Risk Factors Comparison 2024-02-26 to 2023-02-28 Form: 10-K

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Investors should carefully consider all of the information set forth in this Annual Report, including the following risk factors, before deciding to invest in any of the Company' s securities. The risks below are not the only ones that the Company faces. Additional risks not presently known to the Company, or that it presently deems immaterial, may also negatively impact the Company. The Company' s business, consolidated financial condition, revenues, results of operations, profitability, reputation or cash flows could be materially impacted by any of these factors. Risks Related to the Company' s Business Including Global Economic and Sociopolitical Factors General or macro- economic factors in the U. S. and globally may have a material adverse effect upon the Company, and significant fluctuations in ~~the~~ **global** ~~economy~~ **economic conditions** ~~, recession, inflation~~ and an increase in the costs of goods and services could negatively impact testing volumes, drug development services, cash collections, profitability **,** and the availability and cost of credit. The Company' s operations are dependent upon ongoing demand for diagnostic testing and drug development services by **Index** patients, physicians, hospitals, MCOs, pharmaceutical, biotechnology and medical device companies and others. Fluctuations in ~~the~~ global ~~economy~~ **economic conditions** , including inflation and the risk of short- or long- term ~~recession~~ **recessions** , ~~inflation and an increase in the costs of goods and services have impacted and in the future~~ could ~~have continued or greater negative~~ **negatively** impact ~~on the~~ demand for diagnostic testing and drug development services, the ability of customers to pay for **the Company' s** services ~~rendered~~ , and the Company' s profitability. In addition, uncertainty in the credit markets and ~~fluctuations in~~ interest ~~rates~~ **rate volatility** could reduce the availability and increase the cost of credit and impact the Company' s ability to meet its financing needs in the future. ~~Index~~ Operations may be disrupted and adversely impacted by the effects of adverse weather, natural disasters, geopolitical events, public health crises, hostilities or acts of terrorism, acts of vandalism, disruption to supply chains, ~~access to~~ **inaccessibility of** natural resources, and other events **beyond** ~~outside of~~ the Company' s control. Natural disasters, such as adverse weather, fires, earthquakes, power shortages and outages, geopolitical events, such as terrorism, war, political instability, or other conflict, public health crises and disease epidemics and pandemics, criminal activities, disruptions to supply chains, ~~access to~~ **inaccessibility of** natural resources, and other disruptions or events **beyond** ~~outside of~~ the Company' s control could negatively affect the Company' s operations. Any of these events may result in a temporary decline of **testing** volumes **and other work** in both segments. In addition, such events may temporarily interrupt the Company' s ability to transport specimens, efficiently commence **, continue, or complete its work on** studies, utilize information technology systems, utilize certain laboratories, and / or ~~ability~~ to receive material from its suppliers. Such events can also affect customer operations and thereby impact testing volume. Long- term disruptions in the infrastructure and operations caused by such events (particularly involving locations in which the Company has operations), could harm the Company' s operating results. An inability to attract ~~and~~ **,** retain **, and develop** experienced and qualified personnel, including key management personnel, and increased personnel costs, could adversely affect the Company' s business. The loss of key management personnel or the inability to attract ~~and~~ **,** retain **, and develop** experienced and qualified employees, at the Company' s clinical laboratories, drug development, and diagnostic facilities, and increased costs related to such personnel and employees, could adversely affect the business. The success of the Company is dependent in part on the efforts of key members of its management team. Success in maintaining the Company' s leadership position in genomic and other advanced testing and diagnostic technologies will depend in part on the Company' s ability to attract and retain skilled research professionals. In addition, the success of the Company' s early discovery, clinical, and commercial laboratories also depend on employing and retaining qualified and experienced professionals, including specialists, who perform laboratory research activities and testing services. The same is true for patient-facing staff with specialized training required to perform activities related to specimen collection or clinical research activities. In the future, if competition for the services of these professionals increases, the Company may not be able to continue to attract and retain individuals in its markets. Changes in key management, or the ability to attract **, develop,** and retain qualified personnel, as a result of increased competition for talent, wage growth, or other market factors, could lead to strategic and operational challenges and uncertainties, distractions of management from other key initiatives, and inefficiencies and increased costs, any of which could adversely affect the Company' s business, financial condition, results of operations, and cash flows. Continued changes in healthcare reimbursement models and products (e. g., health insurance exchanges), changes in government payment and reimbursement systems, or changes in payer mix, including an increase in third- party benefits management and value- based payment models, could have a material adverse effect on the Company' s revenues, profitability and cash flow. **Diagnostics Laboratories' (** Dx **)** ~~' s~~ testing services are billed to MCOs, Medicare, Medicaid, physicians and physician groups, hospitals, patients **,** and employer groups. Most testing services are billed to a party other than the physician or other authorized person who ordered the test. Increases in the percentage of services billed to government and MCOs could have an adverse effect on the Company' s revenues. The Company serves many MCOs. These organizations have different contracting philosophies, which are influenced by the design of their products. Some MCOs contract with a limited number of clinical laboratories and engage in direct negotiation of rates. Other MCOs adopt broader networks with generally uniform fee structures for participating clinical laboratories. In some cases, those fee structures are specific to independent clinical laboratories, while the fees paid to hospital- based and physician- office laboratories may be different, and are typically higher. MCOs may also offer Managed Medicare or Managed Medicaid plans. In addition, an increasing number of MCOs are implementing, directly or through third parties, various types of laboratory benefit management programs that may include laboratory networks, utilization management tools (such as prior authorization and / or prior notification), and claims edits,

which may impact coverage or reimbursement for commercial laboratory tests. Some of these programs address commercial laboratory testing broadly, while others are focused on certain types of testing such as molecular, genetic and toxicology testing. An increase in the use of such programs could lead to increased denial of claims, extended appeals, and reduced revenue. Some MCOs use capitation rates to fix the cost of laboratory testing services for their enrollees. Under a capitated reimbursement arrangement, the clinical laboratory receives a per- member, per- month payment for an agreed upon menu of laboratory tests provided to MCO members during the month, regardless of the number of tests performed. Capitation shifts the risk of increased test utilization (and the underlying mix of testing services) to the commercial laboratory provider. The Company makes significant efforts to obtain adequate compensation for its services in its capitated arrangements. For the year ended December 31, ~~2022~~ **2023** , such capitated contracts accounted for approximately $ ~~332~~ **369** . **9 million, or** 3 ~~million, or 3~~ . ~~2~~ **9** %, of Dx' s revenues. The Company' s ability to attract and retain MCOs is critical given the impact of healthcare reform, related products and expanded coverage (e. g. health insurance exchanges and Medicaid expansion) and evolving value- based care and risk- based reimbursement delivery models (e. g., accountable care organizations (ACOs) and Independent Physician Associations (IPAs)). A portion of the managed care fee- for- service revenues is collectible from patients in the form of deductibles, coinsurance and copayments. As patient cost- sharing has been increasing, the Company' s collections may be adversely impacted. In addition, Medicare and Medicaid and private insurers have increased their efforts to control the cost, utilization and delivery of healthcare services, including commercial laboratory services. Measures to regulate healthcare delivery in general, and clinical laboratories in particular, have resulted in reduced prices, added costs and decreased test utilization for the commercial laboratory industry by increasing complexity and adding new regulatory and administrative requirements. Pursuant to legislation passed in late 2003, the percentage of Medicare beneficiaries enrolled in Managed Medicare plans has increased. The percentage of Medicaid beneficiaries enrolled in Managed Medicaid plans has also increased; however, changes to, or repeal of, the Patient Protection and Affordable Care Act (ACA) may continue to affect coverage, reimbursement, and utilization of laboratory services, as well as administrative requirements, in ways that are currently unpredictable. Further healthcare reform could adversely affect laboratory reimbursement from Medicare, Medicaid or commercial carriers. The Company has periodically experienced delays in the pricing and implementation of coding and billing changes among various payers, including Medicaid, Medicare and commercial carriers. ~~While some delays were expected, payer~~ **Payer** policy changes in coverage **, along with coding and billing changes,** have had a negative impact **over time** on revenue, revenue per requisition, and margins and cash flows. In ~~2022~~ **2023** , limited coding and billing changes were implemented. While limited changes are expected to be implemented in ~~2023~~ **2024** , the Company typically expects some delays in pricing and reimbursement as new codes are introduced. The Company expects the efforts to impose reduced reimbursement, more stringent payment policies, and utilization and cost controls by government and other payers to continue. If Dx cannot offset additional reductions in the payments it receives for its services by reducing costs, increasing test volume, and / or introducing new services and procedures, it could have a material adverse effect on the Company' s revenues, profitability and cash flows. In 2014, Congress passed PAMA, requiring Medicare to change the way payment rates are calculated for tests paid under the CLFS, and to base the payment on the weighted median of rates paid by private payers. On June 23, 2016, CMS issued a final rule to implement PAMA that required applicable laboratories, including Dx, to begin reporting their test- specific private payer payment amounts to CMS **in** ~~during the first quarter of~~ 2017 ~~. CMS exercised enforcement discretion to permit reporting for an additional 60 days~~ , ~~through May 30,~~ **based on data collected in** ~~2017~~ **2016** . CMS used that private market data to calculate weighted median prices for each test (based on applicable current procedural technology (CPT) codes) to represent the new CLFS rates beginning in 2018, subject to certain phase- in limits. For 2018- 2020, a test price could not be reduced by more than 10 % per year. As a result of provisions included within the CARES Act, PAMA rate reductions for 2021 were suspended, and therefore the Company did not experience any incremental reimbursement rate impact due to PAMA in 2021. As a result of the Protecting Medicare and American Farmers from Sequester Cuts Act that became law in December 2021, the data reporting requirements and Medicare reimbursement cuts that would have occurred under PAMA in 2022 were delayed by one additional year, and the Company did not experience incremental reimbursement rate impact due to PAMA in 2022. As a result of the Consolidated Appropriations Act, 2023, which became law in December 2022, the data reporting requirements and Medicare reimbursement cuts that would have occurred under PAMA in 2023 were delayed by one additional year, and the Company ~~will~~ **did** not experience an incremental reimbursement rate impact due to PAMA in 2023. ~~For~~ **In November 2023, provisions in the Further Continuing Appropriations and Other Extensions Act of** 2024 **further delayed** ~~- 2026, a test price cannot be reduced by more than 15. 