Risk Factors Comparison 2024-02-21 to 2023-02-21 Form: 10-K

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We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer, and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. Risk Factors Summary The following is a summary of the principal risks that could adversely affect our business, operations and financial results. Risks Related to our Business and Business Strategy • We may never become profitable **or sustain profitability** . • We may need additional capital to execute our ~~business~~ **strategic** plan. • Our success depends heavily on our Cologuard and ~~Oncotype~~ **Precision Oncology** tests and the successful commercialization of our tests in development. • Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock price **and cause losses to our shareholders** . • We face intense competition from other companies and may not be able to compete successfully. • If any of our facilities or our laboratory equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed. • We heavily rely upon certain suppliers, including suppliers that are the sole source of certain **supplies and** products ~~; the~~ **used in our tests and business operations. The** loss or interruption of supply from our suppliers could have a disruptive effect on our business. • Failure in our information technology, storage systems, or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts. • If the courier delivery services we use in connection with our tests are disrupted or become significantly more expensive, customer satisfaction and our business could be negatively impacted. • The success of our business ~~is~~ substantially ~~dependent~~ **depends** ~~upon~~ **on** the efforts of our senior management team and **qualified personnel and** our ability to ~~attract~~ **foster and maintain** ~~and~~ **an inclusive** ~~retain personnel. • Our results of operations can be adversely affected by labor shortages, turnover,~~ and ~~labor cost increases~~ **collaborative corporate culture** . • Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests. • Our inability to manage growth could harm our business. • We may engage in acquisitions or divestitures that are not successful and which could disrupt our business and reduce our financial resources and shareholder value. • International expansion of our business exposes us to business, regulatory, labor, political, operational, financial, compliance, payment collection, and economic risks associated with doing business outside of the U. S. • Our business ~~is~~ **may be adversely** affected by **global** macroeconomic conditions **and volatility in the capital markets** . • **Public health crises** ~~The ongoing military action by Russia in Ukraine could have negative impact on the global economy which could materially adversely affect our business~~ , **such as the** ~~operations, operating results and financial condition. • The~~ COVID- 19 ~~outbreak has~~ **pandemic, have had,** and ~~may further materially and~~ **could in the future have,** ~~adversely~~ -- **adverse** ~~affect~~ **effects on** our business and financial results ~~. • We currently offer COVID- 19 testing, but there can be no assurance that we will continue to be able to successfully offer, perform, or generate revenues from the test~~ . • Ethical, legal and social concerns related to the use of genetic information could reduce demand for our genetic tests. • ~~Our business and operations are subject~~ **Climate change, or legal or regulatory measures** to **address** ~~risks related to~~ climate change **or other** ~~. • Our business could be negatively impacted by~~ corporate social responsibility and sustainability matters **, could adversely affect our business, financial condition and results of operations. • The use of Artificial Intelligence presents new risks and challenges to our business** . • We may be a party to litigation in the normal course of business or otherwise, which could affect our business and financial position. Risks Relating to Governmental Regulation and Reimbursement • We face uncertainty related to healthcare reform, pricing, coverage, and reimbursement. • If ~~third- party~~ payers, including managed care organizations, do not approve and maintain reimbursement for our tests at adequate reimbursement rates, our commercial success could be compromised. • ~~Because of Medicare billing rules or changes in Medicare billing rules and processes, we may not receive reimbursement for all tests provided to Medicare patients or may experience delays in receiving payments. •~~ If we are unable to obtain or maintain **reimbursement at** adequate reimbursement **rates** for our Oncotype **DX** tests outside of the U. S., our ability to expand internationally will be compromised. • **Failure** ~~If we fail~~ to ~~meet any applicable~~ **comply with federal, state and foreign laboratory licensing and related** requirements ~~of CLIA or similar state laws, that failure~~ could ~~adversely affect any future payer consideration of our technologies, 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~~ **lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions** . • ~~Failure~~ **Our products could be subject** to **recall** ~~maintain compliance with FDA requirements may prevent or delay the development, marketing