Risk Factors Comparison 2024-02-20 to 2023-02-24 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

We are subject to various risks that may materially harm our business, financial condition, and results of operations. They are not, however, the only risks we face. Additional risks and uncertainties not presently known to us or that we currently believe not to be material may also adversely affect our business, financial condition, or results of operations. An investor should carefully consider the risks and uncertainties described below and the other information in this filing before deciding to purchase our common stock. If any of these risks or uncertainties actually occurs, our business, financial condition, or operating results could be materially harmed. In that case, the trading price of our common stock could decline or we may be forced to cease operations. Risk Factors Summary The following is a summary of the ~~principal~~ **material** risks that could adversely affect our business, financial condition or results of operations. Risks Relating to Our Business • Our business is subject to rapid scientific change, which could have a material adverse effect on our business, results of operations, and financial condition. • We face the risk of capacity constraints, which could have a material adverse effect on our business, results of operations, and financial condition. • Increased competition, including price competition, could have a material adverse impact on our net revenues and profitability. • New product development and commercialization involve a lengthy and complex process and we may be unable to develop or commercialize new products on a timely basis, or at all. • Failure to develop, or acquire licenses for, new or improved testing technologies could materially and adversely affect our revenues. • The potential loss or delay of our material ~~Pharma Services~~ **Advanced Diagnostics** customer contracts or of multiple contracts could adversely affect our results ~~. • Clinicians or patients using our services may sue us, and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses~~ . • We may become involved in litigation that may materially adversely affect us **. • Intellectual property dispute over the RaDaR ® assay may necessitate redesign, licensing, discontinuation, or significant damages, potentially harming our overall financial condition, results of operations, or cash flows** . • Our involvement with clinical trials and research services create a risk of liability. • Our investments in marketable securities are subject to certain risks which could affect our overall financial condition, results of operations, or cash flows. • Other manufacturers may discontinue or recall testing products used in our business. • We depend substantially upon third parties for payment of services, which reliance could have a material adverse effect on our cash flows and results of operations. • We may fail to protect our facilities, which could have a material adverse effect on our business, results of operations, and financial condition. • We depend on information technology systems and maintain protected personal data, and a cyber- attack or other breach affecting these information technology systems or protected data could have a material adverse effect on our results of operations. ~~NEOGENOMICS, INC.~~ • Performance issues, service interruptions, or price increases by our shipping ~~carrier~~ **carriers** could adversely affect our business, results of operations, and financial condition, and harm our reputation and ability to provide our specialized diagnostic services on a timely basis. • We use biological and hazardous materials that require considerable expertise and expense for handling, storage, or disposal and may result in claims against us. Risks Related to Our Common Stock and Indebtedness • The price of our common stock may fluctuate significantly. • Servicing our Convertible Notes require a significant amount of cash. We may not have sufficient cash flow from our business to pay our obligations under the Convertible Notes, which could adversely affect our financial condition and operating results. **NEOGENOMICS, INC.** • We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes. • The capped call transactions may affect the value of the 2028 Convertible Notes and our common stock. • Conversion of the Convertible Notes may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock. Risks Relating to Government Regulation and Reimbursement • ~~Regulatory changes, such as proposed government~~ **If the FDA were to begin to enforce** regulation of Laboratory Developed Tests ~~,~~ **it** could require us to conduct additional clinical trials ~~or result in delays~~ , result in increased costs ~~,~~ or ~~the failure~~ **delays, or we could fail** to obtain necessary regulatory approvals, **all of** which could harm our business. • Healthcare reform ~~programs~~ **efforts** may impact our business and the pricing we receive for our services. • Changes in laws, regulations, contracting arrangements with payers, or payer policies, including steps taken by payers to control utilization and reimbursement of healthcare services, may adversely affect coverage or reimbursement for our specialized diagnostic services, which may decrease our revenues and adversely affect our results of operations and financial condition. • Failure to comply with laws and regulations regarding laboratory licensing and operations, including CLIA environmental, health, and safety laws and regulations such as the federal Occupational Safety and Health Administration Act and the Needlestick Safety and Prevention Act, could result in fines and penalties and loss of licensure, and have a material adverse effect upon our business. • Our net revenue will be diminished if payers do not adequately cover or reimburse our services. • ~~Third- party billing is extremely complicated and results in significant additional costs to us.~~ • Our operations are subject to strict laws prohibiting fraudulent billing and other abuse, and our failure to comply with such laws could result in substantial penalties, including exclusion from participation in Medicare, Medicaid, and other governmental payer programs. • The failure to comply with fraud and abuse laws, including physician self- referral laws and anti- kickback laws, may subject us to liability, penalties, or limitation of operations. • Failure to comply with federal, state and international laws related to privacy and security could result in fines, penalties, and damage to the Company' s reputation with customers and could have a material adverse effect upon the Company' s business. General Risk Factors ~~• The COVID- 19 pandemic is highly dynamic in the United States and throughout the world and may adversely affect our operations and financial condition.~~ • We are dependent on key personnel and need to hire additional qualified personnel in order for our business to succeed ~~. • Our~~

~~business operations and reputation may be materially impaired if we do not comply with privacy laws or information security policies~~ . • We may not be able to implement our business strategy, which could impair our ability to continue operations. • We may be unable to realize estimated benefits from our cost reduction and restructuring efforts and our profitability may be hurt or our business might otherwise be adversely affected. • If we are unable to successfully integrate future acquisitions with our legacy business, the anticipated benefits of such transaction may not be realized. • If goodwill and intangible assets that we recorded in connection with our acquisitions become impaired, we may have to take significant charges against earnings. • We may incur greater costs than anticipated, which could result in sustained losses. • We may face fluctuations in our results of operations and we are subject to seasonality in our business which could negatively affect our business operations. • The steps we have taken to protect our proprietary rights may not be adequate, which could result in infringement or misappropriation by third parties **. If we are unable to keep pace with the rapid scientific and technological change characteristic to our industry, or to develop, or acquire licenses for, new or improved testing technologies, our competitive position, business, results of operations, and financial condition could be harmed** . The market for genetic and molecular testing services is characterized by rapid scientific developments, evolving industry standards and customer demands, and frequent new product introductions and enhancements. For example, new tests developed by our competitors may prove superior and replace our existing tests. Additionally, certain technological changes, such as advances in point- of- care testing, could reduce the need for the laboratory tests we provide. Our future success will depend in significant part on our ability to continually improve our offerings in response to both evolving demands of the marketplace and competitive service offerings ~~, and~~ **. If** we **are unsuccessful in keeping pace with scientific and technological changes, or enhancing our products to meet evolving industry standards or developing customer demands, our competitive position, business, results of operations, and financial condition** may be ~~unsuccessful in doing so, which could have a material~~ **materially and** ~~adverse~~ **adversely affected** ~~effect on our business, results of operations, and financial condition. We compete in the market place primarily on three factors: (i) the quality and accuracy of our test results; (ii) the speed or turnaround times of our testing services; and (iii) our ability to provide after- test support to those physicians requesting consultation. Any unforeseen increase in the volume of clients could strain the capacity of our personnel and systems, leading to unacceptable turnaround times or customer service failures~~ . In addition, as the number of our clients and..... competitive bidding for laboratory services, or other actions or pressures reducing payment schedules as..... technology and new product introductions. Other companies or individuals, including our competitors, may obtain patents or other intellectual property rights that would prevent, limit or interfere with our ability to develop, perform or sell our solutions or operate our business or increase our costs. In addition, they could introduce new tests, technologies or services that may result in a decrease in the demand for our services or cause us to reduce the prices of our services. Our success will depend, in part, on our ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. We may not be able to negotiate acceptable licensing arrangements **,** and we cannot be certain that such arrangements will yield commercially successful diagnostic tests. If we are unable to license these testing methods at competitive rates, our research and development costs may increase as a result. In addition, if we are unable to license new or improved technologies to expand our testing operations, our testing methods may become outdated when compared with our competition and testing volume and revenue may be materially and adversely affected. ~~business~~ **actions or pressures reducing payment schedules as a result of increased or additional competition.Furthermore,many competitors are developing information technology- based tools to support the integration of next- generation sequencing testing into the clinical setting.These companies** may **also use their** ~~be adversely affected.Our success depends on~~ **own tests or others to develop an integrated system which could limit** our ~~ability~~ **access** to **certain networks.** ~~develop new tests and other related products~~ **Products** ~~while improving the performance,cost-effectiveness and timeliness of our existing products.Our products~~ that are under development have taken time and considerable resources to develop,and we may not be able to complete the development and commercialization of such products for clinical use on a timely basis,or at all.For example,there can be no assurance that we will be able to produce commercial products for early detection of cancer.Before we can commercialize any new products,we will need to expend significant funds in order to:• conduct substantial research and development,including validation studies and clinical studies;• further develop and scale our laboratory processes to accommodate different products ~~,including the expansion of our medical staff and PhDs~~ ;and • further develop and scale our infrastructure to be able to analyze increasingly large amounts of data ~~;and • seek and obtain regulatory clearance or approvals of our new products,as required by applicable regulations~~ .Our product development process involves a high degree of risk,and product development efforts may fail for many reasons,including:• failure of the product to perform as expected,including defects and errors;• lack of validation data;or • failure to demonstrate the clinical utility of the product.As we develop products,we have made and will have to make significant investments in product development,marketing and selling resources,including investing heavily in clinical studies,which could adversely affect our future cash flows. ~~We expect~~ **Our industry is subject** to **rapidly changing technology and** ~~make significant investments in the development of~~ new ~~genetic tests~~ **product introductions.Other** The revenue attributable to our ~~Pharma Services~~ **Advanced Diagnostics** clients may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. Most of our ~~Pharma Services~~ **Advanced Diagnostics** segment clients can terminate our contracts **without cause** upon proper notice **, and we experience termination or non- renewal of our Advanced Diagnostics contracts in the ordinary course of business** . Our ~~Pharma Services~~ **Advanced Diagnostics** clients may delay, terminate or reduce the scope of our contracts for a variety of reasons beyond our control, including but not limited to actions by regulatory authorities, negative clinical results, lack of patient enrollment, **lack of available financing** or shifts in internal priorities. ~~Delays~~ **In addition** , ~~terminations or reductions in the scope of our contracts impact our ability to convert our backlog into revenue for the Company. If we cannot realize the full benefits of our backlog of contractually committed services due to delay, cancellation or reduction in our client' s contractual commitments, this will materially impact our revenues. Adverse~~ **adverse** speculation about our existing or potential