0 % per year. The process of~~ data reporting **requirements** and ~~repricing will be repeated every three~~ -- **the** ~~years~~ **phase- in of payment reductions** for Clinical Diagnostic Laboratory Tests (CDLTs) ~~beginning~~ **that are not classified as ADLTs under PAMA. As a result, no payment reduction will be applied to CDLTs** in 2024 **, and for 2025- 2027 payment may not be reduced by more than 15 % compared to the payment amount established for a test the previous year** . ~~CFLS~~ - **CLFS** rates for ~~2027~~ **2028** and subsequent periods will not be subject to phase- in limits. The phase- in of rates for CDLTs established in 2018 will resume in ~~2024~~ **2025** . New CLFS rates will be established in ~~2025~~ **2026** based on data from 2019 to be reported in ~~2024~~ **2025** . ~~New CLFS rates~~ **The process of data reporting and repricing under PAMA** will be ~~established in 2028 based on data from 2026 to be reported~~ **repeated every three years for CDLTs beginning** in ~~2027~~ **2025 .** CLFS rates for ~~Advanced Diagnostic Laboratory Tests (~~ADLTs ~~)~~ will be updated annually. CMS published its initial proposed CLFS rates under PAMA for 2018- 2020 on September 22, 2017. Following a public comment period, CMS made adjustments and published final CLFS rates for 2018- 2020 on November 17, 2017, with additional adjustments published on December 1, 2017. For 2020, the Company realized a net reduction in reimbursement of approximately $ 72. ~~01~~ **0** million from all payers affected by the CLFS (approximately $ 107. 0 million in 2019). ~~2021, 2022 and 2023~~ PAMA rates were frozen **for years 2021 through 2024** as described above. Unless implementation of PAMA is further delayed or changed, an additional reduction of approximately $ 100. 0 million is expected for ~~2024~~ **2025** , from all payers

affected by the CLFS. ~~Healthcare reform legislation also contains numerous regulations that will require the Company, as an employer, to implement significant process and record- keeping changes to be in compliance. These changes increase the cost of providing healthcare coverage to employees and their families. Given the limited release of regulations to guide compliance, as well as potential changes to the ACA, the exact impact to employers, including the Company, is uncertain.~~ Changes in government regulation or in practices relating to the pharmaceutical, biotechnology, or medical device industries could decrease the need for certain services that ~~DD~~ **BLS** provides. ~~DD~~ **BLS** assists pharmaceutical, biotechnology **,** and medical device companies in navigating the regulatory approval process. Changes in **government** regulations **,** such as a relaxation in regulatory requirements or the introduction of simplified approval procedures ~~,~~ or an increase in regulatory requirements that ~~DD has~~ **BLS may have** difficulty satisfying or that **may** make its services less competitive, could eliminate or substantially reduce the demand for its services. Also, if government efforts to contain drug and medical product and device costs impact profits from such items, or if health insurers were to change their practices with respect to reimbursement for those items, some of ~~DD~~ **BLS** ' s customers may spend less, or reduce their growth in spending on R & D. In addition, ~~implementation~~ **proposed changes in the U. S. relating to FDA oversight** of ~~healthcare reform~~ **the development and commercialization of LDTs as medical devices pursuant to regulatory interpretation, as well as draft** legislation ~~that adds~~ **, if implemented, could increase** costs **, penalties, or fines. Any such** ~~could limit the profits that can be made from the development of~~ new ~~drugs and medical products and devices. This could adversely affect R & D expenditures by such companies, which could in turn decrease the business opportunities available to DD both in the U. S. and other countries. New~~ laws or regulations may create a risk of liability, increase ~~DD~~ **BLS** costs **and /** or limit service offerings through ~~DD~~ **BLS** . Increased competition, including price competition, could have an adverse effect on the Company' s revenues and profitability. As further described in Item 1 of Part I of this Annual Report, both Dx and ~~DD~~ **BLS** operate in ~~highly~~ competitive industries. The commercial laboratory business is intensely competitive both in terms of price and service. Pricing of laboratory testing services is often one of the most significant factors used by physicians, third- party payers and consumers in selecting a laboratory. As a result of significant consolidation in the commercial laboratory industry, larger commercial laboratory providers are able to increase cost efficiencies afforded by large-scale automated testing. This consolidation results in greater price competition. Dx may be unable to increase cost efficiencies sufficiently, if at all, and as a result, its net earnings and cash flows could be negatively impacted by such price competition. The Company may face increased competition from health system laboratories, due to physicians within those systems directing their testing to the health system laboratory and away from the Company, and as those laboratories seek to expand their testing volume from unaffiliated physicians in their service areas. The Company may also face competition from companies that do not comply with existing laws or regulations or otherwise disregard compliance standards in the industry. Additionally, the Company may also face changes in fee schedules, competitive bidding for laboratory services, or other actions or pressures reducing payment schedules as a result of increased or additional competition. **Following** ~~Competitors in~~ the ~~CRO industry~~ **spin- off of Fortrea, BLS' s main competition** ~~range~~ **ranges** from hundreds of ~~smaller~~ -- **small** ~~CROs~~ **providers** to a limited number of large ~~CROs~~ **companies** with global capabilities. **BLS competes against** ~~DD' s main competition consists of~~ these small and large ~~CROs~~ **businesses** , as well as in- house departments of pharmaceutical, biotechnology ~~and~~ **,** medical device **, and diagnostic** companies ~~and~~ , **and** to a lesser extent, ~~select~~ **selected academic research centers,** universities **,** and teaching hospitals. ~~DD~~ **In addition, BLS** ' s services **periodically** ~~have from time to time experienced~~ - **experience** periods of increased price competition that ~~had~~ **may have** an adverse effect on ~~a~~ **the** segment ~~'~~ **'** s profitability and consolidated revenues and net income ~~. There is competition among CROs for both customers and potential acquisition candidates. Additionally, few barriers to entering the CRO industry further increases possible new competition. These competitive pressures may affect the attractiveness or profitability of Dx' s and DD' s services, and could adversely affect the financial results of the Company~~ . Failure to obtain and retain new customers, the loss of existing customers or material contracts, or a reduction in services or tests ordered or specimens submitted by existing customers, or the inability to retain existing and / or create new relationships with health systems could impact the Company' s ability to successfully grow its business. To maintain and grow its business, the Company needs to obtain and retain new customers and business partners. In addition, a reduction in tests ordered or specimens submitted by existing customers, a decrease in demand for the Company' s services from existing customers, or the loss of existing contracts, without offsetting growth in its customer base, could impact the Company' s ability to successfully grow its business and could have a material adverse effect on the Company' s revenues and profitability. The Company competes primarily on the basis of ~~the quality of services, reporting and information systems,~~ reputation ~~in the medical community and the drug development industry~~ , **efficient** ~~the pricing of services~~ and ~~ability to employ qualified personnel~~ **timely performance, and leadership in science, technology and innovation** . The Company' s failure to successfully compete ~~on~~ **in** any of these ~~factors~~ **areas** could result in the loss of existing customers, an inability to gain new customers **,** and ~~a reduction in~~ **reduced or stagnant growth of** the Company' s business. Discontinuation or recalls of existing testing products; failure to develop or acquire licenses for new or improved testing technologies; or the Company' s customers using new technologies to perform their own tests could adversely affect the Company' s business. From time to time, manufacturers discontinue or recall reagents, test kits **,** or instruments used by the Company to perform laboratory testing. Such discontinuations or recalls could adversely affect the Company' s costs, testing volume and revenue. The commercial laboratory industry is subject to changing technology and new product introductions. The Company' s success in maintaining a leadership position in genomic and other advanced testing technologies will depend, in part, on its ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. The Company may not be able to negotiate acceptable licensing arrangements, and it cannot be certain that such arrangements will yield commercially successful diagnostic tests. If the Company is unable to license these testing methods at competitive rates, its ~~research and development (~~ R & D ~~)~~ costs may increase as a result. In addition, if the Company is unable to license new or improved technologies to expand its esoteric testing operations, its testing methods may become outdated when compared with the Company' s competition, and

testing volume and revenue may be materially and adversely affected. In addition, advances in technology may lead to the development of more cost- effective technologies , such as point- of- care testing equipment that can be operated by physicians or other healthcare providers (including physician assistants, nurse practitioners , and certified nurse midwives, generally referred to herein as physicians) in their offices or by patients themselves without requiring the services of freestanding clinical laboratories. Development of such technology and its use by the Company' s customers could reduce the demand for its laboratory testing services and the utilization of certain tests offered by the Company and negatively impact its revenues . **Similarly, application of artificial intelligence to testing could reduce demand for the Company' s services, or competitors could adopt use of these technologies and derive benefits from them sooner than the Company** . Currently, most commercial laboratory testing is categorized as high or moderate complexity, and thereby is subject to extensive and costly regulation under CLIA. The cost of compliance with CLIA makes it impractical for most physicians to operate clinical laboratories in their offices, and other laws limit the ability of physicians to have ownership in a laboratory and to refer tests to such a laboratory. Manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point- of- care laboratory equipment to physicians and by selling test kits approved for home or physician office use to both physicians and patients. Diagnostic tests approved for home use are automatically deemed to be " waived " tests under CLIA and may be performed in physician office laboratories as well as by patients in their homes with minimal regulatory oversight. Other tests meeting certain FDA criteria also may be classified as " waived " for CLIA purposes. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories, and it has ~~taken~~ responsibility ~~from the U. S. Centers for Disease Control and Prevention~~ for classifying the complexity of tests for CLIA purposes. Increased approval of " waived " test kits could lead to increased testing by physicians in their offices or by patients at home, which could affect the Company' s market for laboratory testing services and negatively impact its revenues. Changes or disruption in services , supplies, or transportation provided by third parties have impacted and could continue to impact or adversely affect the Company' s business. The Company depends on third parties to provide supplies and services critical to the Company' s business. Although the Company has a significant proprietary network of ground and air transport capabilities, certain of the Company' s businesses are heavily reliant on third- party ground and air travel for transport of clinical trial and diagnostic testing supplies and specimens, research products, and people. A significant disruption to these travel systems, or the Company' s access to them, could have a material adverse effect on the Company' s business. The Company is also reliant on an extensive network of third- party suppliers and vendors of certain services and products, including for certain animal populations. Disruptions to the continued supply, or increases in costs, of these services, products, or animal populations may arise from export / import restrictions or embargoes, political or economic instability, pressure from animal rights activists, adverse weather, natural disasters, public health crises, transportation disruptions, ~~cyber attacks~~ **cybersecurity incidents** , or other causes, as well as from termination of relationships with suppliers or vendors for their failure to follow the Company' s performance standards and requirements. Disruption of supply and services has impacted and could continue to impact or have a material adverse effect on the Company' s business. A failure to identify and successfully close and integrate strategic acquisition targets could have a material adverse effect on the Company' s business objectives and its revenues and profitability. Part of the Company' s strategy involves deploying capital in investments that enhance the Company' s business, which includes pursuing strategic acquisitions to strengthen the Company' s scientific capabilities and enhance therapeutic expertise, enhance esoteric testing and global drug development capabilities, and increase presence in key geographic areas. Since ~~2018~~ **2019** , the Company has invested net cash of approximately $ ~~2~~ **3** . ~~9~~ **5** billion in strategic business acquisitions. However, the Company cannot assure that it will be able to identify acquisition targets that are attractive to the Company or that are of a large enough size to have a meaningful impact on the Company' s operating results. Furthermore, the successful closing and integration of a strategic acquisition entails numerous risks, including, among others: • failure to obtain regulatory clearance, including due to antitrust concerns; • loss of key customers or employees **as a result of the acquisition** ; • difficulty in consolidating redundant facilities and infrastructure and in standardizing information and other systems; • unidentified regulatory problems **at the acquired company or business** ; • failure to maintain the quality of services that such companies **or businesses** have historically provided; • unanticipated costs and other liabilities; • potential liabilities related to litigation ~~including~~ **related to** the acquired ~~companies~~ **company or business, or from its prior owners; • failure to timely identify and remediate noncompliant activities of the acquired company or business** ; • potential periodic impairment of goodwill and intangible assets acquired; • coordination of geographically separated facilities and workforces; and • the potential disruption of the **Company' s** ongoing business and diversion of management' s resources. The Company cannot assure that current or future acquisitions, if any, or any related integration efforts will be successful, or that the Company' s business will not be adversely affected by any future acquisitions, including with respect to revenues and profitability. Even if the Company is able to successfully integrate the operations of **companies and** businesses that it ~~may acquire~~ **acquires** in the future, the Company may not be able to realize the benefits that it expects from such acquisitions. Unfavorable labor environments, union strikes, work stoppages, union or works council negotiations, or failure to comply with labor or employment laws could adversely affect the Company' s operations and have a material adverse effect upon the Company' s business. The Company is a party to a limited number of collective bargaining agreements with various labor unions and is subject to employment and labor laws and unionization activity in the U. S. Similar employment and labor obligations exist across other countries in which it conducts business, including appropriate engagement with works councils in Europe. Disputes with regard to the terms of labor agreements or obligations for consultation, potential inability to negotiate acceptable contracts with these unions, unionization activity, or a failure to comply with labor or employment laws could result in, among other things, labor unrest, strikes, work stoppages, slowdowns by the affected workers, fines and penalties. If any of these events were to occur, or other employees were to become unionized, the Company could experience a significant disruption of its operations or higher ongoing labor costs, either of which could have a material adverse effect upon the Company' s business. Additionally, future labor agreements,

or renegotiation of labor agreements or provisions of labor agreements, or changes in labor or employment laws, could compromise its service reliability and significantly increase its costs, which could have a material adverse effect upon the Company' s business. Also, the Company may incur substantial additional costs and become subject to litigation and enforcement actions if the Company fails to comply with legal requirements affecting its workforce and labor practices, including laws and regulations related to wage and hour practices, Office of Federal Contract Compliance Programs ~~(OFCCP)~~ compliance, and unlawful workplace harassment and discrimination. Continued and increased consolidation of pharmaceutical, biotechnology and medical device companies, health systems, physicians and other customers could adversely affect the Company' s business. Many healthcare companies and providers, including pharmaceutical, biotechnology and medical device companies, health systems **,** and physician practices are consolidating through mergers, acquisitions, joint ventures **,** and other types of transactions and collaborations. In addition to these more traditional horizontal mergers that involve entities that previously competed against each other, the healthcare industry is experiencing an increase in vertical mergers, which involve entities that previously did not offer competing goods or services. As the healthcare industry consolidates, competition to provide goods and services may become more intense, and vertical mergers may give those combined companies greater control over more aspects of healthcare, including increased bargaining power. This competition and increased customer bargaining power may adversely affect the price and volume of the Company' s services. In addition, as the broader healthcare industry trend of consolidation continues, including the acquisition of physician practices by health systems, relationships with hospital-based health systems and integrated delivery networks are becoming ~~more~~ **increasingly** important. Dx has a well- established base of relationships with those systems and networks, including collaborative agreements. Dx' s inability to retain its existing relationships with those physicians as they become part of healthcare systems and networks and / or to create new relationships could impact its ability to successfully grow its business. Damage or disruption to the Company' s facilities **or operations therein** could adversely affect the Company' s business. Many of the Company' s facilities **or the operations conducted therein** could be difficult to replace in a short period of time. Any event that causes a disruption of the operation of these facilities might impact the Company' s ability to provide services to customers and, therefore, could have a material adverse effect on the Company' s financial condition, results of operations, and cash flows **. The failure to establish, update, or perform to appropriate quality standards could adversely affect the Company' s business and reputation. The Company has quality control systems and processes to support the performance and delivery of its services. A failure to establish, update, or perform in accordance with those systems or processes could adversely affect the Company' s business operations, resulting in the loss of customers, loss or suspension of licensure or certifications, imposition of sanctions or other penalties, damage to the Company' s reputation, or other adverse effects** . Risks Related to Financial Matters The Company bears financial risk for contracts that, including for reasons beyond the Company' s control, may be underpriced, subject to cost overruns, delayed, or terminated or reduced in scope. The Company has many contracts that are structured as fixed- price for fixed- contracted services or fee- for- service with a cap. The Company bears the financial risk if these contracts are underpriced or if contract costs exceed estimates. Such underpricing or significant cost overruns could have an adverse effect on the Company' s business, results of operations, financial condition **,** and cash flows. Many of ~~DD~~ **BLS** ' s contracts, in particular, provide for services on a fixed- price or fee- for- service with a cap basis and they may be terminated or reduced in scope either immediately or upon notice. Cancellations may occur for a variety of reasons, including: • failure of products to satisfy safety requirements; • unexpected or undesired results of the products; • insufficient clinical trial subject enrollment; • insufficient investigator recruitment; • a customer' s decision to terminate the development of a product or to end a particular study; and • ~~DD~~ **BLS** ' s failure to perform its duties properly under the contract. Although ~~its~~ **BLS'** contracts often entitle ~~it~~ **the Company** to receive the costs of winding down the terminated projects, as well as all fees earned up to the time of termination, the loss, reduction in scope or delay of a large contract or the loss, delay or conclusion of multiple contracts could materially adversely affect ~~DD~~ **BLS** . A significant increase in the Company' s days sales outstanding could have an adverse effect on the Company' s business, including its cash flow, by increasing its bad debt or decreasing its cash flow. Billing for laboratory services is a complex process. Laboratories bill many different payers, including doctors, patients, hundreds of insurance companies, Medicare, Medicaid **,** and employer groups, all of which have different billing requirements. In addition to billing complexities, Dx has experienced an increase in patient responsibility as a result of managed care fee- for- service plans that continue to increase patient deductibles, coinsurance and copayments, or implement restrictive coverage or administrative policies that can further increase patient costs. Dx expects this trend to continue. A material increase in Dx' s days sales outstanding level could have an adverse effect on the Company' s business, including potentially increasing its bad debt rate and decreasing its cash flows. Although ~~DD~~ **BLS** does not face the same level of complexity in its billing processes, it could also experience delays in billing or collection, and a material increase in ~~DD~~ **BLS** ' s days sales outstanding could have an adverse effect on the Company' s business, including potentially decreasing its cash flows. ~~DD~~ **BLS** ' s revenues depend on the pharmaceutical, biotechnology and medical device industries. ~~DD~~ **BLS** ' s revenues depend greatly on the expenditures made by the pharmaceutical, biotechnology and medical device industries in R & D. In some instances, these companies are reliant on their ability to raise capital in order to fund their R & D projects. These companies are also reliant on reimbursement for their products from government programs and commercial payers. Accordingly, economic factors and industry trends affecting ~~DD~~ **BLS** ' s customers in these industries may also affect ~~DD~~ **BLS** . If these companies were to reduce the number of R & D projects they conduct or outsource, whether through the inability to raise capital, reductions in reimbursement from governmental programs or commercial payers, industry trends, economic conditions or otherwise, ~~DD~~ **BLS** could be materially adversely affected. Foreign currency exchange fluctuations could have an adverse effect on the Company' s business. The Company has business and operations outside the U. S., and ~~DD~~ **BLS** derives a significant portion of its revenues from international operations. Since the Company' s consolidated financial statements are denominated in U. S. dollars, fluctuations in exchange rates from period to period will have an impact on reported results. In addition, ~~DD~~ **BLS** may incur costs in one