or manufacturing of our Cologuard test, or future improvements to that test~~ . • Delays in **receipt of, or failure to** ~~obtaining~~ --- **obtain** ~~regulatory~~ **, required FDA** clearances or approvals for **our** ~~new tests,~~ products **in development** ~~, or services~~ , or improvements to or expanded indications for our current offerings, could **materially delay or** prevent ~~, delay,~~ **us from commercializing** or **otherwise** adversely impact future product commercialization. • **The** ~~If the~~ FDA **may** ~~were to~~ change its position with respect to its regulation of the laboratory developed tests we offer or ~~plan~~ **may seek** to offer **in the future** , ~~we could~~ **causing us to** incur substantial costs and time delays and decreased demand for or reimbursement of our tests. • We are subject to numerous U. S. and foreign laws and governmental

regulations, and any governmental enforcement action may materially affect our financial condition and business operations. • Our business is subject to various complex laws and regulations applicable to **providers of** clinical diagnostics ~~. We could be subject to significant fines~~ and **services** ~~penalties if we or our partners fail to comply with these laws and regulations~~ . • Due to billing complexities in the diagnostic and laboratory service industry, we may **have difficulties receiving timely** ~~not be able to collect~~ payment for the tests we perform **, and may face write- offs, disputes with payers and patients, and long collection cycles** . • Some of our activities may subject us to risks under federal, state, and foreign laws prohibiting " kickbacks " and false or fraudulent claims as well as the Foreign Corrupt Practices Act **and similar anti- bribery laws** . • ~~Compliance~~ **Failure to comply** with ~~the~~ privacy **, security, and consumer protection** laws and regulations **could result in fines, penalties and damage to our reputation and have a material adverse effect on our business. • Our employees, independent contractors, consultants, commercial partners, and vendors** may ~~increase~~ **engage in misconduct** ~~our~~ **or** ~~costs~~ **other improper activities, including noncompliance with regulatory standards and requirements** . • We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA or other U. S. or foreign regulatory bodies, and those third parties may not perform satisfactorily. • **Changes in tax** ~~We are subject to increasingly complex taxation rules and practices. • Our business is subject to complex and evolving~~ laws **or** ~~, as well as customer and patient expectations, regarding data privacy, protection, and security. • We are subject to evolving corporate governance and public disclosure expectations and~~ regulations ~~that impact compliance costs~~ **or exposure to tax liabilities could adversely affect our financial condition** and ~~risks~~ **results** of ~~noncompliance~~ **operations** . Risks Relating to Product Development, Commercialization and Sales of our Products ~~• We have finite resources, which may restrict our success in commercializing our products, and we may be unsuccessful in entering into or maintaining third- party arrangements to support our internal efforts. • If we are unable to deploy and maintain effective sales, marketing and medical affairs capabilities, we will have difficulty achieving market awareness and selling our products and services.~~ • The success of our Cologuard test, our ~~Oncotype~~ **Precision Oncology** tests, and any other screening or diagnostic product or service we may offer or develop will depend on the degree of market acceptance by healthcare providers, patients, healthcare payers, and others in the medical community. • Recommendations, guidelines, and quality metrics issued by various organizations may significantly affect payers' willingness to cover, and healthcare providers' willingness to prescribe or order, our products. • We expect to **continue to** make significant investments ~~to~~ **in our** research and ~~develop~~ **development efforts** ~~new cancer tests~~ , which may not be successful. • Our dependence on distributors for sales in many markets outside of the U. S. could limit or prevent us from selling our tests in those markets and impact our revenue ~~. • Our research and development efforts will be hindered if we are not able to obtain samples, contract with third parties for access to samples, or complete timely enrollment in future clinical studies~~ . Risks Relating to our Intellectual Property • We rely on strategic collaborative and licensing arrangements with third parties to develop critical intellectual property. We may not be able to successfully establish and maintain such intellectual property. • We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our tests ~~,~~ as a result of litigation or other proceedings relating to patent or other intellectual property rights. • If we are unable to protect or enforce our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair any competitive advantage we may otherwise have. **• If patent regulations or standards are modified, such changes could have a negative impact on our business.