relationships with our ~~Pharma Services~~ **Advanced Diagnostics** clients may be a catalyst for adverse speculation about us, our products and our technology, which can adversely affect our reputation and business. ~~The~~ **Delays, terminations or reductions in the scope of our contracts impact our ability to convert our backlog into revenue for the Company. Our ability to realize the full benefits of our backlog of contractually committed services due to delay, cancellation or reduction in our client' s contractual commitments, would materially impact our revenues. In addition, the terminability of our contracts puts increased pressure on our quality control efforts, since not only can our contracts be terminated by clients as a result of poor performance, but any such termination may also affect our ability to obtain future contracts from the clients involved and others. We may become involved in litigation, and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses and may adversely affect our business and results of operations. From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including employment, commercial, product liability, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings. For example,** development, marketing, sale, and performance of ~~healthcare~~ **laboratory testing** services expose us to the risk of litigation, including professional negligence or product liability claims, were someone to allege that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to pathologists and oncologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. **Such matters and other litigation against us can be time- consuming, divert management' s attention and resources, cause us to incur significant expenses or liability and / or require us to change our business practices. In addition,** ~~Damages~~ **damages** assessed in connection with, and the costs of defending, any legal action could be substantial ~~. We may be faced with litigation claims that exceed our insurance coverage or are not covered under any of our insurance policies. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business, or hampers our ability to otherwise conduct our business. From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including employment, commercial, product liability, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings. Such matters can be time- consuming, divert management' s attention and resources, cause us to incur significant expenses or liability and / or require us to change our business practices~~ . Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we believe that we have meritorious claims or defenses. **We also may be faced with litigation claims that exceed our insurance coverage or are not covered under any of our insurance policies. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business, or hampers our ability to otherwise conduct our business.** Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, results of operations and financial condition **. One of our competitors has alleged that our RaDaR ® assay and certain tests are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the RaDaR ® assay altogether and / or pay significant damages, among other consequences, any of which may have a material adverse effect on our business as well as our financial condition and results of operations. One of our competitors, Natera, Inc., or Natera, filed a complaint against NeoGenomics Laboratories, Inc. alleging our RaDaR ® assay and multiplex PCR of at least 25 cancer related targets from cell- free DNA infringe on certain of Natera' s U. S. patents. Additionally, Natera filed a motion for a preliminary injunction hearing on July 31, 2023 seeking to enjoin the Company from selling the RaDaR ® assay. A preliminary injunction hearing occurred on November 27, 2023 and on December 27, 2023, the court granted Natera' s preliminary injunction on the basis of a likelihood of infringement of a Natera patent. We may continue to make, use, and sell the RaDaR ® assay solely for continued use of the RaDaR ® assay: (i) for those patients already using it before the entry of this injunction, (ii) in support of research and development with other persons or entities on projects or studies that began before the entry of this injunction, or (iii) for use in or in support of clinical trials in process or already approved by an agency of the United States. Natera posted a $ 10 million bond with the court on January 12, 2024. On December 28, 2023, NeoGenomics appealed the preliminary injunction to the Federal Circuit. The appeal was docketed at the Federal Circuit on January 4, 2024. On February 5, 2024, NeoGenomics filed an Emergency Motion to Stay the Preliminary Injunction pending Appeal and a Motion to Expedite the appeal. The Federal Circuit granted expedited briefing of the appeal with oral arguments scheduled for March 29, 2024. Separately, the court proceedings on the patent infringement claims are in the discovery stage. If our RaDaR ® assay is found to infringe any of Natera' s patents, we could be required to redesign our technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing the RaDaR ® assay and related products. However, we may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to us, and Natera could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing our products that are found to be infringing. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed Natera' s asserted patents. Even if we were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by us of Natera' s asserted patents may have a material adverse effect**

on our business, as well as our financial condition and results of operations . We have conducted clinical trials and presently support many clinical trials run by third parties, which ordinarily involve testing an investigational drug on a limited number of individuals to evaluate ~~a product~~ **the drug** ' s safety, determine a safe dosage range and identify side effects. Errors or omissions could occur during a clinical trial that may result in harm to study volunteers, or if unnoticed and regulatory approval is received, to consumers of the drug, or that may undermine the usefulness of the clinical trial or data from the clinical trial and may delay the entry of a drug to the market **. In addition, failure to operate such clinical trials in accordance with the FDA, the U. S. Drug Enforcement Agency (" DEA "), and other applicable regulations could result in disruptions to our operations** . Our contracts with the pharmaceutical sponsors include provisions entitling us to be indemnified or entitling us to a limitation of liability. These provisions do not uniformly protect us against liability arising from certain of our own actions **or those of our professional staff** , such as gross negligence or misconduct. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim which is not covered by or exceeds the limits of a contractual indemnification provision, or in the event that a party who must indemnify us does not fulfill its indemnification obligations, or which is beyond the level of our insurance coverage. We invest a portion of our available cash and cash equivalents by purchasing marketable securities in a managed portfolio and direct investments in a variety of debt securities, including U. S. Treasury securities and corporate debt securities. The primary objective of our investment activity is to maintain the safety of principal ~~and provide for future liquidity requirements~~ while maximizing yields without significantly increasing risk. Should any of our investments or marketable securities lose value or have their liquidity impaired, it could affect our overall financial condition. Additionally, ~~should~~ **if** we choose to, or are required to, sell these securities in the future at a loss, our consolidated operating results or cash flows may be affected. We rely heavily on reagents, test kits and instruments manufactured by third parties in our testing services. From time to time, manufacturers have discontinued or recalled, and may in the future discontinue or recall, the reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume and revenues. We have had certain tests discontinued by manufacturers and have had to develop alternative solutions for our clients. Our business consists of clinical laboratories that provide medical testing services for doctors, hospitals, and other laboratories on patient specimens that are sent to our laboratories. In the case of some specimen referrals that are received for patients that are not in- patients or out- patients at a hospital or institution or otherwise sent by another reference laboratory, we typically bill the patient' s insurance company or a government program for our services. As such, we rely on the cooperation of numerous third- party payers, including but not limited to Medicare, Medicaid, and various insurance companies, to get paid for performing services on behalf of our clients and their patients. The amount of such third- party payments is governed by contractual relationships in cases where we are a participating provider for a specified insurance company or by established government reimbursement rates in cases where we are an approved provider for a government program such as Medicare or Medicaid. However, we do not have contractual relationships with some of the insurance companies with whom we deal, nor are we necessarily able to become an approved provider for all government programs. In such cases, we are deemed to be a non- participating provider **,** and there is no contractual assurance that we will be able to collect the amounts billed to such insurance companies or government programs. Until such time we become a participating provider with such insurance companies, there can be no contractual assurance that we will be paid for the services we bill to such insurance companies or patients, and such third parties may change their reimbursement policies for non- participating providers in a manner that may have a material adverse effect on our cash flow or results of operations. When new Current Procedural Terminology (" CPT ") codes are introduced by the American Medical Association (" AMA ") it often takes time for commercial insurance providers to recognize the new codes, which can significantly impact the timing of payments, if any, and can increase our days- sales- outstanding. Medicare has also, at times, issued codes or coding guidance that conflicts with the AMA CPT coding, which can cause confusion when secondary insurance is involved. Insurance companies may also try to steer business away from us towards in- network providers by sending letters to physicians and even imposing financial penalties if they continue to send us business. **Additionally, due to the fluctuating and uncertain nature of the reimbursement environment, including the amount that payers reimburse us for any of our services, we estimate the amount of revenue to be recognized at the time services are provided and record revenue adjustments if and when the cash subsequently received for the services differs from the revenue recorded. Due to this inherently uncertain nature of the reimbursement landscape, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. If our facilities become damaged or inoperable due to disasters, power loss, break- ins or similar events, we may be unable to continue our operations or our services could be interrupted or delayed, which could have a material adverse effect on our business, results of operations, and financial condition.** Our operations are dependent in part upon our ability to protect our laboratory operations **, including our information technology systems,** against physical damage from **natural or man- made disasters, such as** explosions, fire, floods, hurricanes, earthquakes, power loss, telecommunications failures, break- ins, **public health issues, epidemics or pandemics, terrorist attacks,** and similar events **beyond our control** . We do not presently have an emergency back- up generator in place at our Tampa, Florida, Nashville, Tennessee, Atlanta, Georgia, or Phoenix, Arizona laboratory locations, which would otherwise mitigate to some extent the effects of a prolonged power outage. The occurrence of any of these events could result in interruptions, delays, or cessations in service to clients, which could have a material adverse effect on our business, results of operations, and financial condition. **We depend on our information technology systems and those of our third- party service providers and maintain protected personal data, and a cyber- attack or other breach affecting these information technology systems or protected data could have a material adverse effect on our business, reputation and results of operations.** Our laboratory operations depend, in part, on the continued performance of our information technology systems **as well as those of our third- party service providers** . ~~Such~~ **Our information technology** systems are susceptible to a cyber- attack, malicious intrusion, breakdown, destruction, loss of ~~confidentiality~~ --- **confidential**

