Risk Factors Comparison 2025-02-27 to 2024-02-29 Form: 10-K

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In addition to the other information contained in this Annual Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. The risks and uncertainties described below are not the only risks and uncertainties that we face **. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future** . Additional risks and uncertainties not known to us or that we currently deem immaterial may also impair our business operations. The occurrence of any of the following risks may materially and adversely affect our business, financial condition, results of operations and future prospects. Risk Factors Summary The following is a summary of the principal risks that could adversely affect our business, results of operations and financial condition: • the highly competitive nature of our industry and market ~~segment~~ **segments** ; • failure to research and successfully develop new technologies, products and services and develop new markets; • adverse developments in global market, macroeconomic and geopolitical conditions; • fluctuations or a decline in sales of our respiratory products; • the loss of any key distributor or the failure to retain or expand our customer relationships; • interruptions and delays in the supply of raw materials, components, equipment and other products and services provided to us, and manufacturing or warehousing problems or delays; • the failure of our collaboration partners to fulfill their obligations to us; • decreases in the number of surgical procedures performed, and the resulting decrease in blood demand; • fluctuations in our cash flows as a result of our reagent rental model; • our inability to achieve market acceptance of our products; • significant changes in the healthcare industry and related industries that we serve, ~~in~~ **including** an effort to reduce costs; • consolidation of our customer base and the formation of group purchasing organizations; • inability to realize the anticipated benefits of acquisitions, divestitures or discontinuances of certain business operations; • **legal and regulatory risks, reputational harm or other adverse business consequences as a result of implementing artificial intelligence (" AI ") and machine learning technologies; •** risks associated with our non- U. S. operations and international sales, including currency translation risks, the impact of possible new **sanctions or** tariffs, trade embargoes or trade wars and compliance with applicable trade measures; • failure to integrate successfully the businesses of Quidel and Ortho in the expected timeframe; • continued incurrence of significant **integration** ~~transaction and merger~~ related costs; • our inability to protect our information systems and personal and confidential information **, including** from data corruption, cyber- attacks ~~and~~ **,** security breaches **or IT errors** ; • interruptions to our third- party IT service providers and / or the inability of our digital solutions to interoperate with certain operating systems; • our inability to develop, obtain and protect our proprietary technology rights or defend against intellectual property infringement suits against us by third parties; • the loss of EUAs on our respiratory products; • our inability to obtain or maintain required clearances or approvals for our products, including approval requirements of the foreign countries in which we sell our products; • our ~~ability~~ **inability** to adequately manage our clinical studies; • failure to comply with applicable regulations **by the FDA and other federal, state and foreign regulatory agencies** , which may result in significant costs ~~or~~ **,** the suspension or withdrawal of previously obtained **regulatory** ~~clearances or~~ approvals **, product recalls, seizure of products or injunctions against the distribution of our products, operating restrictions and criminal prosecution** ; • disruptions at government agencies that prevent them from performing normal business functions or prevent new or modified products from being developed, cleared, approved or commercialized in a timely manner, or at all; • inability to procure government contracts, including due to government- sponsored tendering requirements, lack of funding and compliance and possible sanctions risks associated with ~~our~~ contracts with government entities; • liability claims and harm to our reputation resulting from claims that our products are defective **or do not comply with applicable regulations** ; • failure to comply with **applicable healthcare** laws and ~~regulations, including healthcare~~ regulations, laws and regulations associated with our use of hazardous materials, **anti- bribery and** anti- corruption laws and regulations, and federal, state and foreign privacy, data security and data protection laws and regulations; • risks related to changes in U. S. and foreign income tax laws and regulations; • **our** need to raise additional funds to finance our future capital or operating needs or other business purposes; • risks related to our indebtedness; • our ~~ability~~ **inability** to generate cash flow to service our debt obligations; • restrictions imposed under the agreements governing our indebtedness from time to time, which may limit our operating flexibility; • difficulty attracting, motivating and retaining executives and other key employees; • unexpected payments to any defined benefit plans or other post-employment benefit plans applicable to our employees; • work stoppages, union negotiations, labor disputes and other matters associated with our labor force **; • identified material weaknesses in our internal controls** ; • the outcomes of legal proceedings instituted against us; • additional costs and new risks associated with ~~ESG~~ **sustainability** matters, including evolving legal standards and regulations concerning such matters; • risks that the insurance we maintain may not fully cover any or all potential exposures; • certain provisions of our amended and restated certificate of incorporation (our " Charter "), our amended and restated bylaws (our " Bylaws ") and Delaware law that may make takeover attempts difficult, which could depress the price of our common stock, or limit our stockholders' ability to obtain a favorable judicial forum for disputes; • the volatility of the market price of our common stock; **and** • risks associated with future sales of our common stock by us or our stockholders in the public market ~~; and • failure to develop or maintain an effective system of internal controls~~ . The following is a more complete discussion of the risks facing our business that we have determined are currently material. Risks Relating to Our Business, Strategy and Operations The industry and market ~~segment~~ **segments** in which we operate are highly competitive, and our failure to compete effectively could adversely affect our sales and results of operations. Our diagnostic tests and services

compete with similar products made by our competitors. We may not be able to supply customers with products and services that they deem superior or at competitive prices, and we may lose business to our competitors. There are a large number of multinational and regional competitors making investments in competing technologies, products and services, including several large pharmaceutical and diagnostics companies and diagnostic divisions of diversified healthcare companies and conglomerates. We also face competition from our distributors and retail customers as some have created, and others may decide to create, their own products and services to compete with ours. A number of our competitors have competitive advantages, such as substantially greater financial, managerial, technical, R & D, clinical, manufacturing, and regulatory resources, capabilities and experience, and more established, larger and broader coverage in marketing, sales, distribution and service organizations and other resources than we have. Moreover, some competitors offer broader product lines and have greater name recognition than we have. Our operating results could be materially and adversely affected if: • customers and potential customers believe our competitors' products and services better address their needs and expectations through product performance, product offerings, cost, automation or work- flow efficiencies, and even if we can demonstrate that our products and services meet their needs and expectations, they may resist changing to our products; • our competitors take market share from our products, or we may not win opportunities because our competitors have or are perceived to have more effective servicing or marketing or greater or more timely product availability; • our competitors are able to obtain regulatory approvals for products or services or otherwise ~~bring~~ **deliver** competing products to market earlier than us; or • our competitors offer more competitive pricing or we fail to manufacture, in a cost- effective way, or at all, sufficient quantities of our products to meet customer demand. Competitive and regulatory conditions in many markets in which we operate restrict our ability to fully recover through price increases, higher costs of acquired goods and services resulting from inflation, and other drivers of cost increases. In addition, there has been a trend toward industry consolidation in our markets over the last few years. We may not be able to compete successfully in an increasingly consolidated industry. We expect this trend toward industry consolidation to continue as companies attempt to strengthen or hold their market positions in an evolving industry. If we are unable to compete successfully in this highly competitive industry, it could have a material effect on our business, financial condition and results of operations. In order to remain competitive and profitable, we must expend considerable resources to research and successfully develop new technologies, products and services and develop new markets, and there is no assurance our research efforts and our efforts to develop new technologies, products and services or markets will be successful or such technologies, products and services or markets will be commercially viable or accepted. Our ability to retain customers, attract new customers, grow our business and enhance our brand depends on our success in developing and delivering products and services that meet our customers' needs and expectations. We devote a significant amount of financial and other resources to researching and developing new technologies, products, services and markets. The development, manufacture and sale of diagnostic products and services and new technologies require a significant investment of resources, such as employee time, offices and R & D and manufacturing facilities, and development of new partners and channels. Furthermore, developing and manufacturing new products and services require us to anticipate customers' and patients' needs and emerging technology trends accurately. We may experience R & D, manufacturing, regulatory, marketing and other difficulties that could delay or prevent our introduction of new or enhanced products and services. The R & D process in the healthcare industry generally takes a significant amount of time from design stage to product launch. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. In addition, innovations may not be accepted quickly in the marketplace, or at all, because of, among other things, entrenched patterns of clinical practice or uncertainty over third- party reimbursements. In the event of such failure, we may need to abandon a product or service in which we have invested substantial resources. We cannot be certain that: • any of our products or services under development will be successfully developed, or if developed, will be timely introduced to the market; • any of our products or services under development will prove to be safe and effective in clinical trials; • we will be able to obtain, in a timely manner or at all, necessary regulatory approvals; • the products and services we develop can be manufactured or provided at acceptable cost and with appropriate quality; or • these products and services, if and when approved, can be successfully marketed or will be adopted in the market. If we are unable to deliver reliable products in a timely manner, promptly respond to and address quality issues, provide expected levels of customer service, and comply with applicable regulations and rules, our ability to deliver products that meet our customers' needs and expectations and our competitive position, branding and results of operations may be adversely and materially affected. Global market, macroeconomic and geopolitical conditions may adversely affect our operations and performance. The growth of our business and demand for our products and services are affected by changes in the health of the overall global economy and, in particular, of the healthcare industry. Demand for our products and services could change more dramatically than in previous years based on funding and reimbursement constraints and support levels from governments, universities, hospitals and the private industry, including laboratories. Our global business is adversely affected by decreases in the general level of economic activity, such as decreases in business and consumer spending, increases in unemployment rates, the inflationary environment, ~~rising~~ **high** interest rates, a recessionary environment, instability in financial institutions and budgeting constraints of governmental entities. Disruptions in the U. S., Europe, China or in other geographies, including as a result of the ongoing ~~conflict~~ **conflicts** in Ukraine and the **Middle East** ~~Israel- Hamas conflict~~ , or ~~weakening of~~ **increasing regulation in** emerging markets, such as China, could adversely affect our sales, profitability and / or liquidity. A deterioration in financial markets, including due to instability in financial institutions, or reduction in confidence in major economies or other macroeconomic developments could affect businesses such as ours in a number of ways. A tightening of credit in financial markets could adversely affect the ability of our customers and suppliers to obtain financing for significant purchases and operations, could result in a decrease in or cancellation of orders for our products and services and could impact the ability of our customers to make payments. Similarly, a tightening of credit may adversely affect our supplier base, increase the potential for one or more of our suppliers to experience financial distress or bankruptcy, and could also impact our operations more directly, including any outstanding or contemplated credit