currency related to its services or products for which it is paid in a different currency. As a result, factors associated with international operations, including changes in foreign currency exchange rates, could significantly affect ~~DD~~ **BLS** ' s results of operations, financial condition and cash flows. The Company' s uses of financial instruments to limit its exposure to interest rate and currency exchange fluctuations could expose it to risks and financial losses that may adversely affect the Company' s financial condition, liquidity and results of operations. To limit the Company' s exposure to interest rate fluctuations and currency exchange fluctuations, it has entered into, and in the future may enter into for these or other purposes, financial swaps, or hedging arrangements, with various financial counterparties. In addition to any risks related to the counterparties, there can be no assurances that the Company' s hedging activity will be effective in insulating it from the risks associated with the underlying transactions, that the Company would not have been better off without entering into these hedges, or that the Company will not have to pay additional amounts upon settlement. The Company' s level of indebtedness and debt service requirements could adversely affect the Company' s liquidity, results of operations and business. At December 31, ~~2022~~ **2023**, indebtedness on the Company' s outstanding Senior Notes totaled approximately $ **4** ~~5, 450~~. ~~0~~ **2** ~~million~~ **billion** in aggregate principal **, of which $ 1. 0 billion is payable within the next 12 months**. The Company is also a party to credit agreements relating to a $ 1. 0 billion revolving credit facility. Under the revolving credit facility, the Company is subject to negative covenants limiting subsidiary indebtedness and certain other covenants typical for investment- grade- rated borrowers, and the Company is required to maintain a leverage ratio within certain limits. The Company' s level of indebtedness and debt service requirements could adversely affect its business. In particular, it could increase the Company' s vulnerability to sustained, adverse macroeconomic weakness, limit its ability to obtain further financing or refinance existing debt at maturity, and limit its ability to pursue certain operational and strategic opportunities, including large acquisitions. Additionally, the Company' s cost of funds could increase due to the impact of increases in prevailing interest rates on its variable rate debt and should the Company refinance existing debt at maturity or obtain further financing. The Company may also enter into additional transactions or credit facilities, including other long- term debt, which may increase its indebtedness and result in additional restrictions upon the business. In addition, major debt rating agencies regularly evaluate the Company' s debt based on a number of factors. There can be no assurance that the Company will be able to maintain its existing debt ratings, and failure to do so could adversely affect the Company' s cost of funds, liquidity and access to capital markets. The Company' s quarterly operating results may vary. The Company' s operating results may vary significantly from quarter to quarter and are influenced by factors over which the Company has little control, such as: • changes in the ~~general~~ global economy; • **currency** exchange rate fluctuations; • the commencement, completion, delay or cancellation of large projects or contracts or groups of projects; • the progress of ongoing projects; • **adverse** weather **, natural disasters, geopolitical events, public health crises, hostilities or acts of terrorism, acts of vandalism, disruption to supply chains, inaccessibility of natural resources, and other events beyond the Company' s control** ; • the timing of and ~~charges~~ **costs** associated with completed acquisitions or other events; and • changes in the utilization mix of the Company' s services. The Company believes that operating results for any particular quarter are not necessarily a meaningful indication of future results. While fluctuations in the Company' s quarterly operating results could negatively or positively affect the market price of the Company' s common stock, these fluctuations may not be related to the Company' s future overall operating performance. ~~Risks Related to the Planned Spin- off of the Company' s Clinical Development and Commercialization Services Business~~ The ~~planned spin- off of the~~ Company **depends** ~~' s Clinical Development and Commercialization Services business may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the intended results. The Company is pursuing a spin- off of its wholly owned Clinical Development and Commercialization Services (CDCS) business, which includes the parts of its DD segment focused on providing Phase I- IV clinical trial management, market access, and technology solutions to pharmaceutical and biotechnology organizations, which would result in two independent, publicly traded companies. Unanticipated issues including, but not limited to, the failure to obtain regulatory approval, obtain appropriate assurances regarding the tax- free nature of the spin- off, or have the Form 10 registration statement that will be filed with the SEC declared effective~~ on a ~~timely basis~~ **variety of U. S. and international financial institutions to provide us with banking services. The default** or **failure of one** ~~at all, could delay, prevent,~~ or ~~otherwise~~ **more of the financial institutions that the Company relies on may** adversely affect the ~~planned spin-~~ **Company' s business and financial condition. The Company maintains the majority** ~~off~~ **of its cash and cash equivalents in accounts with major U** . **S. and international financial institutions, and its deposits at certain of these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions** ~~There~~ **where the Company maintains its cash and cash equivalents, there** can be no assurance that the **Company would be able to access uninsured funds in a timely manner or at all. Additionally, bank payment processes could become unavailable which could temporarily impact the Company' s ability to conduct business with suppliers and pay its employees on a timely basis. Any inability to access or delay in accessing these funds could adversely affect the Company' s business and financial** ~~conditions~~ **condition** ~~of~~ **. The Company might not be able to engage in certain desirable capital- raising or strategic transactions. The Company' s ability to engage in certain transactions could be limited or restricted in order to preserve, for U. S. federal income tax purposes,** the **tax- free qualification of the Fortrea** spin- off ~~will be satisfied or that Company will be able to complete~~ **and certain related transactions under Sections 355 and 368 (a) (1) (D) of the Internal Revenue Code. Even if** the spin- off ~~on~~ **and certain related transactions otherwise qualify for tax- free treatment under Section 355 of the Code,** ~~the~~ **they** ~~terms or on~~ **may result in corporate- level taxable gain to the Company if** ~~the~~ **there** ~~anticipated timeline,~~ **is a 50 %** or ~~at all. The~~ **greater change in ownership, by vote or value, of shares of the** Company ~~expects~~ **' s stock, Fortrea' s stock, or the stock of a successor of either occurring as part of a plan or series of related transactions** that **includes** ~~pursuing and implementing~~ the spin- off ~~will continue~~ **, which is generally presumed to include any acquisitions or issuances of stock within** ~~to~~ **two** ~~require significant expenses and management~~ **years of the spin- off. To avoid realizing such taxable gain, the Company may be restricted or limited in its capital- raising or**

in the strategic transactions that it elects to pursue during such time ~~and effort,~~ **period. The recently completed spin- off of Fortrea** may ~~divert management~~ **not achieve the intended results. On June 30, 2023, the Company completed the previously announced spin- off of Fortrea Holdings Inc. (Fortrea). The spin- off poses risks and challenges that could impact the Company** ' s ~~attention~~ **business, including, but not limited to, the failure to achieve the intended benefits** from the ~~Company~~ **spin- off, the failure to receive tax- free treatment for U. S. federal income purposes,** and ~~CDCS' ongoing business operations and~~ **potential exposure to unexpected claims, liabilities, or costs under the Company' s agreements with Fortrea in connection with the spin- off. The spin- off** may adversely impact relationships with customers, suppliers, employees, and other business counterparties ~~. The~~ **and the** Company may experience delays, business disruption, increased costs, including from lost synergies ~~or from restructuring transactions, negative market reaction to the announcement and planning for the transaction, change in market receptiveness to effect transactions in the capital markets, and other challenges during or following the spin- off~~ , which could adversely affect the Company' s business, financial condition, and results of operations. The Company may also experience increased challenges in attracting, retaining, and motivating key personnel ~~during the pendency of the spin- off and following its completion~~ , which could harm the Company' s business. The Company **' s** ~~anticipates that, consistent with any applicable legal and tax requirements, there will be~~ ongoing transitional and commercial arrangements **with Fortrea intend** to provide for a seamless delivery of services to the customers and other stakeholders of the independent companies following the spin- off, but those arrangements may not meet the intended objectives **and could have unexpected costs or challenges** , which could negatively impact the Company' s ~~and CDCS'~~ business, including relationships with customers and other business counterparties ~~. Further~~ , ~~if~~ **and which could also result in a decline in value of** the ~~planned spin~~ **Company. Risks Related to Technology and Cybersecurity Failure to maintain the security of customer** - **related information or compliance with security requirements could damage the Company' s reputation with customers, cause it to incur substantial additional costs and become subject to litigation and enforcement actions. The Company receives and stores certain personal and financial information about its customers. In addition, the Company depends upon the secure transmission** ~~off~~ - **of confidential information over public networks,including information permitting cashless payments.The Company also works with third- party service providers and vendors that provide technology systems and services that are used in connection with the receipt,storage,and transmission of customer personal and financial information.A compromise in the Company' s security systems,or those of the Company' s third- party service providers and vendors,that results in customer personal information being obtained by unauthorized persons,or the Company' s** or a third party' s failure to comply with security requirements for financial transactions,including security standards for payment cards (e.g.,the Payment Card Industry Data Security Standard),could adversely affect the Company' s reputation with its customers and others,as well as the Company' s results of operations,financial condition and liquidity.It could also result in litigation against the Company and the imposition of fines and