information or data (including credit card and other financial information) , or other significant disruption. These systems have been and are expected to continue to be the target of malware and other cyber- attacks. **The continued hybrid working environment following the COVID- 19 pandemic has further increased the risk of cyber- attacks and other cybersecurity risks faced by us and our third- party service providers due to our reliance on the internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.** In addition, third ~~-~~ party hacking attempts may cause our information technology systems and related products, protected data, or proprietary information to be compromised or stolen. A significant attack or other disruption could result in adverse consequences, including increased costs and expenses, manufacturing challenges or disruption, problems with product functionality, damage to customer relations, lost revenue, and legal or regulatory penalties. Sustained system failures or interruption of our systems in one or more of our laboratory operations could disrupt our ability to process laboratory requisitions, perform testing, provide test results in a timely manner, and / or bill the appropriate party. We also **rely on the information technology systems of our third- party service providers for information technology services and application hosting. Their systems are also vulnerable to attack and damage or interruption from telecommunications or network failures, natural disasters, employee theft or misuse, human error, fraud, denial, or degradation of service attacks, sophisticated nation- state and nation- state supported actors or unauthorized access or misuse. Despite any security barriers implemented by these third parties to protect against such threats, which are largely beyond our control, the information technology systems of our third- party service providers may be compromised resulting in potential disruption of their services or loss of business information (including our proprietary and confidential information) stored by these third parties. We also** collect, manage and process **sensitive** ~~protected personal~~ data, including protected health information subject to HIPAA **and genetic information** , in connection with **the operation of our business and** our service offerings. Breaches ~~with respect~~ **resulting in the loss or unauthorized access** to ~~personal data~~ **or use of such information, including that of our employees,** could result in violations of HIPAA, the HITECH Act, GDPR, and other federal, state, and international laws regarding the privacy, confidentiality, and security of such information. A breach of **this** protected **information** ~~personal data~~ could result in adverse consequences, including regulatory inquiries or litigation, increased costs and expenses, including costs related to insurance and remediation of any security vulnerabilities, reputational damage, lost revenue, and fines or penalties. **In addition, we collect and store intellectual property and proprietary business information owned or controlled by us or other third parties for our customers and payers. Cyber- attacks, security breaches, computer viruses, malware and other incidents could cause misappropriation, loss or other unauthorized disclosure of such information. Increasingly complex methods have been used in cyber- attacks, including ransomware, phishing, structured query language injections, social engineering schemes, and distributed denial- of- service attacks. A cyber- attack can also be in the form of unauthorized access or a blocking of authorized access. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.** While we invest in our systems and technology and in the protection of ~~its~~ **our** products and data to reduce the risk of an attack or other significant disruption, there can be no assurance that these measures and efforts will prevent future attacks or other significant disruptions to any of the systems on which we rely. Similarly, there can be no assurance that third party information technology providers with whom we contract will not suffer a significant attack or disruption that impacts customers, such as supply chain attacks. Any significant breach, attack, disruption, or failure of our information technology systems could adversely affect our business, results of operations, and financial condition. **Performance issues, service interruptions, or price increases by our shipping carrier could adversely affect our business, results of operations, and financial condition, and harm our reputation and ability to provide our specialized diagnostic services on a timely basis.** Expedited, reliable shipping is essential to our operations. One of our marketing strategies principally highlights the reliability of our point- to- point transport of patient samples. We rely heavily on a single provider of transport services, FedEx Corporation (the " Carrier "), for reliable and secure point- to- point transport of patient samples to our laboratory and enhanced tracking of these patient samples. Should the Carrier encounter delivery performance issues such as loss, damage, or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis **and, accordingly, our ability to compete with other providers of similar services** . If the Carrier or we were to terminate our relationship, we would be required to find another party to provide expedited, reliable point- to- point transport of our patient samples. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with another provider on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our specialized diagnostic services. Even if we were to enter into an arrangement with such alternative provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by the Carrier. If the new provider does not provide the required quality and reliable transport services, it could adversely affect our business, reputation, results of operations, and financial condition. We work with hazardous materials, including chemicals, biological agents and compounds, blood samples, and other human tissue that could be dangerous to human health and safety or the environment. Our operations also produce hazardous and biohazardous waste products. We have an Employee Health & Safety Department that closely monitors the use of hazardous materials in our laboratory. Federal, state, and local laws and regulations **also** govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and

current or future environmental laws and regulations may impair business efforts. If we do not comply with applicable regulations, we may be subject to fines and penalties. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes **to employees** ~~. Our general liability insurance or workers' compensation insurance policies may not cover damages~~ and **third parties** ~~fines arising from biological or hazardous waste exposure or contamination~~ . **In** ~~Accordingly, in~~ the event of contamination or injury, we could be held liable for **any resulting** damages or penalized with fines ~~in~~ **,** ~~an~~ **and** ~~amount~~ **any liability could** ~~exceeding~~ --- **exceed** our resources ~~, and~~ **. Although we maintain general liability insurance** ~~our~~ - **or** ~~operations could be suspended~~ **workers' compensation insurance policies, such policies and other applicable insurance policies that we maintain may not fully cover any resulting damages and fines arising from biological or hazardous waste. The price of** ~~or~~ **our** ~~otherwise adversely affected~~ **common stock has, and may continue to, fluctuate significantly** . The price of our common stock has been, and is likely to continue to be, volatile and it could decline substantially within a short period of time. The price of our common stock could fluctuate significantly for many reasons including the following: • change in our ~~Leadership~~ **leadership** or Board of Directors; • future announcements concerning us or our competitors; • regulatory developments and enforcement actions bearing on advertising, marketing, or sales; • reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports; • gaining or losing large customers or managed care plans; • introduction of new products or services and related insurance coverage; • acquisition or loss of significant manufacturers, distributors or suppliers, or an inability to obtain sufficient quantities of materials needed to provide our services; • quarterly variations in operating results; • business acquisitions or divestitures; • changes in the regulation of LDTs; • changes in governmental or third- party reimbursement practices and rates; and • fluctuations in the economy, political events, or general market conditions. In addition, stock markets in general and the market for shares of healthcare stocks in particular, have experienced extreme price and volume fluctuations in recent years, **which** ~~fluctuations that~~ frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. ~~The~~ **In the past, companies that experience volatility in the** market price of **their securities have often faced securities class action litigation. Whether** ~~our~~ - **or** ~~common stock~~ **not meritorious, litigation brought against us** could **result** ~~decline below its current price and the market price of our shares may fluctuate significantly~~ in **substantial costs, divert** ~~the future. These fluctuations may be unrelated to~~ our ~~performance~~ **management' s attention and resources and harm our ability to grow our business** . Servicing our Convertible Notes requires a significant amount of cash. We may not have sufficient cash flow from our business to pay our obligations under the Convertible Notes, which could adversely affect our financial condition and operating results. In April 2020, we issued $ 201. 3 million aggregate principal amount of 2025 Convertible Notes, and in January 2021, we issued $ 345. 0 million aggregate principal amount of 2028 Convertible Notes. We may also incur additional indebtedness in the future. Our ability to make scheduled payments of the principal of, pay interest on, or refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our indebtedness and to make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Notes will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Holders of the Convertible Notes have the right to require us to repurchase their Convertible Notes upon the occurrence of a fundamental change at a repurchase price equal to 100 % of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority, or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the respective indenture or to pay any cash payable on future conversions of the Convertible Notes as required by such indenture would constitute a default under the indenture. A default under an indenture or the occurrence of the fundamental change may also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof. In connection with the issuance of the 2028 Convertible Notes, we have entered into capped call transactions with the option counterparties. Upon conversion of any of the 2028 Convertible Notes, we will satisfy our conversion obligation by paying or delivering, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election, and the capped call transactions are intended to reduce the potential dilution upon conversion of the 2028 Convertible Notes and / or offset some or all of any cash payments we are required to make in excess of the principal amount of converted 2028 Convertible Notes, as the case may be, with such reduction and / or offset subject to a cap. In connection with these transactions, the option counterparties or their respective affiliates may modify their hedge positions related to the capped call transactions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the 2028 Convertible Notes (and are likely to do so during any observation period related to a conversion of 2028 Convertible Notes or following any repurchase or redemption of the 2028 Convertible Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2028 Convertible Notes. The conversion of some or all of the Convertible Notes may dilute the ownership interests of