facility or other borrowings. Our financial position, results of operations and cash flows could be materially adversely affected by difficult conditions and volatility in the capital, credit and commodities markets. Fluctuations or a decline in sales of our respiratory products could materially and adversely affect our operating results. A significant percentage of our total revenues is generated from a limited number of our product families. In particular, revenues from the sales of our respiratory products have represented a significant portion of our total revenues. Sales of our respiratory products accounted for approximately ~~24~~ **18** % of our total revenues for the year ended December ~~31~~ **29** , ~~2023~~ **2024** . Demand for our respiratory products has and may continue to fluctuate or decline as a result of a number of factors, including but not limited to the severity of the respiratory season, the emergence and impact of new variants or resurgences, the effectiveness of vaccination efforts, and the increased market supply of respiratory products by our competitors. The gross margins derived from sales of our respiratory products are generally significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our respiratory products fluctuate or decline for any reason, whether as a result of ~~COVID- 19 reaching an endemic stage,~~ a mild respiratory season, market share loss or price pressure, obsolescence, regulatory matters, or any other reason, our operating results would be materially and adversely affected on a disproportionate basis. A significant portion of our total revenues are from a relatively small number of customers, and if we fail to retain or expand our customer relationships or significant customers terminate or do not renew their contracts, our business, operating results and financial condition could be adversely affected. A significant portion of our revenues are from sales of products and services to distributors. Although we have many distributor relationships in the U. S. and globally, the market is dominated by a small number of these distributors and as a result, we rely on certain key distributors for the sales of some of our products. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives are timely found or lost sales to a distributor are taken up by another distributor or in direct sales. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry' s competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. In addition, our efforts to distribute our products directly in some markets may be unsuccessful. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales. In addition to distributors, we also have a number of direct customers who are significant. If our relationships with these customers are terminated, or such customers do not renew their contracts with us, or substantially reduce or stop ordering from us, and if we do not add new large customers over time, our business could be harmed. Our ability to continue to generate revenue from our significant customers will depend on our ability to maintain strong relationships with these customers and introduce competitive new products and services at competitive prices. Moreover, customer consolidation could reduce the number of customers and may increase the risk of our dependence on a small number of customers. If total revenues from some of our significant customers were to decrease or not continue in any material amount in the future, or if we are not successful in growing our current or new customer relationships or timely transitioning our business from a lost or terminated distributor to one or more new distributors or to direct sales, our business, operating results and financial condition could be materially and adversely affected. Interruptions and delays in the supply of raw materials, components, equipment and other products and services could adversely affect our operations and financial results. We depend on third- party manufacturers, suppliers and vendors for some of our materials, components, equipment, packaging and other products and services. Any change in our relationship with our contract manufacturers, suppliers of raw materials and other third- party vendors or changes to terms of our arrangements with any of them could adversely affect our financial condition and results of operations. In addition, we have experienced shortages and delays in receiving certain raw materials and other components for our products and have experienced logistics and distribution challenges, as well as challenges in labor availability and rising labor costs. We cannot predict the frequency, duration or scope of these supply, production, logistics, distribution and labor disruptions and challenges. Unexpected increases in demand for our products or services or supply shortages could require us to incur additional costs to meet customer demand. These costs could involve purchasing or producing a safety stock of components or products, purchasing new machinery, obtaining additional labor resources or even acquiring or constructing new manufacturing facilities. Some supplies require significant ordering lead time and we may not be able to timely access sufficient supplies in the event of an unexpected increase in demand or supply shortage, or the cost of such supplies may be significantly greater. This would increase our capital and other costs, which could adversely affect our earnings and cash resources. Additionally, our reliance on a small number of contract manufacturers and a large number of single and sole source suppliers makes us vulnerable to possible production capacity or other constraints of such suppliers or in their supply chain and reduced control over manufacturing, product availability, delivery schedules and costs. While we proactively work with our suppliers, manufacturers, distributors, industry partners and government agencies to address these challenges in our efforts to meet the needs of our customers, such disruptions and challenges have materially affected and could further materially affect our ability to timely manufacture and distribute our products and have unfavorably impacted and could further unfavorably impact our results of operations. As a result, we have encountered, and may in the future encounter, significant customer backlogs of orders and inventory shipments. Further significant customer backlogs and our inability to meet customer demand for our products and services may adversely impact customer relationships, impair our reputation and affect our financial performance. Our business is also subject to risks associated with U. S. and foreign legislation, regulations and trade agreements relating to the materials we import, including quotas, duties, tariffs or taxes, and other charges or restrictions on imports, which could adversely affect our operations and our ability to import materials used in our products at current or increased levels, if at all. ~~Future~~ **New or increased** quotas, duties or tariffs **, or threats or changes in policy with respect to such trade restrictions,** may have a material adverse effect on our business, financial condition, results of operations or cash flows. Future trade agreements could also provide our competitors with an advantage over us or increase our costs, either of which could have a material adverse effect on our business, financial condition, results of operations or cash flows. In addition,

due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. For example, stringent requirements of the FDA and other regulatory authorities regarding the manufacture of certain of our products may prevent us from quickly establishing additional or replacement sources for the raw materials, products, components or manufacturing services that we use, or from doing so without excessive cost. Further, our suppliers may be subject to regulation or other actions by the FDA and other regulatory authorities that could hinder their ability to produce necessary raw materials, products and components. The implementation of these requirements has caused and will continue to cause increased costs to comply with these requirements and may inhibit our ability to source these materials. If our current contract manufacturers, suppliers of raw materials and other third- party vendors are unable or unwilling to manufacture or supply our products or components or requirements for raw materials in required volumes and at required quality levels or renew or continue existing terms under supply arrangements, we may be required to replace such manufacturers, suppliers and vendors and may be unable to do so in a timely or cost- effective manner, or at all. Any shortage in our supply of raw materials, equipment or components, or our inability to quickly and cost- effectively obtain alternative sources for this supply, could have a material adverse effect on our business, financial condition and operating results. We may experience manufacturing or warehousing problems or delays due to, among other reasons, our volume, specialized processes, natural disasters, public health crises and macroeconomic and geopolitical conditions. The global supply of some of our products depends on the uninterrupted efficient operation of our manufacturing facilities, and the continued performance of our contract manufacturers, suppliers of raw materials and other third- party vendors under our supply arrangements. Many of our manufacturing processes are complex and involve sensitive scientific processes involving the use of unique and often proprietary antibodies and other raw materials that cannot be replicated or acquired through alternative sources without undue delay or expense. Other processes present difficult technical challenges to obtain the manufacturing yields necessary to operate profitably. In addition, our manufacturing processes may require complex and specialized equipment, which can be expensive to maintain, repair or replace with required lead times of up to a year. The manufacturing of certain of our products is concentrated in one or more of our manufacturing plants or those of our contract manufacturers, with no or limited alternate facilities. We have significant operations in California, near major earthquake faults and areas vulnerable to wildfire, which make us susceptible to earthquake and fire risk. We also have significant operations in Rochester, New York, Raritan, New Jersey, Pencoed, Wales, Pompano Beach, Florida, and Athens, Ohio. Severe weather, natural disasters, public health crises, fires, power shortages or outages, terrorism, political change or unrest, failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors, damage to our equipment or one or more of our facilities, catastrophic events or other events outside of our control, or any other event that negatively impacts our manufacturing process, facilities, systems or equipment, or the process, facilities, systems or equipment of our contract manufacturers, suppliers or other third- party vendors on which we depend, could delay, reduce, suspend or terminate production of products or the release of new products, result in the delivery of inferior products or otherwise disrupt our operations. In such circumstances, our revenue would decline and we could incur losses until such time as we or our contract manufacturers are able to restore or rebuild our or their production processes or we are able to put in place alternative contract manufacturers, suppliers or third- party vendors. Similarly, any disruption or other operational challenges to one of our primary warehouse facilities could result in decreased revenue or increased costs given the challenge in finding suitable alternative facilities. Our collaboration arrangements may not operate according to our business strategy if our collaboration arrangement partners fail to fulfill their obligations. As part of our business, we are party to collaboration arrangements with other companies, including the Joint Business with Grifols, and we may enter into additional collaboration arrangements in the future. The nature of a collaboration arrangement requires us to share control over significant decisions with unaffiliated third parties. Since we may not exercise exclusive control over our current or future collaboration arrangements, we may not be able to require our collaboration arrangement partners to take actions that we believe are necessary to implement our business strategy. Disputes between us and our collaboration arrangement partners could also result in litigation, which can be expensive and time- consuming. Additionally, differences in views among collaboration arrangement partners may result in delayed decisions or failures to agree on major issues. If these differences cause our collaboration arrangements to deviate from our business strategy, our results of operations could be materially adversely affected. A decrease in the number of surgical procedures performed, and the resulting decrease in blood demand, could negatively impact our financial results. Our immunohematology and donor screening products are frequently used in connection with the testing of blood prior to transfusion, which is typically associated with surgical procedures. A decrease in the number of surgeries being performed in the markets in which we operate can result in decreased demand for blood for transfusions, resulting in lower testing volumes and, therefore, decreased sales of our products. In addition, blood is a large expense for hospitals and pressure on hospital budgets due to macroeconomic factors and healthcare reform could force changes in the ways in which blood is used and lower blood demand. Fewer surgeries and lower blood demand could negatively impact our revenue, profitability and cash flows. Our reagent rental model reduces our cash flows during the initial part of the applicable contract, which causes our cash flows to fluctuate from quarter to quarter. Leases, rather than sales, of instruments under our reagent rental model have the effect of reducing cash flows during the initial part of the applicable contract as we support those commercial transactions until we are able to recover our investment over the life of the contract. The use of cash in connection with this model causes our cash flows to fluctuate from quarter to quarter and may have a negative effect on our financial condition. We may not achieve market acceptance of our products by customers and this would have a negative effect on future sales. We maintain customer relationships with numerous physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies, wellness screening centers, other POC settings, blood banks and donor centers, individual, non- professional OTC customers and other customers. We believe that sales of our products depend significantly on our customers' confidence in, and recommendations of, our products. In addition, in a number of cases, our success depends on technicians' acceptance and confidence in the effectiveness and ease- of- use of our products