penalties.For example,in connection with the AMCA Incident **(as defined below under " Cybersecurity " in Item 1C)** the Company has incurred,and expects to continue to incur,costs,and the Company ~~is involved in pending and threatened litigation,as well as various government and regulatory inquiries and processes.For additional information about the AMCA Incident,see Note 14 Commitments and Contingencies to the Consolidated Financial Statements of Part III of the Annual Report.Failure in the Company' s information technology systems or delays or failures in the development and implementation of new systems or updates or enhancements to existing systems could disrupt the Company' s operations or customer relationships.The Company' s operations and customer relationships depend,in part,on the continued performance of its information~~ is ~~completed~~ **involved in pending and threatened litigation** , as well as various government and regulatory inquiries and processes.For additional information about the AMCA Incident,see Note ~~14~~ **15** Commitments and Contingencies to the Consolidated Financial Statements of Part III of the Annual Report.Failure in the Company' s information technology systems or delays or failures in the development and implementation of new systems or updates or enhancements to existing systems could disrupt the Company' s operations or customer relationships.The Company' s operations and customer relationships depend,in part,on the continued performance of its information technology systems.A failure of the network or data- gathering procedures could impede the processing of data,delivery of databases and services,customer orders and day- to- day management of the business and could result in the corruption or loss of data.Despite network security measures and ~~the~~ **other** ~~anticipated benefits~~ **precautions the Company has taken, including the development** of **disaster recovery plans, its information technology systems are potentially vulnerable to physical or electronic break- ins, computer viruses, fire, natural disaster, power loss, telecommunications failures, cybersecurity incidents and similar disruptions, and** ~~the~~ **there** ~~transaction~~ may not be ~~realized~~ **adequate protections,mitigation plans or redundant facilities available in the event of such system failures.In addition,the Company may experience system failures or interruptions as it integrates the information technology systems of newly acquired businesses.Failures or interruption of the Company' s systems in one or more of its operations** could result in interruptions of service,disrupt the Company' s ability to process laboratory requisitions,perform testing,provide test results or drug development data in a timely manner and / or conduct timely billing operations.Such system failures could require the Company to transfer operations to an alternative provider of services,which could result in ~~a~~ delays in the delivery of products and services to customers.Additionally,significant delays in the planned delivery of system enhancements or improvements,or inadequate performance of the systems once they are complete could damage the Company' s reputation and harm the business.Furthermore,failure of the Company' s information technology systems could adversely affect the Company' s business,profitability,financial condition,and reputation. ~~Security breaches~~ **Cybersecurity incidents** and unauthorized access to the Company' s or its customers' data could harm the Company' s reputation and adversely affect its business.The Company has experienced and expects to continue to experience attempts by computer programmers and hackers to ~~attack and~~ penetrate the Company' s layered ~~security~~ **cybersecurity** controls,like the 2018 ransomware attack.The Company has also experienced and expects to continue to experience similar attempts to ~~attack and~~ penetrate the systems of third- party suppliers and vendors to

whom the Company has provided data,like the 2019 AMCA data breach.These attempts,if successful,could result in the misappropriation or compromise of personal information or proprietary or confidential information stored ~~within the Company' s systems or within the systems of third parties,create system disruptions or cause shutdowns.External actors are developing and deploying viruses,worms and other malicious software programs that attack the Company' s systems,the systems of third- parties,or~~ within the ~~expected time periods~~ **Company' s systems** or ~~at~~ **within** the systems of third parties,create system disruptions or cause shutdowns.External actors are developing and deploying viruses,worms and other malicious software programs that attack the Company' s systems,the systems of third- parties,or otherwise exploit any security vulnerabilities.Outside parties may also attempt to fraudulently induce employees to take actions,including the release of confidential or sensitive information or to make fraudulent payments through illegal electronic spamming,phishing,spear phishing,or other tactics.The Company has robust information security procedures and other safeguards in place,including evaluating the cybersecurity status of third- party suppliers and vendors that will have access to the Company' s data or information technology systems,which are monitored and routinely tested internally and by external parties.However,because the techniques used to obtain unauthorized access,disable or degrade service,or sabotage systems change frequently and often are not recognized until launched against a target,the Company may be unable to anticipate ~~all~~ all ~~. Failure~~ **of these techniques or** to implement **adequate preventive measures. In addition** ~~the planned spin- off effectively or the negative reaction of customers~~ , **as cyber threats continue to evolve, the Company may be required to expend additional resources to continue to enhance** the Company' s ~~employees,~~ **information security measures or to investigate** and ~~other stakeholders~~ **remediate any information security vulnerabilities. The Company' s remediation efforts may not be successful and could result in interruptions, delays or cessation of service. This** could also **impact the cost and availability of cyber insurance to the Company. Cybersecurity incidents affecting the Company' s or third parties' security measures and the unauthorized dissemination of personal, proprietary or confidential information about the Company or its customers or other third parties could expose customers' private information. Such incidents could expose customers to the risk of financial or medical identity theft or expose the Company or other third parties to a risk of loss or misuse of this information,** result in **litigation and potential liability for the Company, damage the Company' s brand and reputation or otherwise harm the Company' s business. Any of these disruptions or incidents could have** a **material adverse effect** ~~decline in value of one~~ - **on the Company' s business, regulatory compliance, financial condition and results of operations. In addition, the Company faces increased cybersecurity risks due to the number of employees that continue to work remotely, which remains at levels higher than prior to the COVID- 19 pandemic as a result of changes in the workplace and to management and employee expectations. Increased levels of remote access create additional opportunities ~~or~~ for ~~both~~ cybercriminals to exploit vulnerabilities, and employees may be more susceptible to phishing and social engineering attempts. In addition, technological resources may become strained due to the number** of **remote users. The Company also faces potential cybersecurity risks from the use of artificial intelligence and machine learning (AI) tools. The Company, or its customers' sensitive, proprietary, or confidential information could be leaked, disclosed, or revealed as a result of or in connection with employees' or vendors' use of generative AI technologies. In addition, the Company may use AI outputs to inform certain decisions, and AI models may create incomplete, inaccurate, or otherwise flawed outputs, some of which may appear correct. Due to the potential flaws in the use of AI, the Company could make incorrect decisions, including decisions that could bias certain individuals or classes of individuals and adversely impact their rights. As a result, the Company could face adverse consequences, including exposure to reputational and competitive harm, customer loss, and legal liabilities. The AI tools may also be subject to additional, and as yet unidentified, security threats. The Company depends on third parties to provide services critical to the Company' s business, and depends on ~~the~~ them ~~companies~~ to** comply with applicable laws and regulations.Additionally,any ~~breaches of~~ **cybersecurity incidents affecting** the information technology systems of third parties could have a material adverse effect on the Company' s operations.The Company depends on third parties to provide services critical to the Company' s business,including supplies,ground and air transport of clinical and diagnostic testing supplies and specimens,research products,and people,among other services.Third parties that provide services to the Company are subject to similar risks related to security of customer- related information and compliance with U.S.,state,local,or international environmental,health and safety,and privacy and security laws and regulations as the Company.Any failure by third parties to comply with applicable laws,or any failure of third parties to provide services more generally,could have a material impact on the Company,whether because of the loss of the ability to receive services from the third parties,legal liability of the Company for the actions or inactions of third parties,or otherwise.In addition,third parties to whom the Company outsources certain services or functions may process personal data,or other confidential information of the Company.A **cybersecurity incident** ~~breach or cyber attack~~ affecting these third parties,like the AMCA Incident,could also harm the Company' s business,results of operations and reputation . Risks Related to Regulatory and Compliance Matters Changes **in payer regulations or policies, insurance regulations or approvals, or changes in laws, regulations, or policies in the U. S. or globally** , including changes in **their** interpretation ~~, in payer regulations, policies or approvals, or changes in laws, regulations or policies in the U. S. or globally~~ , may adversely affect the Company. U. S. and state government payers, such as Medicare and Medicaid, as well as insurers, including MCOs, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, Congress has considered and implemented changes in Medicare fee schedules in conjunction with budgetary legislation. The first phase of reductions pursuant to PAMA came into effect on January 1, 2018, and will continue ~~annually~~ subject to certain delays in implementation and phase- in limits through ~~2026~~ **2027** , and without limitations for subsequent periods. Further reductions due to changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization, diagnosis code and other claims edits, may be implemented from time to time. **Medicare** ~~Reimbursement~~ **reimbursement** for pathology services performed by Dx **, which are paid for under the PFS,** is also subject to statutory and