existing stockholders to the extent we deliver shares of our common stock upon conversion of any of the Convertible Notes. We have entered into capped call transactions with respect to the 2028 Convertible Notes to reduce the risk of dilution, but to the extent that the conversion price of the 2028 Convertible Notes exceeds the cap price of the capped calls or to the extent that the Convertible Notes are converted, such conversions will dilute the ownership interests of our existing stockholders. The Convertible Notes may from time to time in the future be convertible at the option of their holders prior to their scheduled terms under certain circumstances. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market ~~prices~~ **price** of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because conversion could be used to satisfy short positions, and the anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock. We frequently develop diagnostic tests for clients that cannot currently be provided using test kits approved or cleared by the FDA. ~~The FDA has been considering changes to the way that it regulates these LDTs.~~ Currently, all LDTs are conducted and offered in accordance with **the requirements of** CLIA ~~,~~ and individual state licensing procedures ~~. The~~ **, but the** FDA has **had a policy of enforcement discretion with regard to LDTs. On September 29, 2023, the FDA** published a **proposed rule** ~~draft guidance document~~ that **, if finalized,** would ~~require~~ **end this policy of enforcement discretion for virtually all LDTs in five stages over a four- year period from the date** FDA ~~clearance~~ **publishes a final rule, and provide** ~~or~~ **for LDTs to be regulated as medical devices. In Phase 1 (effective one year post- finalization), laboratories would be required to comply with medical device (adverse event) reporting and correction and removal reporting requirements. In Phase 2 (effective two years post- finalization), laboratories would be required to comply with all other medical device regulatory requirements (including registration and listing, labeling, and investigational use exemptions), except for quality system and premarket review requirements. In Phase 3 (effective three years post- finalization), laboratories would be required to comply with quality system requirements (i. e., good manufacturing practices). In Phase 4 (effective three and a half years post- finalization, but not before October 1, 2027), laboratories would be required to comply with premarket review requirements for high- risk tests (i. e., tests subject to premarket** approval ~~of a~~ **requirements). Finally, in Phase 5 (effective four years post- finalization, but not before April 1, 2028), laboratories would be required to comply with premarket review requirements for moderate- and low- risk tests (i. e., tests** ~~subset~~ **subject to de novo or full 510 (k) premarket notification requirements). Unlike previous FDA proposals, the proposed rule does not " grandfather " any currently marketed tests. The content and timing** of **any final rule on** LDTs ~~,~~ **is uncertain at this time and the FDA** ~~as~~ **has taken** ~~well as~~ a ~~modified approach for some lower risk~~ **number of prior steps towards regulation of** LDTs that **have not been implemented** ~~may require FDA oversight short of the full premarket approval or clearance process~~ . **Nevertheless** ~~Congress may enact legislation to provide a regulatory framework for the FDA' s role with regard to LDTs. As a result~~ , there is a risk that the FDA' s proposed regulatory process could delay the offering of certain tests and result in additional validation costs and fees. There is also an associated risk that some tests currently offered might become subject to FDA premarket approval or clearance. This FDA approval or clearance process may be time- consuming and costly, with no guarantee of ultimate approval or clearance. If our diagnostic tests are allowed to remain on the market but there is uncertainty about the regulatory status of such tests, if they are labeled investigational by FDA, or if FDA limits our labeling claims, orders or reimbursement may decline. ~~In 2014, FDA issued draft guidance announcing that it would end its historical policy of enforcement discretion regarding LDTs and outlining the first of multiple frameworks that have been proposed for their regulation. FDA announced in 2016 that it no longer planned to finalize its draft guidance and that it would continue to exercise enforcement discretion with respect to LDTs. On January 13, 2017, the FDA published a non- binding " Discussion Paper " proposing a framework of LDT oversight largely consistent with the draft guidance, " to spur further dialogue " and give " congressional authorizing committees the opportunity to develop a legislative solution. " Recent agency announcements made in the context of the COVID- 19 public health emergency have produced a shifting policy landscape and further uncertainty regarding FDA' s role in regulating LDTs: in August 2020, HHS announced that FDA would not require premarket review of LDTs absent notice- and- comment rulemaking, but in November 2021, HHS issued a statement withdrawing that prior announcement, indicating a return to FDA' s longstanding approach to the regulation and enforcement discretion toward LDTs.~~ Congress has also considered a number of legislative proposals in recent years that would amend the regulatory framework for LDTs, including, among other requirements, FDA premarket review of certain LDTs. The most recent such proposal, the VALID Act, was introduced in both the House and Senate on June 24, 2021. The VALID Act was expected to be included in the Omnibus bill signed at the end of 2022, but ultimately was not included **. The** ~~and that, as such, it remains unclear whether the~~ VALID Act **was then reintroduced in March 2023. The bill would subject many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would grandfather many existing LDTs from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (including registration and listing and adverse event reporting). To market a high- risk IVCT, reasonable assurance of analytical and clinical validity for the intended use would be needed to be established. Under the VALID Act, a pre- certification process would be established that would allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre- certified, low- risk IVCTs, developed by the laboratory would not be subject to pre- market review. The new regulatory framework would include quality control and post- market reporting requirements. The FDA would have the authority to withdraw approvals for IVCTs for various reasons, including (for example) if there were a reasonable likelihood that the test would cause death or serious adverse health consequences. We cannot predict if the VALID Act (or any other bill)** will be ~~passed 2023~~ **enacted in its current (** or **any other) form** ~~whether FDA will proceed through rulemaking~~ . ~~It~~ **However, it** is possible that legislation and resulting FDA regulation may result in increased regulatory burdens and costs for us to seek marketing authorization for and maintain ongoing compliance for our existing tests, any modifications thereto, or any future tests we may

develop. If the government begins to regulate our tests, it could require a significant volume of applications, which would be burdensome. Furthermore, governmental bodies could take a long time to review such applications and / or document responses if other laboratories were also required to file applications and / or document responses for each of their LDTs. In the event that the FDA begins to regulate our tests, it may require additional pre- market clinical testing prior to submitting a ~~regulatory~~ **premarket approval, premarket** notification **,** or **other** application ~~for~~ **to permit** commercial sales. Such **additional** pre- market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and interrupt sales of our current tests. Additionally, the results of pre- clinical trials or previous clinical trials may not be predictive of future results, and clinical trials may not satisfy the requirements of the FDA or other non- U. S. regulatory authorities. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, and the eligibility criteria for the clinical trial. We also cannot be certain that FDA will not enact rules or guidance that could impact our ability to purchase materials necessary for the performance of our LDTs, such as products labeled for research use only. Should any of the reagents we obtain from third party suppliers and use in conducting our LDTs be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying and limiting or prohibiting the purchase of reagents necessary to perform testing. We may find it necessary to engage **CROs** ~~contract research organizations~~ to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions, and **CROs** ~~contract research organizations~~ to perform the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness, or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed, or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests and / or to achieve sustained profitability. In March 2010, healthcare reform legislation known as the " Patient Protection and Affordable Care Act, " also known as the ACA, was passed into law. The ACA makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, the ACA contains several provisions that seek to limit Medicare spending in the future. One key provision in the ACA is the establishment of " Accountable Care Organizations " (" ACOs "), under which hospitals and physicians are able to share savings that result from improved coordination of healthcare. ACOs continue to develop, and we cannot predict how the continued establishment and implementation of these new business models will impact our business. There is the possibility that value- based payment models, such as ACOs, will drive down the utilization and / or reimbursement rates for our services. We may not be able to gain access into certain ACOs. These changes could have an adverse and material impact on our operations. Following the 2016 election cycle, there were substantial efforts to repeal all or portions of the ACA. In December 2017, Public Law No. 115- 97, which made changes to the tax code and included, among other things, a repeal of the ACA' s penalties for the individual mandate, a provision that required individuals to buy health insurance or pay a fine, became law **. On June 17, 2021, the U. S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA** . While efforts to repeal all or part of the ACA have subsided, in part due to the results of the 2020 election, we cannot be certain that there will not be further legislative efforts or judicial challenges in the future **. The 2024 presidential election may also significantly alter the current regulatory framework and the health care industry, including any further challenges, extensions or expansions of certain ACA provisions. These changes could have an adverse and material impact on our operations** . Governmental payers, as well as private insurers and private payers, have implemented and will continue to implement measures to control the cost, utilization, and delivery of healthcare services, including clinical laboratory and pathology services. Congress and federal agencies, such as CMS, have, from time to time, implemented changes to laws and regulations governing healthcare service providers, including specialized diagnostic service providers. These changes have adversely affected and may in the future adversely affect coverage for our services. We also believe that healthcare professionals may not use our services if third- party payers do not provide adequate coverage and reimbursement for them. These changes in federal, state, local, and third- party payer regulations or policies may decrease our revenues and adversely affect our results of operations and our financial condition. We will continue to be a non- contracted provider until such time as we enter into contracts with third- party payers with whom we are not currently contracted. Because a portion of our revenues is from third- party payers with whom we are not currently contracted, it is likely that we will be required to make positive or negative adjustments to accounting estimates with respect to contractual allowances in the future, which may adversely affect our results of operations, our credibility with financial analysts and investors, and our stock price. We face efforts by government payers to reduce utilization as well as reimbursement for laboratory testing services. Changes in governmental reimbursement may result from statutory and regulatory changes, prospective and / or retroactive rate adjustments, administrative rulings, and other policy changes. From time to time, legislative freezes and updates affect some of our tests that are reimbursed by the Medicare program under the Medicare Physician Fee Schedule (" MPFS "), or the Clinical Laboratory Fee Schedule (" CLFS "). The MPFS is updated on an annual basis. In the past, the MPFS was updated using a prescribed statutory formula (i. e., the sustainable growth rate formula). The Medicare Access and CHIP Reauthorization Act of 2015 (" MACRA ") repealed the previous statutory formula and specified new annual conversion factors for calendar years 2015 and beyond. If the new annual conversion factor results in negative reimbursement in