and services, including our new products. If we do not capture sales at the levels anticipated, our total revenues will not be at the levels that we expect and the costs we incur or have incurred may be disproportionate to our sales levels. In order to achieve acceptance by healthcare professionals, we seek to educate the healthcare community as to the distinctive characteristics, perceived benefits, clinical efficacy and cost- effectiveness of our products and services compared to alternative products. Acceptance of our products also requires effective training of healthcare professionals in the proper use and application of our products. Failure to effectively educate and train our technician end- users, continue to develop relationships with leading healthcare professionals or achieve market acceptance from healthcare providers or other customers with respect to the use of our diagnostic products could result in lower acceptance or fewer recommendations of our products, which may adversely affect our sales and profitability. The healthcare industry and related industries that we serve have undergone, and are in the process of undergoing, significant changes ~~in~~ **, including** an effort to reduce costs, which could adversely affect our business, financial condition and results of operations ~~. The healthcare industry and related industries that we serve have undergone, and are in the process of undergoing, significant changes in an effort to reduce costs~~ . Many of our customers, and the end- customers to whom our customers provide products, rely on private or government funding of and reimbursement for healthcare products and services and research activities. In the U. S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third- party payors, principally private health insurance plans and federal Medicare and Medicaid, to reimburse all or part of the cost of the procedure, and these payors may reduce or modify reimbursement rates. For example, CMS implemented certain provisions of PAMA, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. The revised reimbursement methodology under PAMA results in relatively lower reimbursement under Medicare for clinical diagnostic lab tests than has been historically available. Such changes in the U. S., healthcare austerity measures in Europe and other potential global healthcare reform changes and government austerity measures may reduce the amount of government funding or reimbursement available to customers or end- customers of our products and services and / or the volume of medical procedures using our products and services. Third- party reimbursement and coverage may not be available or adequate in either the U. S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, legislative amendments, regulation or reimbursement policies of third- party payors may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis. Governmental and private healthcare providers and payors around the world are increasingly utilizing managed care for the delivery of healthcare services, forming group purchasing organizations to improve their purchasing leverage and using competitive bid processes to procure healthcare products and services. Health insurance premiums, co- payments and deductibles have also generally increased in recent years. These increases may cause individuals to forgo health insurance, as well as medical attention. This behavior may reduce the demand for certain of our diagnostics products and services. Such changes may cause participants in the healthcare industry to purchase fewer of our products and services, reduce the prices they are willing to pay for our products or services, reduce the amounts of reimbursement and funding available for our products or services from governmental agencies or third- party payors, reduce the volume of medical procedures that use our products and services and increase our compliance and other costs. Moreover, we believe the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Any of the factors described above could adversely affect our business, financial condition and results of operations. Consolidation of our customer base, the formation of group purchasing organizations and government- sponsored tendering processes could materially adversely affect our sales and results of operations. Consolidation among healthcare providers and the formation of buying groups and, with respect to our international operations, government-sponsored tendering processes, have put pressure on pricing and sales of our products, and in some instances, required payment of fees to group purchasing organizations or required us to provide lower pricing in the tendering process. Our success in these areas depends partly on our ability to enter into contracts with integrated health networks and group purchasing organizations. If we are unable to enter into contracts with these group purchasing organizations and integrated health networks on terms acceptable to us or if we fail to have our pricing terms accepted in the tendering process, our sales and results of operations may be adversely affected. Even if we are able to enter into these contracts or have our pricing terms accepted in the tendering process, they may be on terms that negatively affect our current or future profitability. For example, the Chinese government has started to expand its volume- based procurement (" VBP ") program to diagnostics at the provincial level, which aims to lower prices in exchange for high volume purchases. Some of our immunoassay products fall within the VBP scope in Anhui Province in China. Furthermore, given the average industry contract length for our Ortho instruments is five to seven years, if we are unable to enter into a contract with a new customer or renew a given contract with an existing customer, it may be several years before we have an opportunity to acquire or reacquire, as applicable, such customer' s business, which may have a material adverse effect on our results of operations in the interim period. We may engage in acquisitions or divestitures or discontinue business operations, and may encounter difficulties integrating acquired businesses with, or disposing of divested or discontinued businesses from, our current operations; therefore, we may not realize the anticipated benefits of these acquisitions, divestitures or discontinuances. We may seek to grow through strategic acquisitions. Our due diligence reviews of our acquisition targets may not identify all of the material issues necessary to accurately estimate the cost or potential loss contingencies with respect to a particular transaction, including potential exposure to regulatory sanctions resulting from an acquisition target' s previous activities as well as potential vulnerability to cybersecurity risks. We may incur unanticipated costs or expenses, including post- closing asset impairment charges, expenses associated with eliminating duplicate facilities, litigation and other liabilities. We also may encounter difficulties in integrating acquisitions with our operations, applying our internal controls processes to these acquisitions, retaining key technical and management personnel, complying with regulatory requirements, or managing strategic investments. Additionally, we may not achieve the benefits we anticipate when we first enter into a transaction in the amount or timeframe anticipated, if at all. Any of the foregoing could adversely affect our business

and results of operations. In addition, accounting requirements relating to business combinations, including the requirement to expense certain acquisition costs as incurred, may cause us to experience greater earnings volatility and generally lower earnings during periods in which we acquire new businesses. We may also make strategic divestitures or discontinue certain business operations from time to time if certain of our businesses do not meet our strategic, growth or profitability objectives. For example, in February 2024, we initiated a ~~wind- down~~ plan to transition out of ~~the~~ **our** U. S donor screening portfolio **through the wind- down of the VIP platform and microplate assays** , which ~~has~~ **are only sold in the U. S. and have** a lower growth and margin profile ~~than other parts of our Transfusion Medicine business~~ . Divestitures may result in continued financial involvement in the divested businesses, such as through guarantees, indemnity obligations or other financial arrangements, following those transactions. Under these arrangements, nonperformance by those divested businesses could result in financial obligations imposed upon us and could affect our future financial results. There can be no assurance that we will be able to complete any such divestiture on terms favorable to us. The divestiture or discontinuance of certain businesses could result, individually or in the aggregate, in the recognition of material losses and a material adverse effect on our results of operations. **We have been incorporating AI into our internal operations and may incorporate AI into our products and services. Implementation of AI and machine learning technologies may result in legal and regulatory risks, reputational harm or have other adverse consequences to our business. We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our internal operations and may incorporate AI into our products and services, which may enhance their operation and effectiveness internally and for our customers, suppliers, and consumers. There can be no assurance that we or our customers will realize the expected benefits from such implementation of AI. AI innovation presents risks and challenges that could impact our business. Our, or our vendors', AI algorithms may be flawed. Our datasets or AI training algorithms may be insufficient or contain biased information. Additionally, many countries and regions, including the EU, have proposed new and evolving regulations related to the use of AI and machine learning technologies. The regulations may impose onerous obligations and may require us to unexpectedly rework or reevaluate improvements to be compliant, which may result in the development of products that are subsequently unacceptable under new or revised regulatory frameworks. Use of AI technologies may expose us to an increased risk of regulatory enforcement and litigation. Moreover, some AI features involve the processing of personal data and may be subject to laws, policies, legal obligations, and codes of conduct related to privacy and data protection. AI development and deployment practices could subject us to competitive harm, regulatory enforcement, increased cybersecurity risks, reputational harm, and legal liability.** Risks Relating to Our International Operations As a global business, we face risks relating to our non- U. S. operations and international sales, including inherent macroeconomic, geopolitical and regulatory risks, that could impact our financial performance, cause interruptions in our current business operations and impede our growth strategy. We conduct our business on a global basis, as our products are sold internationally, with the majority of our international sales to our customers in our EMEA and China regions. Our international operations are subject to inherent macroeconomic, geopolitical and regulatory risks, which could adversely impact our financial performance, cause interruptions in our business operations, impede our international growth and subject us to civil or criminal penalties, other remedial measures and legal expenses. These ~~foreign~~ risks include, among others: • compliance with multiple different registration requirements and new and changing product registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations; • compliance with complex foreign and U. S. laws and regulations that apply to our international operations, including **regulations in the U. S., EU and other jurisdictions impacting the marketing of our products,** U. S. laws on import / export limitations, the FCPA, and local laws prohibiting corrupt payments to governmental officials **, including anti-corruption laws in China** ; • lost revenue as a result of macroeconomic developments, including the inflationary environment and recessionary fears; • the imposition **or threat of, or changes in policy regarding, trade barriers (such as sanctions, tariffs, quotas, preferential bidding, import restrictions or other barriers)** by **U. S. or** foreign governments ~~of trade barriers such as tariffs, quotas, preferential bidding, import restrictions or other barriers~~ ; • exposure to currency exchange fluctuations against the U. S. dollar; • decreased liquidity resulting from longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection and enforcing agreements through foreign legal systems; • lower productivity resulting from difficulties we may encounter in staffing and managing sales, customer support and R & D operations across many countries; • difficulties associated with navigating foreign laws and legal systems; • difficulties in identifying potential third- party distributors or distribution channels; • import or export licensing requirements, both by the U. S. and foreign countries; • **U. S. or** international sanction regimes, including future regulations and sanctions that could further limit the countries in which our products may be manufactured or sold, increase the cost of conducting business in these countries, or restrict our access to, or increase the cost of obtaining, products from foreign sources; • reduced or lack of protection for and enforcement of our intellectual property rights; • social, geopolitical or macroeconomic instability in some of the regions where we currently sell our products or operate or where we may expand into in the future, including as a result of conflicts, including the ongoing ~~conflict~~ **conflicts** in Ukraine and the **Middle East** ~~Israel- Hamas conflict~~ , acts of terrorism, civil unrest, wars, pandemics, endemics or other public health crises, environmental incidents and disruptions in global transportation; • increased financial accounting and reporting burdens and complexities; • import and export duties, changes to import and export regulations, customs regulations and processes, and restrictions on the transfer of funds, including currency controls; • complex and potentially adverse tax consequences resulting from international tax laws; • transportation difficulties and delays resulting from inadequate local infrastructure; and • diversion of our products into the U. S. or other markets that are sold into other international markets at lower prices. The occurrence of any of these or other factors over which we do not have control could lead to reduced revenue and profitability. Currency translation risk and currency transaction risk may adversely affect our financial condition, results of operations and cash flows. We transact business in numerous countries around the world and

expect that a significant portion of our business will continue to take place in international markets. Because our financial statements are presented in U. S. dollars, we must translate earnings as well as assets and liabilities into U. S. dollars at exchange rates in effect during or at the end of each reporting period, as applicable. Therefore, increases or decreases in the value of the U. S. dollar against other currencies in countries where we operate will affect our results of operations and the value of balance sheet items denominated in foreign currencies. Furthermore, many of our local businesses generate revenues and incur costs in a currency other than their functional currency, which can impact the operating results for these operations if we are unable to mitigate the impact of foreign currency fluctuations. Accurately predicting the effects of exchange rate fluctuations upon our future operating results is difficult because of the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates. Accordingly, our profitability could be affected by fluctuations in foreign exchange rates. Given the volatility of exchange rates, we may not be able to effectively manage our currency transaction and / or translation risks, and any volatility in currency exchange rates may have an adverse effect on our financial condition, results of operations and cash flows. We have entered into hedging agreements to address certain of our currency risks and intend to utilize local currency funding of expansions when appropriate. Risks Relating to **Our Integration** ~~the Consummation of the Combinations~~ and ~~our Transformation~~ **Business Efficiency** Efforts The failure to integrate successfully the businesses of Quidel and Ortho would adversely affect our future business and financial performance. As a result of the Combinations, we have been and continue to devote significant management and employee attention and resources to integrate the business practices and operations of Quidel and Ortho. The integration process may disrupt our business and, if implemented ineffectively, could preclude realization of the full benefits we expect to result from the Combinations. Any failure to meet the challenges involved in successfully integrating the operations of Quidel and Ortho or otherwise to realize the anticipated benefits of the Combinations could also seriously harm our results of operations. In addition, the integration of Quidel and Ortho may result in material unanticipated problems, expenses and liabilities. The difficulties of combining the operations of Quidel and Ortho, some of which we have already experienced, include, among others: • managing a significantly larger company and expanded business operations and the associated increased costs and complexity; • aligning and executing our strategy; • inconsistencies in standards, controls, systems, procedures and policies; • the possibility of faulty assumptions underlying expectations regarding the integration process and results; • coordinating sales, distribution and marketing efforts; • integrating IT, enterprise resource planning (" ERP "), customer relationship management and other systems, including the implementation of a new ERP system to integrate certain existing business, operational and financial processes, which requires significant investment of capital and human resources and the reengineering of many business processes; • managing tax costs or inefficiencies associated with integrating the operations of Quidel and Ortho; and • taking actions that may be required in connection with obtaining regulatory approvals. Many of these factors are outside of our control and any one of them could subject us to increased costs, decreased revenues and diversion of management' s and employees' time and energy, which could materially impact our business, financial condition and results of operations. In addition, we are transitioning from integration efforts of the two independent businesses to focusing on ~~transformation~~ **business efficiencies** of the combined company with the goal of creating a more efficient and agile company. We may not realize the full benefits of the Combinations **and our business efficiency initiatives** , including the synergies, cost savings or sales or growth opportunities that we expect ~~from the Combinations and transformation~~ , or these benefits may take longer to realize than expected. If we are unable to realize the anticipated benefits and synergies expected from the Combinations and ~~transformation~~ **our business efficiency initiatives** within the anticipated timeframe, our business, financial condition and operating results may be adversely affected. We will continue to incur significant **integration** ~~transaction and merger~~ - related costs in connection with the Combinations. We have incurred and expect to continue to incur a number of non- recurring direct and indirect costs associated with the Combinations. There are processes, policies, procedures, operations, technologies and systems that still must be integrated in connection with the Combinations and the integration of Quidel' s and Ortho' s businesses. While we have assumed that a certain level of expenses would be incurred in connection with the Combinations and continue to assess the magnitude of these costs, there are many factors beyond our control that could affect the total amount or the timing of the integration and implementation expenses. Although we expect that the strategic benefits of the Combinations will offset the ~~transaction~~ **integration and implementation** expenses ~~and implementation costs~~ over time, this net benefit may not be achieved in the near term or at all. Risks Relating to Our IT Systems Our ability to protect our information systems and personal and confidential information **, including** from data corruption, cyber- attacks ~~and~~ **,** security breaches **or IT errors,** is critical to the success of our business. We are highly dependent on IT networks and systems, including our office networks, operational environment, special purpose networks, systems and software used to provide our products and services, including operating our instruments and devices, and those networks and systems managed by vendors or third parties, to securely collect, process, transmit, disclose, share, use and store electronic information (including sensitive personal information and proprietary or confidential information) (collectively, " information systems "). Our information systems may prove inadequate to our business needs and necessary upgrades may not be available or operate as designed, which could result in excessive costs or disruptions in portions of our business. These risks may be heightened as we integrate the combined systems and operations of Quidel and Ortho. Like any large corporation, from time to time the information systems on which we rely, including those controlled and managed by third parties, **are** ~~may be~~ subject to computer viruses, malicious software, attacks by hackers and other forms of cyber intrusions or unauthorized access, any of which can create system disruptions, shutdowns or unauthorized disclosure of personal or confidential information, all of which can be timely and costly to remediate. In addition, a security breach that impacts personal information could require us to comply with breach notification requirements under applicable data privacy and security laws, result in litigation or regulatory action, or otherwise subject us to liability under those laws. If we experience a significant incident, such as a serious product vulnerability or security breach, or any other disruptions, delays or deficiencies from our ERP systems, it could adversely affect our ability to, among other processes, process orders, procure supplies, manufacture and ship products, track inventory, provide services and customer