regulatory reduction. Reductions in the reimbursement rates and changes in payment policies of other third- party payers may occur as well. Such changes in the past have resulted in reduced payments as well as added costs and have decreased test utilization for the commercial laboratory industry by adding more complex new regulatory and administrative requirements. Further changes in third- party payer regulations, policies, or laboratory benefit or utilization management programs may have a material adverse effect on Dx' s business. Actions by federal and state agencies regulating insurance, including healthcare exchanges, or changes in other laws, regulations, or policies may also have a material adverse effect upon Dx' s business. The Company could face significant monetary damages and penalties and / or exclusion from government programs if it violates anti- fraud and abuse laws. The Company is subject to extensive government regulation at the federal, state, and local levels in the U. S. and other countries where it operates. The Company' s failure to meet governmental requirements under these regulations, including those relating to billing practices and financial relationships with physicians, hospitals, and health systems **, and others** could lead to civil and criminal penalties, exclusion from participation in Medicare and Medicaid and possible prohibitions or restrictions on the use of its laboratories. While the Company believes that it is in material compliance with all statutory and regulatory requirements, there is a risk that government authorities might take a contrary position. This risk includes, but is not limited to, the potential that government enforcement authorities may take a contrary position with respect to the Eliminating Kickbacks in Recovery Act, given the lack of associated regulations to clarify or add exceptions. Such occurrences, regardless of their outcome, could damage the Company' s reputation and adversely affect important business relationships. The Company' s business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or interpretations of, the law or regulations of CLIA, Medicare, Medicaid or other national, state **,** or local agencies in the U. S. and other countries where the Company operates laboratories. The commercial laboratory testing industry is subject to extensive U. S. regulation, and many of these statutes and regulations have not been interpreted by the courts. CLIA extends federal oversight to virtually all clinical laboratories operating in the U. S. by requiring that they be certified by the federal government or by a federally approved accreditation agency. The sanction for failure to comply with CLIA requirements may be suspension, revocation **,** or limitation of a laboratory' s CLIA certificate, which is necessary to conduct business, as well as significant fines and / or criminal penalties. In addition, the Company is subject to regulation under state law. State laws may require that laboratories and / or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. The Company also operates laboratories outside of the U. S. and is subject to laws governing its laboratory operations in the other countries where it operates. Applicable statutes and regulations could be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect the Company' s business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates **,** and authorizations, which could have a material adverse effect on the Company' s business. In addition, compliance with future legislation could impose additional requirements on the Company, which may be costly. Failure of the Company or its third- party service providers to comply with privacy and **data** security laws and regulations could result in fines, penalties and damage to the Company' s reputation with customers and have a material adverse effect upon the Company' s business. If the Company and its third- party service providers do not comply with existing or new laws and regulations related to protecting the privacy and security of personal or health information, it could be subject to monetary fines, civil penalties **, litigation,** or criminal sanctions. In the U. S., the Health Insurance Portability and Accountability Act of 1996 ~~(HIPAA) privacy and security regulations~~ , ~~including~~ the ~~expanded requirements under~~ U. S. Health Information Technology for Economic and Clinical Health ~~Act~~ (HITECH) **Act** , **and their implementing privacy and security regulations (collectively, HIPAA)** establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities **as well as their" business associates" as defined in HIPAA** , in addition to setting standards to protect the confidentiality, integrity and security of PHI. HIPAA restricts the Company' s ability to use or disclose PHI, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. HIPAA ~~and HITECH provide~~ **provides** for significant fines and other penalties for wrongful use or disclosure of PHI in violation of the privacy and security regulations, including potential civil and criminal fines and penalties. The regulations establish a complex ~~regulatory~~ framework on a variety of subjects, including: • the circumstances under which the use and disclosure of PHI are permitted or required without a specific authorization by the patient, including, but not limited to, treatment purposes, activities to obtain payments for the Company' s services, and its healthcare operations activities; • a patient' s rights to access, amend and receive an accounting of certain disclosures of PHI; • the content of notices of privacy practices for PHI; • administrative, technical and physical safeguards required of entities that use or receive PHI; and • the protection of computing systems maintaining electronic PHI. The Company has implemented policies and procedures designed to comply with the HIPAA privacy and security requirements as applicable. The privacy and security regulations establish a " floor " and do not supersede state laws that are more stringent. Therefore, the Company is required to comply with both additional federal privacy and security regulations and varying state privacy and security laws. ~~In~~ **To the extent applicable, newer laws like the California Consumer Privacy Act (" CCPA ") as amended by the California Privacy Rights Act (" CPRA "), the Washington My Health My Data Act, and similar consumer privacy laws in other states, may impose** ~~addition~~ **additional** ~~,~~ **obligations on the Company.** ~~federal~~ **Federal** and state laws that protect the privacy and security of patient information may be subject to enforcement and interpretations by various governmental authorities and courts, resulting in complex compliance issues. ~~For example~~ **In addition** , **laws regulating artificial intelligence and machine learning, including the use of algorithms and automated processing, may impact the Company and lead to increases in the cost of compliance. Noncompliance with** ~~the~~ **these** ~~Company~~ **laws** could ~~incur damages under state laws~~ **result in the imposition of fines** , ~~including pursuant~~ **penalties, or orders** to **stop certain activities,** ~~an~~ **and potentially expose the Company to** ~~action~~ **actions** ~~brought by a private party~~ for the wrongful use or disclosure of health information or other personal information. The

Company may also be required to comply with the data privacy and security laws of other countries in which it operates or with which it transfers and receives data. For example, the EU' s General Data Protection Regulation (GDPR), which took effect May 25, 2018, created a range of compliance obligations for subject companies and imposes penalties for noncompliance of up to the greater of € 20 million or 4 % of worldwide revenue **for the most serious breaches of data protection obligations** . The Company has established processes and frameworks to manage compliance with the GDPR. Potential fines and penalties in the event of a violation of the GDPR could have a material adverse effect on the Company' s business and operations. In addition, similar data protection regulations addressing access, use, disclosure and transfer of personal data have been enacted or updated in regions where the Company does business, including in Asia, Latin America, and Europe. The Company expects to make changes to its business practices and to incur additional costs associated with compliance with these evolving and complex regulations. The Company' s international operations could subject it to additional risks and expenses that could adversely impact the business or results of operations. The Company' s international operations expose it to risks from potential failure to comply with foreign laws and regulations that differ from those under which the Company operates in the U. S. In addition, the Company may be adversely affected by other risks of ~~expanded~~ operations in foreign countries, including, but not limited to ~~,~~ **:** changes in reimbursement by foreign governments for services provided by the Company; compliance with export controls and trade regulations; changes in tax policies or other foreign laws; compliance with foreign labor and employee relations laws and regulations; restrictions on currency repatriation; judicial systems that less strictly enforce contractual rights; countries that do not have clear or well- established laws and regulations concerning issues relating to commercial laboratory testing or drug development services; countries that provide less protection for intellectual property rights; and procedures and actions affecting approval, production, pricing, reimbursement and marketing of products and services. Further, international operations could subject the Company to additional expenses that the Company may not fully anticipate, including those related to enhanced time and resources necessary to comply with foreign laws and regulations, difficulty in collecting accounts receivable and longer collection periods, and difficulties and costs of staffing and managing foreign operations. In some countries, the Company' s success will depend in part on its ability to form relationships with local partners. The Company' s inability to identify appropriate partners or reach mutually satisfactory arrangements could adversely affect the business and operations. ~~Expanded international~~ **International** operations may increase the Company' s exposure to liabilities under ~~the~~ **applicable** anti- corruption laws. Anti- corruption laws in the countries where the Company conducts business, including the ~~U. S. Foreign Corrupt Practices Act (~~FCPA ~~)~~, U. K. Bribery Act, and similar laws in other jurisdictions, prohibit companies and their intermediaries from engaging in bribery including improperly offering, promising, paying or authorizing the giving of anything of value to individuals or entities for the purpose of corruptly obtaining or retaining business. The Company operates in ~~some~~ parts of the world where corruption may be common and where anti- corruption laws may conflict to some degree with local customs and practices. The Company maintains an anti- corruption program including policies, procedures, training and safeguards in the engagement and management of third parties acting on the Company' s behalf. Despite these safeguards, the Company cannot guarantee protection from corrupt acts committed by employees or third parties associated with the Company. Violations or allegations of violations of anti- corruption laws could have a significant adverse effect on the business or results of operations. Failure to comply with the regulations of pharmaceutical and medical device regulatory agencies, such as the FDA, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom ~~(U. K.)~~, the European Medicines Agency, the National Medical Products Administration in China (NMPA), and the Pharmaceuticals and Medical Devices Agency in Japan, could result in fines, penalties, and sanctions against ~~DD~~ **BLS** and have a material adverse effect upon the Company. The operation of ~~DD~~ **BLS** ' s preclinical laboratory facilities and ~~clinical trial~~ **central laboratory** operations must conform to good laboratory practice (GLP) and good clinical practice (GCP), as applicable, as well as all other applicable standards and regulations, as further described in Item 1 of Part I of this Annual Report. The business operations of ~~DD~~ **BLS** ' s clinical and preclinical laboratories also require the import, export and use of medical devices, in vitro diagnostic devices, reagents, and human and animal biological products. Such activities are subject to numerous applicable local and international regulations with which ~~DD~~ **BLS** must comply. If ~~DD~~ **BLS** does not comply, ~~DD~~ **BLS** could potentially be subject to civil, criminal or administrative sanctions and / or remedies, including suspension of its ability to conduct preclinical and clinical studies, and to import or export to or from certain countries, which could have a material adverse effect upon the Company. Additionally, certain ~~DD~~ **BLS** services and activities must conform to current good manufacturing practice (cGMP), as further described in Item 1 of Part I of this Annual Report. Failure to maintain compliance with GLP, GCP, or cGMP regulations and other applicable requirements of various regulatory agencies could result in warning or untitled letters, fines, unanticipated compliance expenditures, suspension of manufacturing, and civil, criminal or administrative sanctions and / or remedies against ~~DD~~ **BLS** , including suspension of its laboratory operations, which could have a material adverse effect upon the Company. Increased regulations and restrictions on the import of research animals, limitations of supply of research animals, and actions of animal rights activists may have an adverse effect on the Company. ~~DD~~ **BLS** ' s preclinical services utilize animals in preclinical testing of the safety and efficacy of drugs and devices. Such activities are required for the development of new medicines and medical devices under regulatory regimes in the U. S., Europe, Japan, and other countries. Increased regulations and restrictions on the import of research animals into various countries, as well as limitations of supply ~~, such as those the Company and others experienced in 2022 due to market factors in certain global regions,~~ could impact ~~DD~~ **BLS** ' s ability to conduct preclinical research and could have an adverse effect on ~~DD~~ **BLS** ' s financial condition, results of operations, and cash flows. In addition, acts of vandalism and other acts by animal rights activists who object to the use of animals in drug development could have an adverse effect on the Company. Animal populations may suffer diseases that can damage ~~DD~~ **BLS** ' s inventory, harm its reputation, or result in other liability. It is important that research products be free of diseases, including infectious diseases. The presence of diseases can distort or compromise the quality of research results, cause loss of animals in ~~DD~~ **BLS** ' s inventory, result in harm to humans or outside animal populations if the disease is not contained to animals in inventory, or result in other