future years, the resulting decrease in payment may adversely affect our revenue, business, operating results, financial condition, and prospects. In addition, recent laws have made changes to Medicare reimbursement for our tests that are reimbursed under the CLFS, many of which have already gone into effect. The Protecting Access to Medicare Act of 2014 (" PAMA ") made significant changes to how Medicare pays for clinical diagnostic laboratory tests under the CLFS. As part of the changes made under PAMA, beginning in 2017, Medicare CLFS reimbursement rates were to be based on the volume- weighted median of the private payer payment rates for these tests. This led to reductions from prior rates, and without further legislative changes, will continue to result in reductions as the Medicare CLFS reimbursement rate converges towards the median private payer rate. Reductions were capped at 10. 0 percent per annum from 2017 through 2020, and this cap was set to increase to 15. 0 percent for 2020. However, the Coronavirus Aid, Relief, and Economic Security Act (" CARES Act ") and Protecting Medicare and American Farmers from Sequester Cuts Act delayed the implementation of the 15. 0 percent rate reduction cap to 2023 and capped reductions at 0. 0 percent for 2021 and 2022. The Consolidated Appropriations Act 2023 further delayed the implementation of the 15. 0 percent rate reduction cap to 2024 and extended the 15. 0 percent rate reduction cap through 2026. **The Further Continuing Appropriations and Other Extensions Act of 2024 was passed in 2023 and further delayed the implementation of the 15. 0 percent rate reduction cap to 2025 and extended the 15. 0 percent rate reduction cap through 2027.** When rate reductions begin to take effect again in 2024, this will further reduce Medicare program payments for CLFS tests. It is possible that additional reductions could be enacted in the future. CMS also adopts regulations and policies, from time to time, revising, limiting, or excluding coverage or reimbursement for certain of the tests that we perform. Likewise, many state governments are under budget pressures and are also considering reductions to their Medicaid fees. Further, Medicare, Medicaid, and other third- party payers audit for overutilization of billed services. Even though all tests performed by us are ordered by our clients who are responsible for establishing the medical necessity for the tests ordered, we may be subject to recoupment of payments, as the recipient of the payments for such tests, in the event that a third- party payer such as CMS determines that the tests failed to meet all applicable criteria for payment. When third- party payers like CMS revise their coverage regulations or policies, our costs generally increase due to the complexity of complying with additional administrative requirements. Furthermore, Medicaid reimbursement and regulations vary by state. Accordingly, we are subject to varying administrative and billing regulations, which also increase the complexity of servicing such programs and our administrative costs. Finally, state budget pressures have encouraged states to consider several courses that may impact our business, such as delaying payments, restricting coverage eligibility, service coverage restrictions and imposing taxes on our services. In certain jurisdictions, Palmetto GBA administers the Molecular Diagnostic Services Program (" MolDx ") and establishes coverage and reimbursement for certain molecular diagnostic tests, including many of our tests. To obtain Medicare coverage for a molecular diagnostic test (FDA- approved or LDT), laboratories must apply for and obtain a unique test identifier or what is known as a " Z " code. For newly developed tests or for established tests that have not been validated for clinical and analytical validity and clinical utility, laboratories must submit a detailed dossier of clinical data to substantiate that the test meets Medicare' s requirements for coverage. We have received favorable coverage for many of our molecular tests, however, we have also received non- coverage determinations for many newer tests. The field of molecular diagnostics is evolving very rapidly, and clinical studies on many new tests are still underway. We cannot be assured that some of our molecular tests will ever be covered services by Medicare, nor can we determine when the medical literature will meet the standard for coverage that Medicare administrative contractors have set. In November 2017, CMS initiated a national coverage analysis for the use of NGS diagnostic tests for patients with advanced cancer. The proposed decision memorandum was released and open to a public comment period. On March 16, 2018, CMS issued a final decision memorandum for NGS as a diagnostic laboratory test and determined it to be reasonable and necessary, and covered nationally when performed in a CLIA- certified laboratory, ordered by a treating physician, and all of the following requirements are met: (a) the patient has either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; (b) the patient has either not been previously tested using the same NGS test for the same primary diagnosis of cancer or has had repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and (c) the patient has decided to seek further cancer treatment (e. g., therapeutic chemotherapy). CMS also determined that the diagnostic laboratory test using NGS must have: FDA approval or clearance as a companion in vitro diagnostic; an FDA approved or cleared indication for use in that patient' s cancer; and results provided to the treating physician for management of the patient using a report template to specify treatment options. On October 29, 2019, CMS issued a proposed decision memorandum open to a public comment period that would expand coverage of NGS test when performed in a CLIA- certified laboratory, ordered by a treating physician, and all of the following requirements are met (a) the patient has ovarian or breast cancer; (b) the patient has clinical indications for germline (inherited) testing; (c) the patient has risk factors for germline (inherited) breast or ovarian cancer; and (d) the patient has not been previously tested using NGS. These CMS changes to reimbursement for NGS testing could directly affect our revenue for this test type. In recent years, Medicare has encouraged beneficiaries to participate in managed care programs, known as " Medicare Advantage " programs, and has encouraged beneficiaries from the traditional fee- for- service Medicare program to switch to Medicare Advantage programs. This has resulted in rapid growth of health insurance and managed care plans offering Medicare Advantage programs and growth in Medicare beneficiary enrollment in these programs. Also, in recent years, many states have increasingly mandated that Medicaid beneficiaries enroll in managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid fee- for- service beneficiaries to managed care programs. As a result, we would be required to contract with those private managed care programs in order to be reimbursed for services provided to their Medicare and Medicaid members. There can be no assurance that we will be successful in entering into agreements with these managed care programs at rates of payment similar to those we realize from our non- managed care lines of business. We expect the initiatives such as those described above to continue and, if they do, to reduce reimbursements for clinical laboratory services, to impose more stringent cost controls on clinical laboratory services and to reduce utilization of clinical laboratory

services. These efforts, including changes in law or regulations that may occur in the future, may each individually or collectively have a material adverse impact on our business, results of operations, financial condition, and prospects. We are subject to extensive state and federal regulatory oversight regarding laboratory licensing and operations. Each of our laboratories must satisfy federal requirements under CLIA and ~~to~~ maintain the appropriate CLIA Certificate for all testing performed at the lab. Additionally, most states have adopted various laws and regulations setting standards for laboratories performing clinical laboratory testing, and requiring laboratories to obtain and maintain a state laboratory license before the laboratory is authorized to perform testing. These state licensure laws address a host of requirements and often establish permissible and prohibited practices involving digital health, including but not limited to telehealth and telepathology. Periodic inspections or surveys are performed to determine whether our laboratory locations are compliant with CLIA requirements or with applicable state licensure or certification laws. If we fail to meet any applicable requirements of CLIA or similar state laws, that failure could adversely affect payment for our products and services, prevent their approval entirely, and / or interrupt the commercial sale and / or marketing of any products and services and otherwise cause us to incur significant expense. The sanctions for failure to comply with CLIA, state licensure requirements, or other applicable laws and regulations include the suspension, revocation, or limitation of the right to perform clinical laboratory services or receive compensation for those services, as well as the requirement to enter into a corrective action plan to monitor compliance, and the imposition of civil or criminal penalties or administrative fines. In addition, any new legislation or regulation or the application of existing laws and regulations in ways that we have not anticipated could have a material adverse effect on our business, results of operations, and financial condition. We are subject to licensing and regulation under federal, state, and local 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. The federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers, including clinical laboratories, whose workers may be exposed to blood- borne pathogens such as HIV and the hepatitis B virus. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow- up, vaccinations, and other measures designed to minimize exposure to, and transmission of, blood- borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles, if found to be effective at reducing the risk of needlestick injuries in the workplace. Failure to comply with such federal, state and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties and / or other enforcement actions, any of which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements for us, which may be costly. There has been, and will continue to be, significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, private payers continually seek ways to reduce and control overall healthcare costs, and increasing emphasis on managed care in the United States will continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications and services. Third- party payers, including governmental payers such as Medicare and private payers, are scrutinizing new medical products and services and may not cover or may limit coverage and the level of reimbursement for our services. Third- party insurance coverage may not be available to patients for any of our existing tests or for tests we discover and develop, and a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third- party payers. Likewise, any pricing pressure exerted by these third- party payers on our clients may, in turn, be exerted by our clients on us. If government and other third- party payers do not provide adequate coverage and reimbursement for our tests, it could adversely affect our operating results, cash flows and / or our financial condition. ~~Billing for laboratory services is extremely complicated. Depending on the billing arrangement and applicable laws, we must bill various payers, such as patients, insurance companies, Medicare, Medicaid, physician practices, employer groups, hospitals, and other laboratories, all of which have different billing requirements. Additionally, we undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Insurance companies and government payers, such as Medicare and Medicaid, also impose routine external audits to evaluate payments, which adds further complexity to the billing process. Among others, the primary factors which complicate our billing practices are: • pricing differences between our fee schedules and the reimbursement rates of the payers; • changes in payer rules or contracts; • disputes with payers as to the party who is responsible for payment; • disparity in coverage and information requirements among various carriers; and • differing pre- authorization requirements across payers. We incur significant additional costs as a result of our participation in the Medicare and Medicaid programs, as billing and reimbursement for clinical laboratory services are subject to considerable and complex federal and state regulations. The costs we expect to continue to incur include those related to: (i) complexity added to our billing processes and systems; (ii) training and education of our employees and clients; (iii) implementing compliance procedures and oversight; (iv) collections and legal costs; and (v) costs associated with, among other factors, challenging coverage and payment denials and providing patients with information regarding claims processing and services, such as advance beneficiary notices.~~ Of particular importance to our operations is ensuring compliance with federal and state laws prohibiting fraudulent billing and the retention of overpayments. In particular, if we fail to comply with federal and state documentation, coding, and billing rules, we could be subject to liability under the federal False Claims Act, including civil penalties, loss of licenses, and exclusion from the Medicare and Medicaid programs. The False Claims Act prohibits individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government. If an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus substantial civil penalties for each separate false claim. Further, False Claims Act liability may lead to exclusion from participation in Medicare, Medicaid, and other federal healthcare programs. There are a number of potential bases for liability