support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. If this happens, our revenues could decline and our business could suffer, and we may need to make significant further investments to protect our information systems, data and infrastructure. An actual or perceived vulnerability, failure, disruption or breach of our information systems also could adversely affect the market perception of our products and services, as well as our perception among new and existing customers. Additionally, a significant security breach could result in theft of trade secrets and intellectual property, cause us to incur increased costs from insurance premiums and remediation measures and subject us to potential liability, litigation and regulatory or other government action. If any of the foregoing were to occur, our business strategy, results of operations or financial condition could be materially and adversely affected. We attempt to mitigate the above risks by employing a number of measures, including implementing technical, physical and organizational security measures, monitoring and testing our security controls, conducting employee training and maintaining protective systems and contingency plans. Further, our contractual arrangements with service providers aim to appropriately mitigate third- party cybersecurity risks. We also maintain insurance coverage for cybersecurity incidents, which may not be adequate or cover all incidents. It is impossible to eliminate all cybersecurity risk and thus our information systems, products and services, as well as those of our service providers, remain potentially vulnerable to known or unknown threats. Additionally, our information systems may be vulnerable to damage or interruption from circumstances beyond our control, including fire, natural disasters, power outages and system failures. Cybersecurity risks have generally increased in recent years because of the increased proliferation, sophistication and availability of complex malware and hacking tools to carry out cyber- attacks. As a result of the increased number of our employees with flexible work arrangements, we may also face increased cybersecurity risks due to our reliance on internet technology, which may create additional opportunities and vulnerabilities for cybercriminals to exploit. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period of time. As cybersecurity risks continue to evolve, we may be required to expend additional resources to mitigate new and emerging threats, while continuing to enhance our information security capabilities and investigate and remediate security vulnerabilities. For more information on our cybersecurity risk management, strategy and governance, ~~see~~ **refer to** Part I, Item 1C, " Cybersecurity. " Interruptions to our third- party IT service providers and / or the inability of our digital solutions to interoperate with certain operating systems could impair the delivery of our cloud- based solutions and negatively impact our business. We rely on a small number of third- party service providers to host and deliver our cloud- based solutions, and any interruptions or delays in services from these service providers could impair the delivery of our cloud- based solutions. We do not control the hosting of these solutions, including data center facilities, or our or other parties' access to the Internet. These facilities are vulnerable to damage or interruption from severe weather, natural disasters, fires, power loss, telecommunications failures, global pandemics and similar events. They are also subject to break- ins, computer viruses, sabotage, intentional acts of vandalism and other misconduct. We also depend on the interoperability of our mobile applications with popular mobile operating systems that we do not control, such as Android and iOS. Any changes in such systems that degrade the functionality of our digital solutions could negatively impact our business. Risks Relating to Our Intellectual Property To remain competitive, we must continue to develop, obtain and protect proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling lower priced or technologically superior products or services that compete with ours. Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology, and our competitive position is therefore heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses to proprietary technology from others. We own significant intellectual property, including patents, patent applications, trade secrets, know- how and trademarks in the U. S. and certain other countries. We make strategic decisions on whether to apply for intellectual property protection and the types of protection to pursue based on a cost- benefit analysis. While we endeavor to protect our intellectual property rights in certain jurisdictions in which our products are produced or used and in jurisdictions into which our products are imported, the decision to file for intellectual property protection is made on a case- by- case basis. Because of the differences in foreign trademark, patent and other laws concerning proprietary rights, our intellectual property rights may not receive the same degree of protection in foreign countries as they would in the U. S. **Furthermore, in recent years, the U. S. Supreme Court has ruled on several patent cases and several laws have been enacted that, in certain situations, potentially narrow the scope of patent protection available and weaken the rights of patent owners. As a result, companies may pursue an " efficient infringement " strategy, having concluded that it is cheaper to infringe third- party intellectual property rights than to acquire, license or otherwise respect them. There can be no assurance that we will be successful in securing additional patents on commercially desirable improvements, that such additional patents will adequately protect our innovations or offset the effect of expiring patents, or that competitors will not be able to design around our patents. In addition, third parties may challenge our issued patents through procedures such as Inter- Partes Review (" IPR "). In many IPR challenges, the U. S. Patent and Trademark Office (the " PTO ") may cancel or significantly narrow issued patent claims. IPR challenges could increase the uncertainties and costs associated with the maintenance, enforcement and defense of our issued and future patents and could have an adverse effect on our business, financial condition and results of operations. Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a**

European patent is granted, the patent owner can request unitary effect, thereby getting a European patent with unitary effect (a " Unitary Patent "). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (the " UPC "). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that we request to be treated or obtain as Unitary Patents remain under the jurisdiction of the UPC and may be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of the new unitary patent system. Certain of our intellectual property rights are held through license agreements and collaboration arrangements with third parties. **If we cannot retain these agreements or arrangements, we may not be able to sell, develop or commercialize our products.** We also rely on trade secrets and certain other know- how and unregistered rights in and to our products and it is possible that others will independently develop the same trade secrets, know- how and unregistered rights or obtain access to our trade secrets, know- how and unregistered rights. We license some of the rights to use our patents, trade secrets and know- how to third parties. Further, we rely on confidentiality agreements **, intellectual property assignment agreements** and other similar arrangements with our employees, consultants, advisors, collaborators and other persons who have access to our proprietary and confidential information, which may not **be enforceable or** provide meaningful protection for our proprietary technology **information in the event of unauthorized use or disclosure or other breaches of the agreements, or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to our brands and the names of some of our products, each providing different levels of protection. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations** . If we cannot continue to improve upon or develop, obtain and protect proprietary technology, we may lose market share or need to reduce prices as a result of competitors selling lower priced or technologically superior products or services that compete with our products. Failure to obtain or maintain adequate protection of our intellectual property rights for any reason, including failure to file patent or trademark applications successfully or at all, failure to obtain licenses on commercially reasonable terms if at all, failure to retain intellectual property rights, including upon termination of our licenses or collaboration agreements, or failure to police our intellectual property, including through our licensees, could have a material adverse effect on our business, results of operations and financial condition. Intellectual property risks, third- party claims of infringement, misappropriation or violation of proprietary rights and other claims against us could adversely affect our ability to market our products and services, require us to redesign our products or services or attempt to seek licenses from third parties, and materially adversely affect our operating results. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees. Companies in or related to our industry often aggressively protect and pursue their intellectual property rights. We are and have been subject to litigation with parties that claim, among other matters, that we infringed their patents or misappropriated intellectual property rights. We have hired and will continue to hire individuals or contractors who have experience in medical diagnostics and these individuals or contractors may have confidential trade secret or proprietary information of third parties. These individuals or contractors may use third- party information in connection with performing services for us or otherwise reveal third- party information to us. For these and other reasons, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations. In addition, to the extent that individuals or contractors apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such technical or scientific information and may result in litigation. Our customers may also be sued by other parties that claim that our products have infringed their patents or misappropriated their proprietary rights or that may seek to invalidate one or more of our patents. The defense and prosecution of patent and trade secret claims are both costly and time- consuming and could divert management' s attention from other business matters. Moreover, an adverse determination in any of these types of disputes could prevent us from developing, using, manufacturing or selling some of our processes or products and services; limit or restrict the type of work that employees involved with such products may perform for us; require us to obtain a license on the disputed rights, which may not be available on commercially reasonable terms, if at all; subject us to significant liability in the form of royalty payments, penalties, special and punitive damages and attorneys' fees; cause our distributors or end users to reduce or terminate purchases of our products; or require us to re- design our products or processes, any of which could materially and adversely affect our business, financial condition and results of operations. In addition to the foregoing, we may also be required to indemnify certain customers, distributors and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities have infringed upon, misappropriated or misused another person' s proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages. Risks Relating to Government Regulation Regulation of Our Industry and Products Some of our respiratory products were authorized by the FDA through an EUA and the loss of such authorization could have a material adverse effect on our business, results of operations, financial position and cash flows. The FDA can authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the HHS Secretary has made a declaration of emergency justifying authorization of emergency use ~~. An EUA allows use in a public health emergency to diagnose~~ , **as further described in Part I** ~~treat or prevent serious or life- threatening diseases or conditions caused by emerging infectious disease threats when~~