** Risks Relating to our Securities • ~~We are required~~ **If we fail** to ~~assess our~~ **maintain an effective system of** internal control over financial reporting **,** ~~on an annual basis and any future adverse results from such assessment could result in a loss of investor~~ **investors may lose** confidence ~~and~~ **in the accuracy** ~~an~~ **and** ~~adverse effect on~~ **completeness of our reported financial information and** our stock price **may be** ~~. • We face risks associated with currency exchange rate fluctuations, which could~~ adversely **impacted** ~~affect our operating results. • Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations~~ . • Our stock price has fluctuated widely and is likely to continue to be volatile. • Our balance sheet includes significant amounts of goodwill and intangible assets. The impairment of a significant portion of these assets would negatively affect our results of operations. • Our **significant** ~~management has broad discretion over the use of our available cash and marketable securities and might not spend available cash and marketable securities in ways that increase the value of your investment. • Our~~ indebtedness could adversely affect our business, financial condition, and results of operations and our ability to meet our payment obligations under such indebtedness and limit our ability to raise additional capital to fund our operations. We have incurred losses since we were formed. From our date of inception on February 10, 1995 through December 31, ~~2022~~ **2023** , we have accumulated a total deficit of approximately $ 3. ~~27~~ **47** billion **. Our net loss was $ 204. 1 million, $ 623. 5 million and $ 595. 6 million for the years ended December 31, 2023, December 31, 2022 and December 31, 2021, respectively** . We expect to continue investing significantly toward development and commercialization of our colorectal cancer screening technology, our ~~Oncotype~~ **precision oncology** tests, our **MCED and MRD** ~~blood- based multi- cancer early detection test~~ **tests ,** and other products and services. ~~If~~ **Although our net losses have diminished considerably over the last several years, if** our revenue does not **continue to** grow faster than our **cost of sales and** operating expenses, we will not ~~be~~ **become** profitable. We cannot be certain that the revenue from the sale of any products or services based on our technologies will be sufficient to make us profitable. Although we believe that we have sufficient capital to fund our operations for at least the next ~~twelve~~ **12** months, we may require additional capital to fully fund our current strategic plan, which includes continuing to scale our Cologuard and ~~Oncotype~~ **precision oncology** tests and developing a pipeline of future products and services. Additional financing may not be available in amounts or on terms satisfactory to us or at all. Our success in raising additional capital may be significantly affected by general market conditions, the market price of our common stock, our financial condition **and existing indebtedness** , uncertainty about the future commercial success of our current products and services, the development and commercial success of future products or services, regulatory developments, the status and scope of our intellectual property, any ongoing litigation, our compliance with applicable laws and regulations and other factors. If we raise additional funds through the sale of equity, convertible debt or other equity- linked securities, our ~~stockholders~~ **shareholders** ' ownership will be diluted, and the market price of our common

stock could be depressed. We may issue securities that have rights, preferences and privileges senior to our common stock. If we raise additional funds through collaborations, licensing arrangements or other structured financing transactions, we may relinquish rights to our technologies ~~or~~ **,** products or services, grant security interests in our assets or grant licenses to third parties on terms that are unfavorable to us. Our ~~success depends heavily on our Cologuard and Oncotype DX tests and the successful commercialization of our tests in development. For at least the next 12 months, our~~ ability to generate revenues ~~will depend~~ **depends** very substantially on the commercial success of our Cologuard and ~~Oncotype~~ **precision oncology** tests **. Additionally, we are devoting significant resources to developing new tests in colorectal cancer screening, MRD, MCED, and other areas of cancer diagnostics** . There can be no assurance that we will **be able to continue to grow sales of our Cologuard and precision oncology tests or that we will** develop or commercialize any other products or services that will generate significant revenue. The **knowledge and experience we have gained commercializing our Cologuard and precision oncology tests may not translate into successful commercialization efforts with respect to new and different products. The** commercial success of our tests **, our successful commercialization of any new products** and our ability to generate revenues will depend on a variety of factors, including the following: • acceptance in the medical community; • inclusion in healthcare guidelines and recommendations, such as those developed by ACS, USPSTF, American Society of Clinical Oncology, and NCCN **,** and similar guidelines and recommendations outside the ~~United States~~ **U. S.