under the federal False Claims Act. For example, liability arises when an entity knowingly submits, or causes another to submit, a claim for reimbursement to the federal government for a service which was not provided or which did not qualify for reimbursement. Submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could also result in liability under the False Claims Act. Following enactment of the ACA, knowing retention of overpayments is also considered a false claim and could lead to liability under the False Claims Act. The False Claims Act' s " whistleblower " or " qui tam " provisions are used with frequency to challenge the reimbursement practices of providers and suppliers. Those provisions allow a private individual to bring an action on behalf of the government alleging that the defendant has submitted false claims for payment to the government. The government must decide whether to intervene in the lawsuit and whether to prosecute the case. If it declines to do so, the individual may pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. The successful qui tam relator who brought the case is entitled to a portion of the proceeds and his or her attorneys' fees and costs. In addition, various states have enacted laws modeled after the federal False Claims Act, which prohibit submitting false claims for payment to the state, or, in some states, to commercial payers. If we fail to comply with federal and state documentation, coding, and billing rules, we could be subject to liability under analogous state laws as well as criminal liability through a variety of federal and state criminal statutes. Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. Governmental enforcement action or qui tam civil litigation against us may result in material costs and occupy significant management resources, even if we ultimately prevail. In addition, governmental enforcement action may result in substantial fines, penalties or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which could entail significant obligations and costs. When we submit bills for our services to third- party payers, we must follow complex documentation, coding, and billing rules which are based on federal and state laws, rules and regulations, various government publications, and on industry practice. A large number of laboratories have entered into substantial settlements with the federal and state governments for alleged noncompliance under these laws and rules. Private payers have also brought civil actions against laboratories, which have resulted in substantial judgments. Failure to follow these rules could result in potential civil liability under the False Claims Act, under which extensive financial penalties can be imposed. It could further result in criminal liability under various federal and state criminal statutes. We submit thousands of claims for payment to governmental programs and private payers, and we cannot guarantee that there have not been errors in our claims. While we maintain a robust compliance program that includes consistent, detailed review of our documentation, coding, and billing practices, the rules are frequently vague, complex, and continually changing and we cannot assure that governmental authorities, private insurers, or private whistleblowers will not challenge our practices. Such a challenge could result in a material adverse effect on our business. We therefore could be exposed to potential liability, penalties, or limitations on our operations due to failure to comply with significant government regulation and laboratory operations. Existing federal laws governing Medicare and Medicaid, as well as other state and federal laws, also regulate certain aspects of the relationship between healthcare providers, including clinical laboratories, and their referral sources, including physicians, hospitals and other laboratories. Some of these laws, including the federal AKS and the federal Stark Law contain extremely broad proscriptions. Violation of these laws can result in criminal or civil penalties, exclusion from participation in the Medicare, Medicaid, and other federal healthcare programs, repayment of reimbursement received related to services tied to any impermissible referrals, or civil monetary penalties, which may be significant, as well as potential False Claims Act liability. Government authorities may determine that our arrangements with physicians and other clients do not comply with the federal AKS, Stark Law, and similar state laws, and may impose civil monetary penalties or exclude us from participation in federal healthcare programs based on our arrangements with physicians and other clients. The Company ~~,~~ voluntarily conducted an internal investigation, with the assistance of outside counsel, that focused on the compliance of certain consulting and service agreements with federal healthcare laws and regulations, including those relating to fraud, waste, and abuse. Based on this internal investigation, the Company voluntarily notified the OIG of the Company' s internal investigation in November 2021. The Company' s interactions with regulatory authorities and the Company' s related review of this matter are ongoing. As of December 31, ~~2022~~ **2023** , the Company has accrued a reserve of $ 11. 2 million in other long- term liabilities on the Consolidated Balance Sheets for potential damages and liabilities associated with the federal healthcare program revenue received by the Company in connection with the agreements at issue that were identified during the course of this internal investigation. This reserve reflects management' s best estimate of the minimum probable loss associated with this matter. As a result of the internal investigation and ongoing interactions with regulatory authorities, the Company may accrue additional reserves for any related potential damages and liabilities arising out of this matter. At this time, the Company is unable to predict the duration, scope, result, or related costs associated with any further investigation, including by the OIG, or any other governmental authority, or what penalties or remedial actions they may seek. Accordingly, at this time, the Company is unable to estimate a range of possible loss in excess of the amount reserved. Determinations that the Company' s operations or activities do not, or did not, comply with laws or regulations, however, may result in the imposition of civil or criminal fines, penalties, disgorgement, restitution, equitable relief, exclusion from participation in federal healthcare programs or other losses or conduct restrictions, which could be material to the Company' s financial results or business operations. The federal Civil Monetary Penalties Law (" ~~federal~~ **Federal** CMP Law ") imposes civil monetary penalties and potential exclusion from Medicare and Medicaid programs on any person who offers or transfers remuneration to any patient, who is a Medicare or Medicaid beneficiary, when the person knows or should know that the remuneration is likely to induce the patient to receive medical services from a particular provider. The ~~federal~~ **Federal** CMP Law applies, among other things, to many kinds of inducements or benefits provided to patients, including complimentary items or services that are of more than nominal value. Government authorities may determine our operations and provision of services do not comply with the law and its interpretations and impose civil monetary penalties and exclude us from participation in

Medicare and Medicaid for past or present practices related to patient incentive, coordination of care and need- based programs. Tests which are reimbursed by Medicare and other ~~Government~~ **government** payers (for example, State Medicaid programs) accounted for approximately **15 %,** 16 % ~~,~~ **and** 18 ~~% and 17 %~~ of our revenues for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , respectively. The Medicare program imposes extensive and detailed requirements on diagnostic service providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit claims for reimbursement, and how we provide specialized diagnostic laboratory services. Further, we are prohibited from contracting with any individuals or entities who have been excluded from participation in Medicare or Medicaid and are listed on the OIG' s List of Excluded Individuals and Entities List (" LEIE ") or in the System for Award Management, which includes the previously independent Government Services Administration' s Excluded Parties List System (" GSA- EPLS "). Contracting with excluded individuals or entities, such as hiring an excluded person or contracting with an excluded vendor, can result in significant penalties. Our failure to comply with applicable Medicare, Medicaid, and other governmental payer rules could result in our inability to participate in a governmental payer program, an obligation to repay funds already paid to us for services performed, civil monetary penalties, criminal penalties, False Claims Act liability, and / or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payer program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition. We are subject to the federal Stark Law, as well as similar state statutes and regulations, which prohibit billing Medicare for certain healthcare services, which are referred to as DHS, rendered as a result of referrals by physicians to DHS entities with which the physicians (or their immediate family members) have a financial relationship unless an exception is met. A " financial relationship " includes both an ownership interest and / or a compensation arrangement with a physician, both direct and indirect, and DHS includes, but is not limited to, laboratory services. The Stark Law prohibits an entity that receives a prohibited DHS referral from seeking payment from Medicare for any DHS services performed as a result of such a referral, unless an arrangement is carefully structured to satisfy every requirement of a regulatory exception. The Stark Law is a strict liability statute, and thus any technical violation requires repayment of all " tainted " referrals, regardless of the intent, unless an exception applies. Penalties for violating the Stark Law may include the denial of payment to an entity for the impermissible provision of DHS, the requirement to refund any amounts collected in violation of the Stark Law, and substantial civil monetary penalties for each circumvention arrangement or scheme. Other implications of a Stark Law violation may include exclusion from Medicare and Medicaid programs, and potential False Claims Act liability, including via " qui tam " action. Further, many states have promulgated self- referral laws and regulations similar to the federal Stark Law, and these vary significantly based on the state. In addition to services reimbursed by Medicaid or government payers, these state laws and regulations can encompass services reimbursed by private payers and self- pay patients as well. Penalties for violating state self- referral laws and regulations vary based on the state, but often include civil penalties, exclusion from Medicaid, and loss of licenses. Our financial arrangements with physicians are governed by the federal Stark Law, and we rely on certain exceptions to the Stark Law with respect to such relationships. If we are found by the government to be in violation of the Stark Law, we could be subject to significant penalties, including fines as specified above, exclusion from participation in government and private payer programs and requirements to refund amounts previously received from government. Further, as our operations expand into new states and jurisdictions, we must continually evaluate whether our relationships with physicians comply with such new jurisdiction' s laws. This may require structural and organizational modifications to our relationships with physicians, which could adversely affect our results of operations and financial condition. We are subject to the federal AKS, which is a criminal felony statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing, or arranging for or recommending the ordering, purchasing, or leasing of items or services payable by Medicare, Medicaid, or any other federally funded healthcare program. Remuneration has been broadly interpreted to include anything of value, in cash or in kind, and thus can implicate financial relationships involving payments not commensurate with fair market value, such as in the form of office space, equipment leases, professional or technical services, or anything else of value. The AKS is an " intent- based " statute, meaning that a violation occurs when one or both parties intend the remuneration to be in exchange for or to induce referrals. In 2010, the ACA, amended the intent requirement of the AKS. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that a claim submitted for reimbursement for items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. Violations of the AKS may result in substantial civil or criminal penalties, including criminal fines, imprisonment, civil penalties under the ~~federal~~ **Federal** CMP Law, civil penalties and damages under the federal False Claims Act and exclusion from participation in the Medicare and Medicaid programs. If we face these penalties or exclusion from participation in Medicare and Medicaid, it could significantly reduce our revenues and could have a material adverse effect on our business **. Further, non- compliant activities and unlawful conduct by sales and marketing personnel could give rise to significant risks under the AKS. We require extensive, comprehensive training of all sales and marketing personnel, but cannot guarantee that every staff member will comply with the training. Thus, we could face liability under the AKS for non- compliance by individuals engaged in prohibited sales and marketing activities** . Further, most states have adopted similar anti- kickback laws prohibiting the offer, payment, solicitation, or receipt of remuneration in exchange for referrals, and typically impose criminal and civil penalties as well as loss of licenses. Some of these state laws apply to items and services paid for by private payers as well as by government payers. In addition, many states have adopted laws prohibiting the splitting or sharing of fees between physicians and non- physicians, as well as between treating physicians and referral sources. If we are found to be in violation of the AKS or a similar state anti- kickback law, we could be subject to significant penalties, including fines, exclusion from