~~there are no adequate~~ , ~~approved and available alternatives~~ **Item 1, " Business — Government Regulations " of this Annual Report** . These EUA standards for marketing authorization are lower than if the FDA had reviewed our tests under its traditional marketing authorization pathways, and we cannot assure you that our EUA- approved tests would be cleared or approved under those more onerous clearance and approval standards. The FDA has also established certain conditions **of** ~~that must be met in order to maintain authorization under these~~ -- **the** ~~EUAs~~ - **EUA** ~~. The~~ **, including labeling and marketing** requirements **, which** ~~that apply to the manufacture and sale of these products~~ may be unclear and are subject to change ~~. The FDA may also waive otherwise applicable cGMP requirements to accommodate emergency response needs~~ . Some of our current respiratory products were initially authorized by the FDA under EUAs. HHS intends to publish advance notice of termination of each EUA declaration pertaining to medical devices in the Federal Register 180 days before the day on which the EUA declaration is terminated. HHS has not yet published such notice of termination for the EUAs we hold. While we have been working closely with the FDA to obtain traditional premarket clearance for some of our respiratory products by submitting de novo and 510 (k) submissions, the loss of one or more of our EUAs for our respiratory products, if we are unable to timely obtain traditional premarket clearance, could have a material adverse effect on our business, results of operations, financial condition or cash flows. If we are unable to obtain or maintain required clearances or approvals for the commercialization of our products in the U. S. and certain foreign countries, we will not be able to sell those products in such jurisdictions, which could negatively impact our results of operations. Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval, clearances or authorizations for new products in the U. S. and certain foreign countries where we intend to sell our products. The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U. S. and globally. Regulatory clearance and approval can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. In addition, regulatory processes are subject to change, and new or changed regulations can result in increased costs, unanticipated delays, or lengthened review times of our products. We may not be able to obtain U. S. and foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from selling our products in the U. S. or certain foreign countries, which may have a material adverse effect on our business, financial condition and results of operations. In the U. S., the FDA regulates most of our products. Clearance or approval to commercially distribute new medical devices is received from the FDA through a 510 (k) clearance, or through approval of a PMA application. Approval to commercially distribute biologics is received from the FDA through approval of a BLA and may also require state licensing for the movement of biologics products in interstate commerce. The FDA may deny 510 (k) clearance because, among other reasons, it determines that our product is not substantially equivalent to another U. S. legally marketed device. The FDA may deny approval of a PMA or BLA because, among other reasons, it determines that our product is not sufficiently safe or effective. Failure to obtain FDA clearance or approval would preclude commercialization in the U. S., which could materially and adversely affect our future results of operations. Modifications or enhancements to a cleared or approved product that could significantly affect safety or effectiveness, or that constitute a major change in the intended use of the product, could require new 510 (k) clearances or possibly approval of a new PMA or BLA, or a supplement to those applications. We determine in the first instance whether a change to a product requires a new 510 (k) clearance or premarket submission, but the FDA may review our decision not to seek a new 510 (k). If the FDA disagrees with our determinations and requires us to submit a new 510 (k), PMA or ~~PMA~~ supplement, or BLA or ~~BLA~~ supplement for any product modification, we may be required to cease marketing such product or to recall the modified product until we obtain clearance or approval, and we may be subject to civil, criminal, monetary and non-monetary penalties and damage to our reputation. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory authorizations, approvals or clearances, changes in laws and regulations, the loss of previously received authorizations, approvals or clearances or the placement of limits on the manufacture, marketing and use of our products. In addition, the advertising, marketing and labeling of medical devices are highly regulated by the FDA and FTC. Our efforts to promote our products, including via direct- to- consumer marketing or social media initiatives, could subject us to additional scrutiny of our communication of risk information, benefits or claims by the FDA, FTC or both. If the results of clinical studies required to gain regulatory approval to sell our products are not available when expected, or do not demonstrate the safety and effectiveness of those products, we may be unable to obtain regulatory approval and sell those products. Before we can sell certain of our products, we must conduct clinical studies intended to demonstrate that those products are safe and effective and perform as expected. The results of these clinical studies ~~(which are experiments involving human patients having the diseases or medical conditions that the product is trying to evaluate or diagnose)~~ are used to obtain regulatory clearance or approval from government authorities, such as the FDA. Conducting clinical studies that may be required for regulatory approvals or clearances is a complex, time- consuming and expensive process, requiring months or years to complete, and our studies are not guaranteed to generate data that demonstrate safety and effectiveness or substantial equivalence of the evaluated product. If we fail to adequately manage our clinical studies, those clinical studies and corresponding regulatory clearances or approvals may be delayed or we may fail to gain clearance or approval for our products altogether. Even if we successfully manage our clinical studies, we may not obtain favorable results and may not obtain regulatory clearance or approval for the applicable product. **For example, upon reviewing the performance of our Savanna RVP4 assay against the clinical market' s expectations, we withdrew our FDA 510 (k) submission for this assay in March 2024 because the final dataset did not meet our expectations.** If we are unable to market and sell our new products or are unable to obtain clearances or approvals in the time frame needed to execute our product strategies, our business and results of operations would be materially and adversely affected. Our business is subject to substantial regulatory oversight, and our failure to comply with applicable regulations may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained **regulatory** ~~clearances or~~ approvals **, product recalls, seizure of products or injunctions against the distribution of our products, operating restrictions and criminal prosecution** . Our businesses are extensively regulated by the FDA and other federal,

state and foreign regulatory agencies. These regulations impact many aspects of our operations, including development, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, physician interaction and record-keeping. Any material failure by us to comply with such applicable governmental regulations could result in product recalls, the imposition of fines, restrictions on our ability to conduct or expand our operations or the cessation of all or a portion of our operations. The FDA and corresponding foreign regulatory agencies may require post- market testing and surveillance to monitor the performance of cleared or approved products or may place conditions on any product clearances or approvals that could restrict the commercial applications of those products. The discovery of problems with a product may result in restrictions on the product, including withdrawal of the product from the market. In addition, in some cases, we may sell products or provide services that are reliant on the use or commercial availability of third- party products, including medical devices or equipment, and regulatory restrictions placed upon any such third- party products could have a material adverse impact on the sales or commercial viability of our related products or services. We are subject to routine inspection by the FDA and other agencies for compliance with such agency' s requirements applicable to our products, including, without limitation, the FDA' s Quality System Regulation and Medical Device Reporting requirements in the U. S., and other applicable regulations worldwide. Our manufacturing facilities and those of our suppliers and distributors also are, or can be, subject to periodic regulatory inspections. We are also subject to laws relating to matters such as privacy, safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products or injunctions against ~~our~~ **the** distribution of **our** products, termination of our service agreements by our customers, disgorgement of money, operating restrictions and criminal prosecution. Disruptions at the FDA and other government agencies, including disruptions caused by funding shortages or statutory, regulatory or policy changes, could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent them from performing normal business functions on which the operation of our business may rely, or otherwise prevent new or modified products from being developed, cleared, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new or modified products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result of these factors. In addition, government funding of other government agencies, such as those that fund R & D activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may increase the time it takes for new or modified medical devices and biologics to be reviewed and / or cleared or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, or to provide feedback on our submissions, which could have a material adverse effect on our business. Further, future government shutdowns or other disruptions to normal operations could impact our ability to access the public markets and obtain funding necessary to properly capitalize and continue our operations. We may encounter challenges entering into contracts with government entities due to government- sponsored tendering requirements, and any contracts that we have entered into or will enter into with government entities may involve future funding, compliance and possible sanctions risks. We endeavor to enter into contracts with government entities for grant- funded projects or the sale of our products. This may require us to follow government- sponsored tendering processes involving stringent restrictions, including pricing restrictions, ~~ESG~~ **sustainability** requirements, and other compliance obligations. As a result, we may face challenges meeting such government-sponsored tendering requirements, and ultimately, may not be awarded such contracts with government entities. In addition, any government contract that we have entered into or will enter into may expose us to higher potential liability than do other types of contracts due to government funding shortfalls, the government' s right to terminate for convenience, heightened legal compliance requirements, challenges from other industry participants, and our inability to meet key deliverables and milestones. Government funding applicable to our government grant contracts may be limited, and there is no guarantee that budget pressure at the federal, state and local level or changing governmental priorities will not eliminate funding availability. In addition, government contracts typically are subject to procurement laws that include socio- economic, employment practices, environmental protection, recordkeeping and accounting and other requirements. For example, our contracts with the U. S. government generally require us to comply with the Federal Acquisition Regulations, the FCA, the Procurement Integrity Act, the Buy American Act and the Trade Agreements Act. Government contracts subject us to government audits, compliance investigations and oversight proceedings. Government agencies routinely review and audit government contractors or other vendors to determine whether they are complying with applicable contractual and legal requirements. Implementing policies, procedures and controls relating to the accounting and recordkeeping requirements is expensive and time- consuming. If we fail to comply with these requirements relating to any government contract that we have entered into or will enter into, or we fail an audit, we could be subject to various sanctions, including monetary damages, criminal and civil penalties, termination of contracts and suspension or debarment from government contract work. These requirements complicate our business and increase our compliance burden. The failure to meet key deliverables, milestones or compliance requirements could harm our reputation and may have a materially adverse impact on our business operations and our financial position or results of operations. If one or more of our products is claimed to be defective **or does not comply with applicable regulations**, we could be subject to claims of liability and harm to our reputation that could adversely affect our business. Our product development and production processes are complex and could expose our products to claims of defectiveness **or claims that**

they do not comply with applicable regulations . Alleged manufacturing and design defects **or regulatory non- compliance** could lead to recalls (either voluntary or required by the FDA or other government authorities) and could result in the removal of one or more of our products from the market. Similarly, our diagnostic products could lead to a false positive or false negative result, affecting the eventual diagnosis or treatment of a patient and could lead to allegations that our products have caused injury or are found to be unsuitable for their intended use. Our immunohematology business in particular is subject to the risk of product liability claims, as even the slightest inaccuracies in a specimen' s analysis can lead to critical outcomes in the life of a patient, thereby leaving little to no room for error in the precision and accuracy of such testing. In addition, our marketing of monitoring services may cause us to be subject to various product liability or other claims, including, among others, claims that inaccurate monitoring results lead to injury or death, or, in the case of our toxicology monitoring services, the imposition of criminal sanctions. The risk of a product liability claim is also heightened for at- home tests that may be purchased and administered by the end- user customer and not a medical professional and our communication of risk information, benefits or claims, which is highly regulated by the FTC and the FDA, could be alleged to be misleading or erroneous. If the FTC or the FDA alleges or establishes that any of our communications are misleading, we could be subject to litigation and material penalties and fines. Depending on the corrective action we take to redress a product' s deficiencies, we may be required to obtain new clearances or approvals before we may market or distribute the corrected device. A defect or claim of a defect in the design or manufacture of our products could also have a material adverse effect on our reputation in the industry and decrease sales of our products, and we could also face additional regulatory enforcement action, including FDA warning letters, untitled letters, product seizures, injunctions, administrative penalties, or civil or criminal fines. Moreover, any product liability or other claim brought against us, regardless of merit, could be costly to defend and could result in an increase to our insurance premiums. If we are held liable for a claim, that claim could materially affect our business and financial condition. We are subject to healthcare **laws and** regulations that could result in liability, require us to change our business practices and restrict our operations in the future. We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the governments of states and foreign countries in which we conduct our business. In the U. S., these healthcare laws and regulations include the federal Physician Self- Referral Law, federal Anti- Kickback Statute, federal civil and criminal false claims laws, including the FCA, the federal Civil Monetary Penalties Law, **HIPAA** ~~the Health Insurance Portability and Accountability Act of 1996~~ , the federal Physician Payments Sunshine Act, **FDCA** ~~the federal Food, Drug, and Cosmetics Act~~ , U. S. federal consumer protection and unfair competition laws, and state law equivalents of each of the foregoing, as further described in Part I, Item 1, " Business — Government Regulations " of this Annual Report. These laws and regulations, among other things, constrain our business, marketing and other promotional and research activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. In particular, these laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements, as well as interactions with healthcare professionals through consultant arrangements, product training, sponsorships or other activities. Efforts to support compliance of our third- party business arrangements with applicable healthcare and other laws and regulations involve substantial costs. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, governmental authorities may conclude that our business practices do not comply with healthcare laws and regulations. To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, the medical device industry' s relationship with physicians has been under increasing scrutiny by the U. S. Department of Health and Human Services Office of Inspector General (" OIG "), the U. S. Department of Justice (" DOJ "), the state attorney generals and other foreign and domestic government agencies. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of federal or state governments, with potential liability under the FCA, including mandatory treble damages and significant per- claim penalties. Additionally, as a result of these investigations and qui tam actions, we may need to agree to additional compliance and reporting requirements as part of a consent decree, corporate integrity agreement or other type of government resolution. Any such investigation, or failure to comply with such investigation, including those led by the OIG or the DOJ, or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of the ~~federal, state or foreign~~ laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, oversight if we become subject to a consent decree, corporate integrity agreement or other government resolution, and disgorgement, and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations. Certain Other Regulations Relating to Our Business We use hazardous materials in our business that may result in substantial compliance costs or claims against us relating to handling, storage or disposal. Our operations and facilities are subject to various foreign, federal, state and local environmental, health and safety laws, rules, regulations and other requirements, including those governing the generation, use, manufacture, handling, transport, storage, treatment and disposal of, or exposure to, regulated materials, discharges and emissions to air and water, the cleanup of contamination and occupational health and safety matters. Compliance with such laws and regulations requires significant effort and costs. For example, our R & D and manufacturing activities involve the controlled use of hazardous materials that may be subject to federal statutes commonly known as the Comprehensive Environmental Response,

