially reasonable terms, or at all. We may need to adopt one or more alternatives, such as reducing or delaying planned expenses and capital expenditures, selling assets, restructuring debt, or obtaining additional equity or debt financing. These alternative strategies may not be ~~affected~~ **effected** on satisfactory terms, if at all. Our ability to refinance our indebtedness or obtain additional financing, or to do so on commercially reasonable terms, will depend on, among other things, our financial condition at the time, restrictions in agreements governing our indebtedness, and other factors, including the condition of the financial markets and the markets in which we compete. If we do not generate sufficient cash flow from operations, and additional borrowings, refinancings or proceeds from asset sales are not available to us, we may not have sufficient cash to enable us to meet all of our obligations. A significant portion of our indebtedness is subject to floating interest rates, which may expose us to higher interest payments. A significant portion of our indebtedness is subject to floating interest rates, which makes us more vulnerable in the event of adverse economic conditions, increases in prevailing interest rates, or a downturn in our business. As of September ~~24~~ **30** , ~~2022~~ **2023** , approximately $ 1. 5 billion aggregate principal of our indebtedness, which represented the outstanding principal under our credit facilities, was subject to floating interest rates. We currently have ~~a~~ hedging ~~arrangement~~ **arrangements** (**interest rate swaps) in place to partially mitigate the impact of higher interest rates. We have** an interest rate swap ~~that expires~~ **in the notional amount of $ 1. 0 billion expiring** on December 17, 2023 ~~) in place~~ **, and have entered into** ~~to~~ **two** ~~partially mitigate~~ **consecutive interest rate swaps that will provide us with a continued hedge, in** the ~~impact~~ **notional amounts** of **$ 500 million, through September 25, 2026, following the expiration of our current interest rate swap. The new interest rate swaps are at** higher interest rates **than the current swaps** . ~~We cannot assure~~ **As a result of the lower notional amount and higher interest rates, we expect** that we **will continue** ~~would be able~~ to ~~extend this hedge~~ **have exposure to increased interest rates and incur charges for interest** at ~~an attractive price and terms~~ **a higher rate, following the expiration of our current interest rate swap on December 17, 2023** . GENERAL RISK FACTORS Provisions in our charter, bylaws, and indebtedness may have the effect of discouraging advantageous offers for our business or common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. Our charter, bylaws, and the provisions of the Delaware General Corporation Law include provisions that may have the effect of discouraging or preventing a change of control. Our indebtedness also contains provisions which either accelerate or require us to offer to repurchase the indebtedness at a premium upon a change of control. These provisions could limit the price that our stockholders might receive in the future for shares of our common stock. Our stock price is volatile. The market price of our common stock has been, and may continue to be, highly volatile. We believe that a variety of factors could cause the price of our common stock to fluctuate, perhaps substantially, including: • new, or changes in, recommendations, guidelines or studies that could affect the use of our products; • announcements and rumors of developments related to our business, including changes in reimbursement rates or regulatory requirements, proposed and completed acquisitions, or the industry in which we compete; • published studies and reports relating to the comparative efficacy of products and markets in which we participate; • quarterly fluctuations in our actual or anticipated operating results and order levels; • general conditions in the U. S. or worldwide economy; • our stock repurchase program; • announcements of technological innovations; • new products or product enhancements by us or our competitors; • developments in patents or other intellectual property rights and litigation; • developments in relationships with our customers and suppliers; • the implementation of healthcare reform legislation and the adoption of additional reform legislation in the future; and • the success or lack of success of integrating our acquisitions. In addition, the stock market in general and the markets for shares of " high- tech " and life sciences companies, have historically experienced extreme price fluctuations which have often been unrelated to the operating performance of affected companies. Any such fluctuations in the future could adversely affect the market price of our common stock, and the market price of our common stock may decline.