participation in government and private payer programs, or obligations to refund amounts previously received from government payers. We also could be required to restructure or terminate our contractual and other arrangements with physicians, which could result in a loss of revenue and have a material adverse effect on our business. Some states have also adopted laws prohibiting the corporate practice of medicine, or prohibiting business corporations from employing physicians or engaging in activities considered to be the " practice of medicine. " In these states, we rely on service agreements with physicians and / or professional associations owned by physicians, to perform needed professional pathology services. We cannot be certain that a physician or physician' s professional organization will not seek to terminate an agreement with us on any basis, nor can we be certain that governmental authorities in those states will not seek termination of these arrangements on the basis of state laws prohibiting the corporate practice of medicine. In the U. S., HIPAA, as expanded through the HITECH Act and as implemented through the HIPAA Rules, and similar state laws contain provisions that require the electronic exchange of health information, such as claims submission and receipt of remittances, using standard transactions and code sets, which we refer to as " Standards, " and regulate the use and disclosure of patient records and other PHI. These provisions, which address security and confidentiality of patient information as well as the administrative aspects of claims handling, have very broad applicability and govern many healthcare providers, including physicians and clinical laboratories. Failure to comply with the Standards, the HIPAA Rules, and applicable state privacy and security laws, could result in material adverse effects on our business, results of operations, and our financial condition and could subject us to liability. The HIPAA Rules establish comprehensive federal standards with respect to the uses and disclosures of PHI by certain entities including health plans and healthcare providers, and set standards to protect the confidentiality, integrity, and availability of electronic medical records. The regulations establish a complex regulatory framework governing the use and disclosure of PHI, including, for example, the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient; a patient' s right to access, amend, and receive an accounting of certain disclosures of PHI; the content of notices of privacy practices describing how PHI is used and disclosed and individuals' rights with respect to their PHI; and implementation of administrative, technical, and physical safeguards to protect privacy and security of PHI. The federal privacy regulations restrict our ability to use or disclose certain individually identifiable patient health information, 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 HIPAA Rules. The HIPAA Rules do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. The HIPAA Rules also require healthcare providers like us to notify affected individuals, the Secretary of the U. S. Department of Health and Human Services, and in some cases, the media, when PHI has been " breached, " as defined by HIPAA. Many states have similar breach notification laws. In the event of a breach, we could incur substantial operational and financial costs related to mitigation and remediation, including preparation and delivery of notices to affected individuals. Additionally, HIPAA and its implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, we could incur damages under state laws to private parties for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, HIPAA allows state Attorneys General to bring an action against a covered entity, such as us, for a violation of HIPAA. We insure some of our risk with respect to HIPAA security breaches, but operational costs and penalties associated with HIPAA breaches easily could exceed our insured limits. HIPAA imposes additional requirements, restrictions, and penalties on covered entities and their business associates to, among other things, deter breaches of security. As a result, in addition to the aforementioned reporting requirements, covered entities and their business associates may be required to take preventative and remedial actions, as well as face stringent sanctions for a breach. Our electronic health records system is periodically modified to meet applicable security standards. Despite our implementation of various security measures, our infrastructure may be vulnerable to computer viruses, break- ins, and other disruptive problems inadvertently introduced by authorized users such as employees and clients, or purposefully targeted by hackers and other cybercriminals which could lead to interruption, delays, or cessation in service to our clients. Further, such incidents, whether electronic or physical, could jeopardize the security of confidential information, including PHI and other sensitive information stored in our computer systems related to clients, patients, and other parties connected through us, which may deter potential clients and give rise to uncertain liability to parties whose security or privacy has been infringed. A significant security breach could result in fines, loss of clients, damage to our reputation, direct damages, costs of repair and detection, costs to remedy the breach, government penalties, and other expenses. We insure some of our risk with respect to security breaches but the occurrence of any of the foregoing events could have a material adverse effect on our business, results of operations, and our financial condition. In the United States, in addition to the HIPAA Rules described above, the Company is subject to additional federal and state laws regarding the handling and disclosure of patient records and patient health information. Effective April 5, 2021, HHS published a final rule implementing the information blocking provisions (**"** Information Blocking Rules **"**) of the 21st Century Cures Act. The Information Blocking Rules prohibit covered actors, including healthcare providers, from engaging in activity that is likely to interfere with the access, ~~exchanges~~ **exchange** , or use of ~~electronic health information (" EHI ")~~ unless such activity falls into one of eight exceptions. The Information Blocking Rules provide for civil monetary penalties for noncompliance by healthcare IT vendors and, separately, " appropriate disincentives " for noncompliance by healthcare providers. The HIPAA Rules do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations as well as varying state privacy and security laws and regulations. These laws vary widely. For example, many states have implemented genetic testing and privacy laws imposing specific patient consent requirements and limiting the disclosure of genetic test results. Penalties for violation include sanctions against a laboratory' s licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action

against the Company for violations of a state' s privacy laws. Numerous other federal, state, and international laws govern the collection, use, and disclosure of personal information and may complicate our compliance efforts. Failure to comply with these laws can result in the imposition of significant fines and impact our ability to process certain personal data. For example, in the U. S., the CCPA affords California residents expanded privacy rights and protections and provides for civil penalties for violations and a private right of action related to certain data security breaches. These protections have been expanded by the ~~California Privacy Rights Act (" CPRA ")~~, which became operational in most key respects on January 1, 2023. Similar laws have been proposed or passed at the U. S. federal and state level, including the Virginia Consumer Data Protection Act, which took effect on January 1, 2023, the Colorado Consumer Protection Act, which **took** ~~will take~~ effect on July 1, 2023, the Connecticut Data Privacy Act, which **took** ~~will take~~ effect on July 1, 2023, and the Utah Consumer Privacy Act, which **took** ~~will take~~ effect on December 31, 2023 **. A number of other states have enacted laws related to the privacy and security of consumer health information and personal data which will become effective within the next two years, including Delaware, Florida, Indiana, Iowa, Montana, Nevada, Oregon, Tennessee, Texas, and Washington, and more states have proposed legislation under consideration** . The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including laws in all 50 states requiring security breach notification in some circumstances. These and other laws could **increase regulatory compliance risk,** create liability for us or increase our cost of doing business. Outside of the U. S., the **European Union' s data privacy law, the** GDPR, for example, imposes penalties of up to 4. 0 % of annual global ~~turnover~~ **revenue** . The GDPR imposes a number of strict obligations and restrictions on the ability to process (which includes collection, analysis, and transfer of) personal data, including health data from performance of clinical tests, clinical trials and adverse event reporting. The GDPR also includes requirements relating to establishing a legal basis for processing personal data, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities, standards for binding vendors that process personal data, and the security and confidentiality of the personal data. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the European Commission to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements. **In July 2020,** ~~Following the Schrems II decision of~~ the Court of Justice of the European Union (~~" CJEU "~~) ~~on July 16, 2020, which~~ invalidated the ~~EU~~ **E. U.** ~~US~~ **U. S.** Privacy Shield Framework **,** ~~(the " Privacy Shield ")~~ under which personal data could be transferred from the EEA to ~~US~~ **U. S.** entities ~~who~~ **that** had self- certified under the Privacy Shield scheme ~~,~~**. This framework has been replaced by the E. U.- U. S. Data Privacy Framework for which the European Commission adopted an adequacy decision in July 2023. It is likely** there ~~is considerable uncertainty as~~ **will be legal challenges** to **this framework in the future, which could draw into question the legitimacy of** ~~the~~ **other cross- border** ~~permissibility of international data transfers~~ **transfer mechanisms, including** ~~under the GDPR. While the CJEU upheld the adequacy of~~ the standard contractual clauses ~~(~~**which remain** a **commonly used mechanism used to transfer** ~~standard form of contract approved by the European Commission as an adequate~~ personal data **from** ~~transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them~~ **the EEA** ~~alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. On June 4, 2021, the European Commission released two~~ **to** ~~revised sets of standard contractual clauses, which have been designed in part to assist organizations in meeting the requirement of the CJEU' s judgment. However, it is unclear how the use of these~~ **the** ~~clauses will be scrutinized~~ **U. S.** and **other jurisdictions** ~~enforced by supervisory authorities and privacy interest groups~~ . These recent developments may require us to review and amend the legal mechanisms by which we make and / or receive personal data transfers to / in the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. ~~In addition to the GDPR, numerous other countries have implemented laws governing the use, processing, and cross- border transfer of personal data, such as Switzerland' s FADP, Singapore' s PDPA, and China' s PIPL. We are subject to risks related to the public health crises such as the global COVID- 19 pandemic. Economic and health conditions in the United States and across most of the globe continue to change rapidly. Due to the COVID- 19 pandemic, the Company has experienced significant volatility, including periods of material decline compared to prior year periods, in testing volumes in the Company' s base business (which excludes COVID- 19 molecular and antibody testing). Demand may fluctuate depending on the duration and severity of the COVID- 19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and / or extensions of time for restrictions that have been imposed to date, and numerous other uncertainties. Such events may result in business disruption, reduced revenues and reduced number of tests, any of which could materially affect our business, financial condition, and results of operations. The COVID- 19 pandemic is affecting the Company' s customers, suppliers, vendors, and other business partners, but the Company is not able to assess the full extent of the current impact nor predict the ultimate consequences that may result. At this time, we have not experienced significant interruptions in our operations due to supplier delays. We have established a COVID- 19 procurement team to partner with our suppliers to reduce the risk of disruption. Distribution channels have not been disrupted as incoming and outgoing tests are delivered via major carriers. While the potential economic impact brought by and the duration of COVID- 19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets and a recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our common**