Compensation, and Liability Act, the Resource Conservation and Recovery Act, and the Clean Water Act, among other laws and regulations. Noncompliance with such laws and regulations can result in fines or penalties or limitations on our operations or liability for remediation costs, as well as claims alleging personal injury, property, natural resource or environmental damages. We may also incur liability as a result of any contamination or injury arising from a release of or exposure to such regulated hazardous materials. Under some environmental laws and regulations, we could also be held responsible for costs relating to any contamination at our past or present facilities and at third- party disposal sites where we have sent wastes for treatment or disposal. Liability for contamination at contaminated sites may be imposed without regard to whether we knew of, or caused, the release or disposal of such regulated substances and, in some cases, liability may be joint or several. Any such future expenses or liability could have a negative impact on our financial condition and results of operations. In addition, if any governmental authorities impose new regulations with additional compliance burdens or alter their interpretation of the requirements of such existing regulations, such requirements or regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs, restrictions or compliance procedures on our business or operations. Given the nature of the penalties provided for in some of these regulations, we could be required to pay sizable fines, penalties or damages in the event of noncompliance with laws. Any violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. Further, our workers, properties and equipment may be exposed to potential operational hazards such as fires, safety incidents, releases of regulated materials, malfunction of equipment, accidents and natural disasters, which could result in personal injury or loss of life, damage to or destruction of property and equipment or environmental damage, and could potentially result in a suspension of operations, harm to our reputation and the imposition of civil or criminal fines or penalties, all of which could adversely affect our business. We will be exposed to significant risks in relation to compliance with anti- **bribery and anti-** corruption laws and regulations and economic sanctions programs. Doing business on a worldwide basis requires us to comply with the laws and regulations of the U. S. government and those of various international and sub- national jurisdictions, and our failure to successfully comply with these rules and regulations may expose us to liabilities. These laws and regulations apply to companies and individual directors, officers, employees and agents, and may restrict our operations, trade practices, investment decisions and partnering activities. In particular, our international operations are subject to U. S. and foreign anti- corruption laws and regulations, such as the FCPA, the Bribery Act and the Brazilian Anti- Bribery Act, among others, and economic and trade sanctions, including those administered by the United Nations, the **EU, China** ~~E. U.~~, the Office of Foreign Assets Control of the U. S. Department of the Treasury (" OFAC ") and the U. S. Department of State. The FCPA prohibits providing anything of value to foreign officials for the purposes of obtaining or retaining business or securing any improper business advantage. We may deal with state- owned business enterprises, the employees and representatives of which may be considered foreign officials for purposes of the FCPA. We are subject to the jurisdiction of various governments and regulatory agencies outside of the U. S., which may bring our personnel into contact with foreign officials responsible for issuing or renewing permits, licenses or approvals or for enforcing other governmental regulations. The FCPA also contains accounting provisions requiring issuers of securities listed in the U. S. to make and keep books and records that accurately and fairly reflect the transactions and dispositions of the assets of the company, and to devise and maintain an adequate system of internal accounting controls. The provisions of the Bribery Act extend beyond bribery of foreign public officials and are more onerous than the FCPA in a number of other respects, including jurisdiction, non- exemption of facilitation payments and penalties **. Under China' s Anti- Unfair Competition Law and Criminal Law regime, China has launched an intensified nationwide anti- corruption campaign in the healthcare sector, with strengthened enforcement actions and stricter regulations on both healthcare professionals and enterprises, which has delayed and could continue to delay the processing of public tenders or installations of certain of our instruments, which may have a negative impact on our commercial activities** . Economic and trade sanctions restrict our transactions or dealings with certain sanctioned countries, territories and designated persons, absent authorizations or exemptions under applicable law, such as OFAC' s licenses permitting certain humanitarian trade. While we endeavor to have a strong culture of compliance and an adequate system of internal controls, including procedures to minimize and detect fraud in a timely manner, as well as processes for complying with OFAC authorizations or exemptions, there can be no assurance that our policies and procedures will be followed at all times or will effectively detect and prevent violations of applicable laws by one or more of our employees, consultants, agents or partners and, as a result, we could be subject to penalties and material adverse consequences on our business, financial condition or results of operations. Our collection, use and disclosure of personal information, including health information, and confidential information is subject to federal and state privacy, data security and data protection regulations, as well as privacy, data security and data protection laws outside the U. S., including in the EEA, the U. K. and ~~the People' s Republic of~~ China, and our failure to comply with those laws and regulations or to adequately secure this information could result in significant liability or reputational harm. In the ordinary course of business, we collect, process, transfer, disclose, share and use personal and confidential information, including from customers, employees and business contacts. These activities ~~may~~ subject us and our partners to federal, state and foreign privacy, data security and data protection laws, regulations, guidance, self- governing rules, industry standards, contractual requirements and other obligations as further described in Part I, Item 1, " Business — Government Regulations " of this Annual Report. In the U. S., there are various laws regulating data privacy and security at the federal, state and local level, some of which are further described in the " Business — Government Regulations " section of this Annual Report. We are also subject to other regulations, guidance, self- governing rules, industry standards and contractual requirements. The legislative and regulatory landscape for privacy, data security and data protection continues to evolve, with jurisdictions in which we and our customers operate adopting or considering adopting new privacy, data security and data protection laws and regulations regarding the collection, use, processing, transfer, disclosure, sharing, security and storage of information obtained from consumers, employees and other individuals, including health- related information. There is also an

increasing focus on incident response and breach notification requirements with regulations dictating how to prepare for, respond to and report security incidents and breaches. We ~~may~~ **are** also ~~be~~ bound by contractual obligations with **some of** our customers relating to privacy, data protection and data security ~~that are~~ **, some of which may be** more stringent than applicable privacy, data security and data protection laws and regulations, ~~and~~ **as** some companies ~~often~~ will not contract with vendors that do not meet more rigorous standards. Complying with these various laws, regulations, standards and contractual obligations could cause us to incur substantial costs, require us to change our business practices in a manner that does not align with our business objectives (including limiting our ability to collect, control, process, share, disclose and otherwise use personal information (including health and medical information that are subject to strict requirements)), reduce demand for certain of our digital solutions, restrict our ability to offer certain digital solutions in certain jurisdictions or subject us to inquiries by ~~U. S.,~~ federal, state and foreign data protection regulatory agencies, all of which could result in sanctions, investigations, fines, penalties or otherwise negatively impact our business or reputation. Moreover, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply, further increasing costs to comply, and increasing risks of potential failures or perceived failures to comply. Because many of these laws and regulations are recent, it is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as many of the laws are drafted broadly and leave great discretion to the relevant government authorities to exercise. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and data security concerns, even if unfounded, could result in significant cost and liability to us, including civil and / or criminal penalties, injunctions, fines and exposures to private litigation, as a cost of doing business, or due to new or increasing fines or penalties for violations, damage our reputation, and adversely affect our business and results of operations. Further, a cyber- attack or other security breach affecting personal information, including health or employee information, could also result in significant legal and financial exposure and reputational damage that could potentially have an adverse effect on our business, including limiting our ability to process personal information or to operate in certain jurisdictions. We continue to monitor the evolving privacy, data security and data protection landscape to support our efforts to comply with the requirements in the countries in which we do business. We are subject to U. S. and foreign tax laws, and changes to such tax laws or differing interpretation of those laws by the relevant governmental authorities could adversely affect us. We are subject to income taxes in the U. S. and in various non- U. S. jurisdictions. The U. S. Congress, the ~~Organisation~~ **Organization** for Economic Co- operation and Development and other government agencies in jurisdictions where we do business have had an ~~extended~~ **enhanced** focus on issues related to the taxation of multinational corporations. **These agencies** ~~One example is in the area~~ - **are** ~~of~~ **striving to define, legislate and enforce inappropriate** " base erosion and profit shifting ~~,~~ " ~~where~~ **by means of** payments ~~are made~~ between affiliates ~~from a~~ **in different taxing** ~~jurisdiction~~ **jurisdictions at disparate** ~~with high tax rates to a jurisdiction with lower tax~~ rates. Thus, the tax laws in the U. S., the U. K. and other countries in which we do business could change on a prospective or retroactive basis, and any such significant changes could adversely affect our financial statements. In addition, the amount of income taxes we pay is subject to ongoing audits by U. S. federal, state and local tax authorities and by non- U. S. tax authorities. Due to the potential for changes to tax laws (or changes to the interpretation thereof) and the ambiguity and complexity of tax laws, the subjectivity of factual interpretations, the complexity of our foreign operations and intercompany arrangements and other factors, our estimates of income tax assets or liabilities may differ from actual payments, assessments or receipts. If these audits result in payments or assessments different from our reserves, our future results may include unfavorable adjustments to our tax liabilities and our financial statements could be adversely affected. Additionally, our interpretation and application of these laws and regulations could be challenged by the relevant governmental authorities, which could result in material administrative or judicial procedures, actions or sanctions. If we ~~determine to~~ repatriate earnings from foreign jurisdictions that have been considered permanently re- invested under existing accounting standards, it could also increase our effective tax rate. We continue to monitor changes in tax laws and the impact of proposed and enacted legislation in the U. S. and in the various foreign jurisdictions in which we operate. Risks Relating to Corporate Finance We may need to raise additional funds to finance our future capital or operating needs or other business purposes, which could have adverse consequences on the interests of our stockholders, and may not be available on acceptable terms or at all. We may need to seek to raise funds through the issuance of public or private debt or the sale of equity to achieve our business strategy or for other business purposes. In addition, we may need debt or equity financing to complete acquisitions. If we raise funds or acquire other technologies or businesses through issuance of equity, this could dilute the interests of our stockholders. Such financing activities may also depress the market price of shares of our common stock and impair our ability to raise capital through the sale of additional equity securities. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when we cannot otherwise raise additional capital or issue additional debt on acceptable terms, or at all. Our indebtedness could adversely affect our financial condition, limit our ability to raise additional capital to fund our operations and prevent us from fulfilling our obligations under our indebtedness. Our Credit Agreement governs our senior secured credit facilities, which consist of (i) a Term Loan in an original amount of $ 2, 750. 0 million and (ii) an $ 800. 0 million Revolving Credit Facility ~~(each capitalized term as defined in this Annual Report)~~ . As a result of our indebtedness, a portion of our cash flows will be required to pay interest and principal on our outstanding indebtedness, and we may not generate sufficient cash flows from operations, or have future borrowings available under the Revolving Credit Facility, to enable us to repay our indebtedness or to fund our other liquidity needs. As of December ~~31~~ **29** , ~~2023~~ **2024** , we had total indebtedness of $ 2, ~~414~~ **483** . ~~6~~ **1** million, and we had availability under our Revolving Credit Facility of $ ~~787~~ **589** . ~~1~~ **0** million (net of $ ~~12~~ **13** . ~~9~~ **0** million of outstanding letters of credit). Subject to the limits contained in the Credit Agreement, we may incur additional debt from time