losses. Such results could harm ~~DD~~ **BLS** ' s reputation or have an adverse effect on ~~DD~~ **BLS** ' s financial condition, results of operations, and cash flows. Failure to conduct animal research in compliance with animal welfare laws and regulations could result in sanctions and / or remedies against ~~DD~~ **BLS** and have a material adverse effect upon the Company. The conduct of animal research at ~~DD~~ **BLS** ' s facilities must be in compliance with applicable laws and regulations in the jurisdictions in which those activities are conducted. These laws and regulations include the U. S. Animal Welfare Act (AWA), which governs the care and use of warm- blooded animals for research in the U. S. other than laboratory rats, mice and chickens, and is enforced through periodic inspections by the U. S. Department of Agriculture (USDA). The AWA establishes facility standards regarding several aspects of animal welfare, including housing, ventilation, lighting, feeding and watering, handling, veterinary care, and recordkeeping. Similar laws and regulations apply in other jurisdictions in which ~~DD~~ **BLS** conducts animal research, including the UK, EU, and China. ~~DD~~ **BLS** complies with licensing and registration requirement standards set by these laws and regulations in the jurisdictions in which it conducts animal research. If an enforcement agency determines that ~~DD~~ **BLS** ' s equipment, facilities, laboratories or processes do not comply with applicable standards, it may issue an inspection report documenting the deficiencies and setting deadlines for any required corrective actions. For noncompliance, the agency may take action against ~~DD~~ **BLS** that may include fines, suspension and / or revocation of animal research licenses, or confiscation of research animals. U. S. Food and Drug Administration (FDA) regulation of diagnostic products, increased FDA regulation of laboratory- developed tests (LDTs), and regulation by other countries of diagnostic products could result in increased costs and the imposition of fines or penalties, and could have a material adverse effect upon the Company' s business. The FDA has regulatory responsibility for instruments, test kits, reagents and other devices used by clinical laboratories. The FDA enforces laws and regulations that govern the development, testing, manufacturing, performance, labeling, advertising, marketing, distribution, and surveillance of diagnostic products, and it regularly inspects and reviews the manufacturing processes and product performance of diagnostic products. Dx' s point- of- care testing devices are subject to regulation by the FDA. ~~Since the 1990s, the FDA has asserted that it has authority to regulate LDTs as medical devices, but has exercised enforcement discretion to refrain from systematic regulation of LDTs. In 2014, the FDA issued draft guidance describing how it intended to discontinue its enforcement discretion policy and begin regulating LDTs as medical devices; however, that draft guidance has not been finalized, and the FDA has instead continued its enforcement discretion policy and has indicated that it intends to work with Congress to enact comprehensive legislative reform of diagnostics oversight. As such,~~ LDTs developed by high complexity clinical laboratories are currently generally offered as services to health care providers under the CLIA regulatory framework administered by CMS, without the requirement for FDA clearance or approval. ~~There are~~ **However, since** ~~other~~ -- **the 1990s, the FDA has asserted that it has authority to regulate LDTs as medical devices but has exercised enforcement discretion to refrain from systematic** ~~regulatory~~ **regulation of LDTs. In 2014, the FDA issued draft guidance describing how it intended to discontinue its enforcement discretion policy** and **begin regulating LDTs as medical devices; however, that draft guidance has not been finalized, and the FDA has instead continued its enforcement discretion policy and has indicated that it intends to work with Congress to enact comprehensive** legislative **reform of diagnostics** ~~proposals that would increase general FDA~~ oversight ~~of clinical laboratories and LDTs~~. **In** ~~The outcome and ultimate impact of such proposals on the business is difficult to predict at this time. On~~ February ~~20,~~ 2020, the FDA issued a statement with a table of pharmacogenetic associations setting forth certain gene- drug interactions that the agency ~~has~~ determined are supported by the scientific literature to help ensure that claims being made for pharmacogenetic tests are grounded in sound science, thereby reducing the risk of enforcement actions with respect to LDTs offering claims consistent with the table. The FDA noted that ~~while it is committed to work with Congress on new comprehensive diagnostic oversight reform legislation,~~ it could ~~still~~ take enforcement actions under the current medical device framework regarding diagnostic claims the agency determines not to be sufficiently supported. **In addition, in 2021, the Verifying Accurate, Leading- edge, IVCT Development (VALID) Act was introduced to Congress and provided a framework to change in vitro diagnostics and LDTs to in vitro clinical tests. In 2022, the VALID Act was incorporated into the Senate user fee bill but was not included in the year- end Consolidated Appropriations Act of 2022. Following challenges with passing diagnostics reform legislation, the FDA released a proposed rule to clarify its authority to regulate LDTs as medical devices under the federal Food, Drug, and Cosmetic Act in October 2023. If finalized, FDA would phase out its general enforcement discretion approach for LDTs.** Even without issuance of a finalized LDT oversight framework, in light of the April 4, 2019, FDA warning letter issued to Inova Genomics Laboratory related to certain LDTs that Inova offered, ~~as well as~~ the February 2020 pharmacogenetics statement **,** and the ~~failure to pass diagnostic reform legislation in 2022~~ **2023 proposed rule** , there may be an increased risk of FDA enforcement actions for laboratory tests offered by companies without FDA clearance or approval. **However, the outcome and its ultimate impact on the Company' s business is difficult to predict at this time.** Current FDA regulation of the Company' s diagnostic products and the potential for future increased regulation of the Company' s LDTs in the future could result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions, and other civil and criminal sanctions **, and could impair the development and commercialization of new tests** , which could have a material adverse effect upon the Company. Regulation of diagnostics products in jurisdictions outside the U. S. in which the Company operates may impact laboratory testing offered by the Company in both Dx and ~~DD~~ **BLS** . For example, the European Union In Vitro Diagnostics Regulation (Regulation (EU) 2017 / 746 (EU IVDR)) ~~, which became applicable on May 26, 2022, establishes~~ **established** a new legislative framework for in vitro diagnostic devices that are used in certain circumstances, and includes a rule- based classification and quality and safety standards. The EU IVDR, where applicable to ~~DD~~ **BLS** ' s services, could impact ~~DD~~ **BLS** ' s ability to support trials, result in increased costs and administrative and legal actions, and have an adverse effect. Failure to comply with U. S., state, local **,** or international environmental, health and safety laws and regulations, including the U. S. Occupational Safety and Health Administration Act and the U. S. Needlestick Safety and Prevention Act, could result in fines, penalties and loss of licensure,

and have a material adverse effect upon the Company. As previously discussed in Item 1 of Part I of this Annual Report, the Company is subject to licensing and regulation under laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials, as well as regulations relating to the safety and health of laboratory employees. Failure to comply with these laws and regulations could subject the Company to denial of the right to conduct business, fines, criminal penalties and / or other enforcement actions that would have a material adverse effect on its business. In addition, compliance with future legislation could impose additional requirements on the Company that may be costly. **Environmental, social** ~~Risks Related to Technology~~ and ~~Cybersecurity Failure to maintain~~ **governance (ESG) matters and the perception of the Company' s activities in** ~~the~~ **these** ~~security~~ **areas by stakeholders may impact the Company' s business and reputation. Governmental authorities, non- governmental organizations, customers, investors, external stakeholders, and employees are increasingly sensitive to ESG concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability** of **packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing, and distributing the Company' s services and products. The Company' s ability to compete could also be affected by changing** customer ~~-~~ **preferences and requirements and the failure to meet such customer expectations or demand, whether** related ~~information~~ **to environmental concerns** or ~~compliance with security requirements could damage the~~ **other ESG matters. While the** Company **strives to improve** ~~' s reputation with customers, cause it~~ **its ESG performance, has established** ~~to incur substantial additional costs and become subject to litigation and enforcement actions. The Company receives and stores~~ certain ~~personal~~ **ESG goals** and **initiatives** ~~financial information about its customers. In addition~~ , **and participates in various** ~~the Company depends upon the secure transmission of confidential information over public networks, including information permitting cashless payments. The Company also works with~~ third- party **assessments** ~~service providers~~ and ~~vendors that provide technology systems~~ **reporting regimens, the Company risks negative stockholder reaction** and **activism, including from proxy advisory** services ~~that are used in connection with the receipt~~ , ~~storage,~~ **as well as damage to its** ~~and~~ **brand** ~~transmission of customer personal~~ and ~~financial information. A compromise~~ **reputation, if the Company fails to meet its goals and initiatives or if the Company is perceived to not be acting responsibly in key ESG areas, including product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors** in the Company' s ~~security systems, or~~ **operations. Responding to** ~~those~~ **these ESG considerations and implementation** of the Company ~~'~~ **'** s **ESG goals and initiatives involves risks and uncertainties, requires investments, and depends in part on** third- party **performance or data** ~~service providers and vendors,~~ that **is beyond** ~~results in customer personal information being obtained