~~stock. The ultimate extent of the effects of the COVID- 19 pandemic on the Company is highly uncertain and will depend on future developments which cannot be predicted.~~ Our performance is substantially dependent on the performance of our senior management and key **scientific and** technical personnel. In particular, our success depends substantially on the continued efforts of our senior management team. The loss of the services of any of our executive officers, our medical staff, our laboratory directors or other key employees could have a material adverse effect on our business, results of operations, and our financial condition. Our future success also depends on our continuing ability to attract and retain highly qualified managerial **, scientific,** and technical personnel as we continue to grow. Competition for such personnel is intense **among the laboratory testing industry** and we may not be able to retain our key managerial and technical employees or may not be able to attract and retain additional highly qualified managerial and technical personnel in the future. The inability to attract and retain the necessary managerial and technical personnel could have a material adverse effect upon our business, results of operations, and financial condition. Additionally, our ability to retain existing clients for our specialized diagnostic services and attract new clients is dependent upon retaining existing sales representatives and hiring and training new sales representatives, which are expensive and time- consuming processes. **Our growth depends, in particular, on attracting, retaining and motivating highly- trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers.** We face intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales. Even if we are able to increase our sales force, our new sales personnel may not commit the necessary resources or provide sufficient high quality service and attention to effectively market and sell our services. If we are unable to maintain and expand our marketing and sales networks, or if our sales personnel do not perform to our standards, we may be unable to maintain or grow our existing business and our results of operations and financial condition will likely suffer accordingly. If a sales representative ceases employment, such termination could result in the loss of client goodwill based on the impairment of relationships developed between the sales representative and the healthcare professionals for whom the sales representative was responsible. This is particularly a risk if the representative goes to work for a competitor, as the healthcare professionals that are our clients may choose to use a competitor' s services based on their relationship with our former sales representative ~~. Further, non- compliant activities and unlawful conduct by sales and marketing personnel could give rise to significant risks under the AKS. We require extensive, comprehensive training of all sales and marketing personnel, but cannot guarantee that every staff member will comply with the training. Thus, in addition to the cost of training sales and marketing personnel, we could face liability under the AKS for non- compliance by individuals engaged in prohibited sales and marketing activities. In our business, we collect, generate, process, or maintain sensitive information, such as patient data and other personal information. If we use or do not adequately safeguard such information in compliance with applicable requirements under federal, state, and international laws, or if such information were disclosed to persons or entities that should not have access to it, our business could be materially impaired, our reputation could suffer, and we could be subject to fines, penalties, and litigation. In the event of a data security breach, we may be subject to notification obligations, litigation, and governmental investigation or sanctions and may suffer reputational damage, which could have an adverse impact on our business. We are subject to laws and regulations regarding protecting the security and privacy of certain healthcare and personal information, including: (a) HIPAA and the regulations thereunder, which establish (i) a complex regulatory framework including requirements for safeguarding protected health information and (ii) comprehensive federal standards regarding the uses and disclosures of protected health information; (b) state laws, including the CCPA; and (c) the European Union' s GDPR~~ . Implementation of our business strategies will depend in large part on our ability to (i) attract and maintain a significant number of clients; (ii) effectively provide acceptable products and services to our clients; (iii) develop and license new products and technologies; (iv) obtain adequate financing on favorable terms to fund our business strategies; (v) maintain appropriate internal procedures, policies, and systems; (vi) hire, train, and retain skilled employees and management; (vii) continue to operate despite competition in the medical laboratory industry; (viii) be paid reasonable fees by government payers that will adequately cover our costs; (ix) establish, develop, and maintain our name recognition; and (x) establish and maintain beneficial relationships with third- party insurance providers and other third- party payers. Our inability to obtain or maintain any or all these factors could impair our ability to implement our business strategies successfully, which could have material adverse effects on our results of operations and financial condition. We engaged in restructuring activities **beginning** in 2022 and these types of cost reduction and restructuring activities are ongoing and complex. If we do not successfully manage our current restructuring activities, or any other restructuring activities that we may take in the future, any expected efficiencies and benefits might be delayed or not realized, and our operations and business could be disrupted. Restructuring presents potential risks of events occurring that could adversely affect us, including: actual or perceived disruption of service to customers; the failure to preserve supplier relationships and distribution, sales and other important relationships and to resolve conflicts that may arise; diversion of management attention from ongoing business activities; and the failure to maintain employee morale and retain key employees. In addition, the costs associated with implementing restructuring activities might exceed expectations, which could result in additional future charges. Because of these and other factors, we cannot predict whether we will realize the purpose and anticipated benefits of these measures and, if we do not, our business and results of operations may be adversely affected. **If we are unable to successfully integrate future acquisitions with our business, the anticipated benefits of such transaction may not be realized and our business, financial conditions, results of operations and cash flows may be adversely affected.** Acquisitions require us to devote significant management attention and resources to integrating the acquired company' s business practices and operations with our own. Potential difficulties we may encounter as part of the integration process, ~~all of which could materially and adversely affect our business, financial condition, results of operations, and cash flows,~~ include the following: • the potential inability to successfully combine the acquired company' s business with our ~~legacy~~ business in a manner that permits us to achieve the cost synergies expected to be achieved when expected, or at all, and other

benefits anticipated to result from such transaction; • challenges optimizing the customer information and technology of the two companies, including the goal of consolidating to one laboratory information system and one billing system; • challenges effectuating any diversification strategy, including challenges achieving revenue growth from sales of each company' s products and services to the customers of the other company; • difficulties offering products and services across our expanded portfolio; • the need to revisit assumptions about reserves, revenues, capital expenditures, and operating costs, including expected synergies; • challenges faced by a potential diversion of the attention of our management as a result of the integration, which in turn could adversely affect our ability to maintain relationships with customers, employees and other constituencies or our ability to achieve the anticipated benefits of such transaction; • the potential loss of key employees, customers, managed care contracts, or strategic partners, or the ability to attract or retain key management and other key personnel, which could have an adverse effect on our ability to integrate and operate the acquired business; • complexities associated with managing the combined businesses, including difficulty addressing possible differences in corporate cultures and management philosophies and the challenge of integrating complex systems, technology, networks, and other assets of each of the companies in a seamless manner that minimizes any adverse impact on customers, suppliers, employees, and other constituencies; • costs and challenges related to the integration of the acquired company' s internal controls over financial reporting with ours; and • potential unknown liabilities and unforeseen increased expenses. We cannot be assured that all of the goals and anticipated benefits of an acquisition will be achievable, particularly as achievement of the benefits is in many important respects subject to factors that we do not control. These factors would include the reactions of third parties with whom we enter into contracts and do business and the reactions of investors and analysts. If we cannot successfully integrate our ~~legacy~~ business with any future business we may acquire, we may fail to realize the expected benefits of such transaction, including the anticipated cost synergies **, and our business, financial condition, results of operations and cash flows may be materially and adversely affected** . We could also encounter additional transaction and integration costs or be subject to other factors that affect preliminary estimates **. In the future, we may enter into transactions to acquire other businesses, products, services or technologies, which may ultimately be unsuccessful. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by investors, healthcare providers, patients and others. In addition to the risks outlined above, we may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results** . In connection with the accounting for our completed acquisitions, we recorded a significant amount of goodwill and intangible assets. Goodwill and indefinite- lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, sustained market declines and other factors that impact the fair values of our reporting units could result in an impairment of goodwill or intangible assets and a charge against earnings, which could materially adversely affect our results of operations or financial condition in future periods. We **may incur greater costs than anticipated in connection with implementing our business strategy, which could result in sustained losses. We** use reasonable efforts to assess and predict the expenses necessary to pursue our business strategies. However, implementing our business ~~strategies~~ **strategy** may require more employees, capital equipment, supplies, or other expenditure items than management has predicted, particularly as we continue to assess any further needs resulting from the growth of our ~~Pharma Services~~ **Advanced Diagnostics** segment. Similarly, the cost of compensating additional management, employees, and consultants or other operating costs may be more than we estimate, which could result in ongoing and sustained losses. Management expects that our results of operations may fluctuate significantly in the future as a result of a variety of factors, including, but not limited to: (i) the continued rate of growth, usage, and acceptance of our products and services; (ii) demand for our products and services; (iii) the introduction and acceptance of new or enhanced products or services by us or by competitors; (iv) our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; (v) our ability to attract, retain, and motivate qualified personnel; (vi) the initiation, renewal, or expiration of significant contracts with any major clients; (vii) pricing changes by us, our suppliers, or our competitors; (viii) seasonality; and (ix) general economic conditions and other factors. Accordingly, future sales and operating results are difficult to forecast. Our expenses are based in part on our expectations as to future revenues and to a significant extent are relatively fixed, at least in the short- term. We may not be able to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in relation to our expectations would likely have an immediate adverse impact on our business, results of operations, and financial condition. In addition, we may determine from time to time to make certain pricing or marketing decisions or acquisitions that could have a short- term material adverse effect on our business, results of operations, and financial condition and may not result in the long- term benefits intended. Furthermore, in Florida, historically our largest referral market for laboratory testing services, a meaningful percentage of the population returns to their homes in the Northern United States to avoid the hot summer months. This **,** combined with our clients' usual summer vacation schedules typically results in seasonality in our business. Because of all of the foregoing factors, our operating results in future periods could be less than the expectations of investors. **See Part I, Item 1, " Business — Seasonality " in this Annual Report on Form 10- K for further discussion of the seasonality of our business. The steps we have taken to protect our intellectual property and proprietary rights may not be adequate, which could result in infringement or misappropriation by third parties.** We regard our copyrights, trademarks, trade secrets, and similar intellectual property as critical to our success, and we rely upon trademark law, copyright law, trade secret protection, and confidentiality and / or license agreements with our employees, clients, partners, and others to protect our proprietary rights. The steps taken by us to protect our proprietary rights may not be

adequate or third parties may infringe or misappropriate our copyrights, trademarks, trade secrets, and similar proprietary rights. In addition, other parties may assert infringement claims against us.