to time to finance working capital, capital expenditures, investments or business acquisitions, or for other purposes. If we do so, the risks related to our higher level of debt would increase. Specifically, our higher level of debt could have important consequences to us and our stockholders, including: • making it more difficult for us to satisfy our obligations with respect to our debt, and if we fail to comply with these obligations, an event of default could result and our credit worthiness may be impacted; • limiting our ability to refinance or obtain additional financing to fund future working capital, capital expenditures, investments or other general corporate requirements; • limiting us from making strategic acquisitions or causing us to make non-strategic divestitures; • requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, investments and other general corporate purposes; • exposing us to the risk of increased interest rates as our borrowings under the credit facilities are at variable rates of interest; • the Credit Agreement contains, and any agreements to refinance our debt likely will contain, financial and other restrictive covenants, and our failure to comply with them may result in an event of default, which, if not cured or waived, could have a material adverse effect on us; • increasing our vulnerability to, and reducing our flexibility to respond to, changes in our business and industry, general economic downturns and adverse industry and business conditions; • to the extent the debt we incur requires collateral to secure such indebtedness, exposing our assets to risks and limiting our flexibility related to such assets; • any default under our Credit Agreement may result in proceedings against collateral we have used to secure the credit facilities, including substantially all of our and our guarantor subsidiaries' assets; • limiting our flexibility in planning for and reacting to changes in the industry in which we compete and to changing business and economic conditions; • placing us at a disadvantage compared to less leveraged competitors and affecting our ability to compete; and • increasing our cost of borrowing. The occurrence of any one of the foregoing risks could have a material adverse effect on our business, financial condition, results of operations and ability to satisfy our obligations in respect of our outstanding debt. Furthermore, borrowings under our credit facilities are at variable rates of interest and expose us to interest rate risk. Recently, interest rates have increased from historically low levels. If interest rates continue to increase, our debt service obligations on our variable rate indebtedness will increase even though the amount borrowed may remain the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease. We have entered into a series of ~~interest rate cap and~~ interest rate swap agreements to hedge our interest rate exposures related to our variable rate borrowings under the credit facilities. However, it is possible that these hedging instruments or any future hedging instruments we enter into may not fully or effectively mitigate our interest rate risk and we may decide not to maintain hedging instruments in the future. We may not be able to generate sufficient cash flows from operating activities to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful. Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our business, financial position and results of operations and our ability to satisfy our debt obligations. Additionally, if we cannot make scheduled payments on our debt, we will be in default, and the lenders under the credit facilities could terminate their commitments to loan additional money to us, the lenders could foreclose against the assets securing their borrowings and we could be forced into bankruptcy or liquidation. All of these events could result in our stockholders losing all or a part of their investment. Our ability to make scheduled payments on or refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to financial, business, legislative, regulatory and other factors beyond our control. We may not be able to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations. The Credit Agreement restricts our ability to dispose of assets and use the proceeds from such dispositions and may also restrict our ability to raise debt or equity capital to be used to repay other indebtedness when it becomes due. Because of these restrictions, we may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations when due. In addition, we conduct all of our operations through our subsidiaries, some of which are not guarantors of our indebtedness. Accordingly, repayment of our indebtedness is dependent on the generation of cash flows by our subsidiaries and their ability to make such cash available to us, by dividend, debt repayment or otherwise. Unless they are guarantors of our indebtedness, our subsidiaries do not have any obligation to pay amounts due on our indebtedness or to make funds available for that purpose. Our subsidiaries may not be able to, or may not be permitted to, make distributions to enable us to make payments in respect of our indebtedness. Each subsidiary is a distinct legal entity, and, under certain circumstances, legal and contractual restrictions may limit our ability to obtain cash from our subsidiaries. While the Credit Agreement limits the ability of our subsidiaries to incur consensual restrictions on their ability to pay dividends or make other intercompany payments to us, these limitations are subject to qualifications and exceptions. In the event that we do not receive distributions from our subsidiaries, we may be unable to make required principal and interest payments on our indebtedness. The terms of the Credit Agreement impose restrictions that may limit our current and future operating flexibility, particularly our ability to respond to changes in the economy or our industry or to take certain actions, which could harm our long- term interests and may limit our ability to make payments on our indebtedness. The Credit Agreement contains a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long- term best interest, including restrictions on our ability, and the ability of our subsidiaries, to: • incur additional indebtedness and guarantee indebtedness; • pay dividends or make other distributions in respect of, or repurchase or redeem, capital stock; • prepay, redeem or repurchase certain indebtedness; • make business acquisitions; • make loans and investments; • sell, transfer or otherwise dispose of assets; • incur liens; • enter into transactions

with affiliates; • enter into new lines of business or alter the businesses we conduct; • designate any of our subsidiaries as unrestricted subsidiaries; • enter into agreements restricting our subsidiaries' ability to pay dividends; and • consolidate, merge, transfer or sell all or substantially all of our assets or the assets of our subsidiaries. In addition, the Credit Agreement requires us to comply with two financial covenants consisting of a maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) and a minimum Consolidated Interest Coverage Ratio (as defined in the Credit Agreement). ~~See~~ **Refer to** Part II, Item 8, " Financial Statements and Supplementary Data — Note ~~8~~ **10** . Borrowings " for more information related to our financial covenants. Our ability to comply with these covenants may be affected by financial, business, economic, regulatory and other circumstances and events beyond our control, such as prevailing economic conditions, changes in regulations and industry conditions, and we cannot assure you that we will be able to comply with such covenants. For example, compliance with the financial covenants would be more difficult to achieve if we were to experience substantially lower revenues or greater costs than budgeted. The covenants under the Credit Agreement also limit our ability to obtain future financings to withstand a future downturn in our business or the economy in general. Further, in order to respond to market conditions, or if we are unable to comply with any of the covenants, we may need to seek an amendment or waiver from our lenders of various provisions in the Credit Agreement and we may not be able to obtain such an amendment or waiver on reasonable terms, if at all. Additionally, our costs under these agreements would likely increase. A breach of any of the covenants under our Credit Agreement could result in an event of default, which could result in the accelerated payment of outstanding indebtedness or foreclosure on our assets pledged to secure the indebtedness, which could have a material adverse effect on us. Risks Relating to Our Employees We may have difficulty attracting, motivating and retaining executives and other key employees. Our success will depend in part upon our ability to attract, motivate and retain executives and sales, marketing, manufacturing, technical, scientific, technology and other key personnel. Competition for qualified personnel can be intense, both in the industry in which we operate and where our operations are located. Accordingly, no assurance can be given that we will be able to attract or retain executives or key employees. The loss of any executive or other key personnel, particularly key manufacturing, R & D and technical personnel, could harm our business and prospects and could impede the achievement of our R & D, operations or strategic objectives. In addition, there could be disruptions to or distractions for the workforce and management, including in connection with **recent leadership transitions or** activities of labor unions or ~~work~~ **works** councils. While we may employ the use of certain retention programs, there can be no guarantee that they will prove to be successful. Furthermore, we may be required to incur significant costs in identifying, hiring, training and retaining replacements for departing employees and may lose significant expertise and talent relating to our business, which may adversely affect our business. If we are required to make unexpected payments to any defined benefit plans or other post- employment benefit plans (" Benefit Plans ") applicable to our employees, our financial condition may be adversely affected. Some of our current and former employees participate or participated in Benefit Plans that were sponsored by Ortho prior to the closing of the Combinations. We assumed certain underfunded and unfunded Benefit Plan liabilities, which amounted to approximately $ ~~36~~ **32** . ~~0~~ **4** million as of December ~~31~~ **29** , ~~2023~~ **2024** . Several of these plans are unfunded and, while we do not believe the liabilities in relation to these plans are significant, they must be satisfied as they mature from our cash resources. In jurisdictions where the Benefit Plans are intended to be funded with assets in a trust or other funding vehicle, we expect that, while not significant, the liabilities will exceed the corresponding assets in each of the plans. Various factors, such as changes in actuarial estimates and assumptions (including in relation to life expectancy, discount rates and rates of return on assets), as well as actual return on assets, can increase the expenses and liabilities of the Benefit Plans. The assets and liabilities of the plans must be valued from time to time under applicable funding rules and, as a result, we may be required to increase the cash payments we make in relation to these Benefit Plans. We could also be required in some jurisdictions to make accelerated payments up to the full buy- out deficit in our Benefit Plans, which would likely be far higher than the normal ongoing funding cost of the plans. Our operations and financial condition may be adversely affected to the extent that we are required to (i) make any additional payments to any relevant Benefit Plans in excess of the amounts assumed in our current projections and assumptions or (ii) report higher Benefit Plan expenses under relevant accounting rules. We are subject to work stoppages, union negotiations, labor disputes and other matters associated with our labor force, which may adversely impact our operations and cause us to incur incremental costs. As of December ~~31~~ **29** , ~~2023~~ **2024** , we had approximately ~~7~~ **6** , ~~100~~ **600** employees located around the world consisting of commercial, supply chain, quality, regulatory and compliance, R & D and general administrative personnel. As of such date, approximately ~~15~~ **16** % of our employees globally were covered by a union, collective bargaining agreement or works council. Historically, we have not experienced work stoppages; however, in the future, we may be subject to potential union campaigns, work stoppages, union negotiations and other potential labor disputes. Additionally, future negotiations with unions or works councils in connection with existing labor agreements may (i) result in significant increases in our cost of labor, (ii) divert management' s attention away from operating our business or (iii) break down and result in the disruption of our operations. The occurrence of any of the preceding outcomes could impair our ability to manufacture our products and result in increased costs and / or decreased operating results. Further, we may be subject to work stoppages at our suppliers or customers that are beyond our control. General Risk Factors We **identified material weaknesses in our internal control over financial reporting which, if not remediated appropriately or timely, could affect our ability to record, process and report financial information accurately, impair our ability to prepare financial statements, negatively affect investor confidence and cause reputational harm. Effective internal controls are necessary for us to provide reliable and accurate financial reporting and financial statements for external purposes in accordance with GAAP. A failure to maintain effective internal control over financial reporting could lead to violations, unintentional or otherwise, of laws and regulations. As disclosed in Part II, Item 9A, " Controls and Procedures " of this Annual Report, as of December 29, 2024, we identified material weaknesses in our internal control over financial reporting relating to (i) ineffectively designed controls related to financial information generated from certain software solutions and design deficiencies over certain management review**