by unauthorized persons, or~~ the Company' s **control** or a third party' s failure..... in the event of such system failures . In addition, ~~the Company~~ **some stakeholders** may **disagree with the Company' s ESG goals and initiatives. If the Company does not meet the evolving and varied ESG expectations of its investors, customers and other stakeholders, the Company could** experience ~~system failures~~ **reduced demand** ~~or~~ **for** ~~interruptions as it~~ **its** ~~integrates~~ **products, loss of customers, and** ~~the~~ **other negative impacts on** ~~information technology systems of newly acquired businesses. Failures or interruption of~~ the Company' s **business and results** ~~systems in one or more~~ of ~~its~~ operations could result in interruptions of service,..... business, results of operations and reputation . Risks Related to Legal Matters Adverse results in material litigation matters could have a material adverse effect upon the Company' s business. The Company is currently and may continue to be subject in the ordinary course of business to legal actions related to, among other things, intellectual property disputes, contract disputes, data and privacy issues, professional liability and employee- related matters, which may be or may become material. The Company also has received and may in the future receive inquiries and requests for information from governmental agencies and bodies, including Medicare or Medicaid payers, requesting comment and / or information on various matters, including allegations of billing irregularities, billing and pricing arrangements, or privacy practices that are brought to its attention through audits or third parties. Legal actions can result in substantial monetary damages as well as damage to the Company' s reputation with customers, which could have a material adverse effect upon its business. The failure to successfully obtain, maintain **,** and enforce intellectual property rights and defend against challenges to the Company' s intellectual property rights could adversely affect the Company. Many of the Company' s services, products and processes rely on intellectual property, including patents, copyrights, trademarks **,** and trade secrets. In some cases, that intellectual property is owned by another party and licensed to the Company, sometimes exclusively. The value of the Company' s intellectual property relies in part on the Company' s ability to maintain its proprietary rights to such intellectual property. The Company has been in the past and may be unable in the future to obtain or maintain the proprietary rights to its intellectual property, to prevent attempted infringement against its intellectual property, or to defend against claims that it is infringing on another party' s intellectual property, and the Company could be adversely affected. For example, in October 2020, Ravgen Inc. filed a patent infringement lawsuit against the Company alleging infringement of two Ravgen- owned U. S. patents **. In** ~~, and in~~ September 2022, a jury rendered a verdict in favor of Ravgen on the remaining patent at issue ~~,~~ ~~finding that the Company willfully infringed Ravgen' s patent,~~ and awarded damages of $ 272 million. **In May 2023, a judge awarded** Ravgen **additional** ~~has filed post- trial motions seeking~~ enhanced damages **in the amount** of ~~up to~~ $ ~~817~~ **100** million ~~based on the finding of willfulness, as well as attorney' s fees and costs~~ . The Company strongly disagrees with the verdict, based on a number of legal factors, and will vigorously defend the lawsuit through the appeal process. On June 4, 2021, the Company also instituted proceedings before the Patent Trial and Appeal Board of the U. S. Patent and Trademark Office challenging the validity of the Ravgen patent at issue in the trial. In November 2022, the Patent Trial and Appeal Board issued a decision upholding the validity of the Ravgen patent, and the Company has filed an appeal of this decision. Adverse effects resulting from the failure to successfully obtain, maintain, and enforce intellectual property rights and defend against challenges to the Company' s intellectual property rights could include the Company having to abandon, alter and / or delay the deployment of

products, services or processes that rely on such intellectual property; having to procure and pay for licenses from the holders of intellectual property rights that the Company seeks to use **,** ~~; and~~ having to pay damages, fines, court costs and attorney' s fees in connection with intellectual property litigation **, and reputational damage** . Changes in tax laws and regulations or the interpretation of such may have a significant impact on the financial position, results of operations **,** and cash flows of the Company. U. S. and foreign governments continue to review, reform and modify tax laws, including with respect to the Organisation for Economic Co- operation and Development' s base erosion and profit shifting initiative. Changes in tax laws and regulations could result in material changes to the domestic and foreign taxes that the Company is required to provide for and pay. In addition, the Company is subject to regular audits with respect to its various tax returns and processes in the jurisdictions in which it operates. Errors or omissions in tax returns, process failures or differences in interpretation of tax laws by tax authorities and the Company may lead to litigation, payments of additional taxes, penalties and interest. Contract ~~research~~ services in the drug development industry create liability risks. In contracting to work on drug development trials and studies, ~~DD~~ **BLS** faces **potential risks inherent to the provision of diagnostic information services for clinical trial participants. Users of BLS for clinical trials may have** a ~~range~~ **greater sensitivity to errors than the users** of **services or products that are intended for other purposes, such as research only. Other** potential liabilities ~~,~~ **may** ~~including~~ **include** : • Errors or omissions that create harm to clinical trial subjects during a trial or to consumers of a drug after the trial is completed and regulatory approval of the drug has been granted; • ~~General risks associated with clinical pharmacology facilities, including negative consequences from the administration of drugs to clinical trial participants or the professional malpractice of clinical pharmacology physicians; •~~ Risks that animals in ~~DD~~ **BLS** ' s facilities may be infected with diseases that may be harmful and even lethal to themselves and humans despite preventive measures contained in ~~DD~~ **BLS** ' s business policies, including those for the quarantine and handling of imported animals; and • Errors and omissions during a trial or study that may undermine the usefulness of a trial or study, or data from the trial or study or that may delay the entry of a drug to the market. ~~DD contracts with physicians, also referred to as investigators, to conduct the clinical trials to test new drugs on clinical trial subjects. These tests can create a risk of liability for personal injury or death to clinical trial subjects resulting from negative reactions to the drugs administered or from professional malpractice by third party investigators.~~ While ~~DD~~ **BLS** endeavors to include in its contracts provisions entitling it to be indemnified and entitling it to a limitation of liability, these provisions are not always successfully obtained and, even if obtained, do not uniformly protect ~~DD~~ **BLS** against liability arising from certain of its own actions. ~~DD~~ **BLS** could be materially and adversely affected if it were required to pay damages or bear the costs of defending any claim that is not covered by a contractual indemnification provision, or in the event that a party which must indemnify it does not fulfill its indemnification obligations, or in the event that ~~DD~~ **BLS** is not successful in limiting its liability or in the event that the damages and costs exceed ~~DD~~ **BLS** ' s insurance coverage. ~~DD~~ **BLS** may also be required to agree to contract provisions with clinical ~~trial sites~~ **site selection** or its customers related to the conduct of clinical trials, and ~~DD~~ **BLS** could be materially and adversely affected if it were required to indemnify a site or customer against claims pursuant to such contract terms. There can be no assurance that ~~DD~~ **BLS** will be able to maintain sufficient insurance coverage on acceptable terms. ~~Risks Related to the COVID- 19 Pandemic The effects of the outbreak of the COVID- 19 pandemic could have material adverse impacts on the Company' s business, results of operations, cash flows, and financial position. The Company is closely monitoring the impact of the COVID- 19 pandemic on all aspects of its business. Fluctuations in the number of COVID- 19 cases typically result in corresponding fluctuations in the Company' s COVID- 19 PCR and antibody testing (COVID- 19 Testing) volumes and its Base Business (operations except for COVID- 19 Testing), and may have a negative effect on the Company' s business and financial performance. Given the continued unpredictability pertaining to the COVID- 19 pandemic, the impact on the Company' s business continues to be uncertain and depends on a number of evolving factors that the Company may not be able to predict or effectively respond to. A resurgence of COVID- 19, including the rise of variants, and the Company' s initiatives to help limit the spread of the illness, could impact the Company' s ability to carry out its business as usual, which could materially adversely impact its business and financial condition. The Company has incurred additional costs in order to provide for the safety of its employees and patients and the continuity of its operations. Adverse changes in government and third- party payer regulations, reimbursement, or coverage policies (or in the interpretation of current regulations) relating to COVID- 19 testing could materially impact the Company' s results of operations, cash flows and financial position. The Company incurred additional costs to implement operational changes in response to this pandemic. The COVID- 19 pandemic disrupted, and along with other economic factors, a resurgence in COVID- 19 could continue to disrupt, the Company' s supply chain, including its ability to secure test collection and testing supplies and equipment and personal protective equipment for its employees. For similar reasons, the COVID- 19 pandemic has also adversely impacted, and may continue to adversely impact, third parties that are critical to the Company' s business, including vendors, suppliers, and business partners. These developments, and others that are difficult or impossible to predict, could materially impact the Company' s business, financial results, cash flows, and financial position. If there is a resurgence of the pandemic, the Company may be forced to prioritize its application of resources to the continued mitigation of COVID- 19, at the expense of other potentially profitable opportunities or initiatives, such as the development of new products or selected business acquisitions. If the Company does not respond appropriately to the ongoing COVID- 19 pandemic, or if the Company' s customers do not perceive its response to be adequate, the Company could suffer damage to its reputation, which could adversely affect its business. Despite the Company' s efforts to respond to and mitigate the impact of COVID- 19 on its business and operations since the global pandemic was declared on March 11, 2020, the failure of the Company to appropriately and adequately respond as the effects of the pandemic continue may cause the Company' s customers and other stakeholders to perceive the Company' s responses to the pandemic as insufficient, inadequate, or not equivalent to or better than competitors, including with respect to the availability of testing, collection kits, and the amount of time it takes for delivery of test results or fulfillment of kit orders. Factors that may be out of the Company' s control, such as the availability of equipment, supplies, and key personnel and~~

~~geographical changes in demand, may impact the Company' s ability to meet customer demand and may have an adverse effect on the Company' s operations. Any such disruptions could result in negative publicity, and the Company could suffer damage to its reputation, which could adversely affect its business, results of operations, cash flows, and financial position.~~