controls and (ii) insufficient controls over the evaluation of all available evidence to assess realizability of deferred tax assets. As a result, our management concluded that disclosure controls and procedures and internal control over financial reporting were not effective as of December 29, 2024. While we are actively engaged in the process of designing appropriate controls to address these material weaknesses, there can be no assurance that the actions will fully remediate the material weaknesses in a timely manner. If we are unable to remediate the material weaknesses, or are otherwise unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected. Litigation, government investigations or regulatory enforcement actions arising out of any such failure or alleged failure could subject us to civil and criminal penalties that could materially and adversely affect our reputation, financial condition and operating results. The material weaknesses, remediation actions, and any related litigation, government investigations or regulatory enforcement actions will require management attention and resources and cause us to incur unanticipated costs, and could negatively affect investor confidence in our financial statements, cause us reputational harm and raise other risks to our operations. We are subject to, and may in the future become subject to, claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us. From time to time, we are involved in litigation and other proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment and other claims related to our business. We may become subject to more proceedings as we expand our business, suppliers, customers and markets. Litigation related to the Company, our business and our operations or financial performance may also involve customers, competitors, suppliers, patients, stockholders, governmental authorities or other third parties. Litigation can be lengthy, expensive and disruptive to our operations, and results cannot be predicted with certainty. An adverse decision could result in significant settlement amounts, monetary damages, fines or injunctive relief that could affect our financial condition or results of operations. Even if lawsuits do not result in an unfavorable outcome, the costs of defending or prosecuting such lawsuits may be material to our business and our operations. Moreover, these lawsuits may divert management' s attention from the operation of our business, which could adversely affect our business and results of operations. Furthermore, in the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators disagree with the manner in which we have sought to comply with applicable laws and regulations, we could be subject to substantial civil and criminal penalties, as well as corrective actions, product recalls, seizures or injunctions with respect to the sale of our products. The FDA may also withdraw any clearances or approvals we have obtained, or decline to issue additional clearances or approvals for any outstanding 510 (k) s, PMAs or BLAs. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and affect our operating results, and any limitation on our ability to manufacture and market our products could also have a material adverse effect on our business. Expectations of our performance related to ~~ESG~~ **sustainability** matters, or the reporting of such matters, may impose additional costs on us and expose us to new risks. There is an increasing focus and scrutiny from ~~the SEC and other~~ regulators, investors, customers, suppliers, vendors, employees and other stakeholders concerning corporate responsibility and sustainability ~~and ESG factors~~ in particular. Government entities are enhancing or advancing legal and regulatory requirements, including disclosure requirements, specific to ~~ESG~~ **sustainability** matters. For example, the state of California has adopted new climate change disclosure requirements and the **EU** ~~E. U.~~ has adopted the Corporate Sustainability Reporting Directive. Compliance with such rules could require significant effort and resources and result in changes to our current ~~ESG~~ **sustainability** goals. Additionally, many investors use ~~ESG~~ **sustainability** factors to help guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ~~ESG~~ **sustainability** performance is inadequate. Moreover, a number of customers who are payors or distributors have adopted, or may adopt, procurement policies that include ~~ESG~~ **sustainability** provisions that their suppliers or manufacturers must comply with, or they may seek to include such provisions in their terms and conditions. Standards for tracking and reporting ~~ESG~~ **sustainability** matters continue to evolve. Our use of disclosure frameworks and standards, and the interpretation or application of those frameworks and standards, may change from time to time or differ from those of others. This may result in a lack of consistent or meaningful comparative data from period to period or between us and other companies in the same industry. Third- party providers of corporate responsibility ratings and reports have also increased in number to meet growing stakeholder demand for measurement of ~~ESG~~ **sustainability** performance. The criteria by which our corporate responsibility practices are assessed must be routinely monitored and may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such evolving standards for identifying, measuring and reporting ~~ESG~~ **sustainability** metrics, including ~~ESG~~ **sustainability** - related disclosures that may be required of public companies by ~~the SEC and other~~ regulators, stakeholders may conclude that our performance related to corporate responsibility and ~~ESG~~ **sustainability** matters is inadequate. Moreover, **if** our market capitalization ~~has increased~~ **increases** ~~significantly in the last few years. Accordingly~~ , we may be benchmarked against larger peer companies, some of which may have more resources than us and thus may have achieved better ~~ESG~~ **sustainability** performance and / or a higher ~~ESG~~ **sustainability** rating profile. We may face reputational damage if our ~~ESG~~ **sustainability** performance or ~~ESG~~ **sustainability** rating profile is, or is perceived as being, below that of our competitors or peer companies. In addition, we could fail, or be perceived as failing, in our achievement of certain ~~ESG~~ **sustainability** - related initiatives or goals, or we could be criticized for the scope of such initiatives or goals or our standards for measuring and reporting such goals. Our failure to **comply with sustainability regulations or to** satisfy stakeholder expectations related to our ~~ESG~~ **sustainability** performance or to accomplish or accurately track and report on our ~~ESG~~ **sustainability initiatives or** goals on a timely basis, or at all, could result in the loss of business **, inability to sell our products in certain jurisdictions,** or difficulty obtaining new business or new supplier relationships, adversely affect our reputation, stock price, financial condition, results of operation or growth, expose us to increased scrutiny from stakeholders and

enforcement authorities, which may result in litigation or regulatory action or otherwise subject us to liability, and present challenges in attracting and retaining talented employees. We are exposed to business risk which, if not fully covered by insurance, could have an adverse effect on our results of operations. We face a number of business risks, including exposure to product liability, property, business interruption and cybersecurity risks. Although we maintain insurance for a number of these risks, we may face claims for types of damages, or for amounts of damages, that are not covered by our insurance, or our insurance coverage may not be sufficient to offset the costs of any payments or other losses, lost sales or increased costs experienced during business interruptions. For some risks, we may not obtain insurance if we believe the cost of available insurance is excessive related to the risks presented. Due to market conditions, premiums and deductibles for certain insurance policies can increase substantially and, in some instances, certain insurance policies may become unavailable or available only for reduced amounts of coverage. Further, our existing insurance may not be renewed at the same cost and level of coverage as currently in effect or may not be renewed at all. As a result, we may not be able to renew our insurance policies or procure other desirable insurance on commercially reasonable terms, if at all. Losses and liabilities from uninsured or underinsured events and delay in the payment of insurance proceeds could have a material adverse effect on our financial condition and results of operations. Some provisions of our Charter, our Bylaws and Delaware law may make takeover attempts difficult, which could depress the price of our common stock and inhibit our stockholders' ability to receive a premium price for their shares. Provisions of our Charter could make it more difficult for a third party to acquire control of our business, even if such change in control would be beneficial to our stockholders. Our Charter allows our Board to issue up to five million shares of preferred stock and to fix the rights and preferences of such shares without stockholder approval. Any such issuance could make it more difficult for a third party to acquire our business and may adversely affect the rights of our stockholders. Our Bylaws include advance notice requirements for stockholder proposals that require stockholders to give written notice of any proposal or director nomination to us within a specified period of time prior to any stockholder meeting and do not permit stockholders to call a special meeting of the stockholders, unless such stockholders hold at least 50 % of our stock entitled to vote at the meeting. These provisions may delay, deter or prevent a change in control of us, adversely affecting the market price of our common stock. Our Bylaws designate the Court of Chancery of the State of Delaware (the " Court of Chancery ") as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents. Our Bylaws provides that, unless we consent in writing to the selection of an alternative forum, (i) the Court of Chancery (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for any claims (other than any cause of action arising under the Securities Act), including claims in the right of the Company that are based on a violation of duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery, and (ii) the federal district courts of the U. S. will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for any cause of action arising under the Securities Act, but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock will be deemed to have notice of, and to have consented to, the provisions of our Bylaws described in the preceding sentence. This forum selection provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons and result in increased costs for a stockholder to bring a claim. There is uncertainty as to whether a court would enforce such provisions and stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our Bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations. The market price of our common stock may be volatile. ~~The market price of our common stock may be volatile.~~ Broad general economic, political, market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance and the success of the integration of Quidel and Ortho. Factors that could cause fluctuations in the price of our common stock include: • global macroeconomic, geopolitical or market conditions; • actual or anticipated variations in quarterly operating results and the results of competitors; • changes in financial projections by us, if any, or by any securities analysts that may cover our shares; • conditions or trends in the industry, including regulatory changes or changes in the securities marketplace; • announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • additions or departures of key personnel; and • issuances, repurchases or sales of our common stock, including sales of common stock by our directors and officers or our significant investors and any stock repurchase program. Future sales of our common stock by us or our stockholders in the public market, or the perception that such sales may occur, could reduce the price of our common stock, and any additional capital raised by us through the sale of equity or convertible securities may dilute ownership in the Company. The sale of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. All of our issued shares of common stock are freely tradable without restriction or further registration under the Securities Act, except for any shares held by our affiliates, as that term is defined under Rule 144 of the Securities Act (" Rule 144 "), including certain of our directors, executive officers and other affiliates, which shares may be sold in the public market only if they are registered under the Securities Act or are sold pursuant to an exemption from registration such as Rule 144. ~~Shares of our common stock covered by registration rights represent approximately 19 % of our outstanding shares as of December 31, 2023. Registration of any of these outstanding shares of~~

~~common stock would result in such shares becoming freely tradable without compliance with Rule 144 upon effectiveness of the registration statement.~~ As restrictions on resale end ~~or if these stockholders exercise their registration rights~~, the market price of our common stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our shares of common stock or other securities. In the future, we may also issue our securities in connection with investments or acquisitions, or otherwise. We cannot predict the size of future issuances of shares of our common stock or securities convertible into shares of our common stock or the effect, if any, that future issuances and sales of shares of our common stock will have on the market price of our common stock. Sales of substantial amounts of our common stock (including shares issued in connection with an acquisition), or the perception that such sales could occur, may adversely affect prevailing market prices of our common stock. ~~If we fail to develop or maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our common stock. Effective internal controls are necessary for us to provide reliable financial reports, prevent fraud and operate successfully as a public company. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results would be harmed. We cannot be certain that our efforts to develop and maintain an effective system of internal controls will be successful, that we will be able to maintain adequate controls over our financial processes and reporting in the future, or that we will be able to comply with our obligations under Section 404 of the Sarbanes- Oxley Act of 2002. Any failure to develop or maintain effective internal controls, including due to the Combinations or otherwise, or difficulties encountered in implementing or improving internal controls, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which would likely have a negative effect on the trading price of our common stock.~~