** ; • inclusion in quality measures **,** including the HEDIS measures and the CMS Medicare Advantage Star Ratings; • recommendations and studies that may be published by government agencies, companies, professional organizations, academic or medical journals or other key opinion leaders; • patient acceptance and demand; • patient compliance with orders for our tests by healthcare providers, and patient adherence to recommendations regarding periodic re- testing; • successful ~~sales~~ **new screening initiatives** , **including gap closure programs through which we partner with health systems and payers to deliver Cologuard test kits to their patients or members who are due for colorectal cancer screening under applicable guidelines; • effective** marketing ~~,~~ and educational programs, including successful direct- to- patient marketing such as television advertising and social media; • the number of patients screened for colorectal cancer, as well as the number of patients who use our Cologuard test for that purpose; • the number of women diagnosed with breast cancer; • sufficient coverage and reimbursement by ~~third- party~~ payers ~~within and outside the U. S.~~ ; • the existence of federal or state laws that mandate coverage for colorectal cancer and other types of screening, the extent to which those laws mandate coverage of our tests and the enforcement of those laws; • the amount and nature of competition from other products and procedures; • maintaining regulatory approvals to legally market; • the ease of use of our ordering process for healthcare providers; • maintaining and defending patent protection for the intellectual property relevant to our products and services; and • our ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities. If we are unable to continue **growing** ~~to grow~~ sales of our Cologuard and ~~Oncotype~~ **precision oncology** tests **, ~~or if~~** we are delayed or limited in doing so **, or we are unable to successfully commercialize our tests in development or other new products** , our business prospects, financial condition and results of operations would be adversely affected. ~~Additionally, we are devoting significant resources to the development of an improved version of our Cologuard test, a MCED test, MRD test, as well as other new products. The successful commercialization of these tests will also be subject to the factors listed above, among others. If we are unable to successfully commercialize these tests in development, our business prospects, financial condition and results of operations would be adversely affected. Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock price and cause losses to our stockholders.~~ Our revenues and results of operations **have historically, and** may **in the future,** fluctuate significantly, depending on a variety of factors, including the following: • ~~the impact of the COVID- 19 pandemic on our business and operations; •~~ our success in marketing and selling, and changes in demand for, our Cologuard and ~~Oncotype~~ **precision oncology** tests, and the level of reimbursement and collection obtained for such tests; • seasonal variations or non- seasonal events or circumstances affecting healthcare provider recommendations for our tests and patient compliance with healthcare provider recommendations, including without limitation, holidays, weather events, and circumstances such as the outbreak of influenza that may limit patient access to medical practices or institutions for diagnostic tests and preventive services; • our success in collecting payments from third- party and other payers, patients and collaborative partners, variation in the timing of these payments and recognition of these payments as revenues; • the pricing of our tests, including potential changes in CMS or other reimbursement rates; • circumstances affecting our ability to provide our tests, including weather events, supply shortages, or regulatory or other circumstances that adversely affect our ability to manufacture our tests or process tests in our clinical laboratories; • fluctuations in the amount and timing of our selling and marketing costs and our ability to manage costs and expenses and effectively implement our business; and • our research and development activities, including the timing, size, complexity, and cost of clinical studies. **If our revenues or operating results fall below the expectations of investors or public market analysts, the trading price of our common stock could decline substantially.** We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products **,** or have announced that they are developing products that compete with ours. Some of our current and potential competitors may have significant competitive ~~advantage~~ **advantages** over us, which may make them more attractive to hospitals, clinics, group purchasing organizations and physicians **. See " Item 1. Business — Competition "** ~~, including: • technology breakthroughs that we do not have access to; • entrenched leaders~~ in ~~new areas that we are entering;~~ **this Annual Report on Form 10- K for additional information regarding our competitors** and ~~• alternative distribution models that customers prefer~~ **the effects of competition on our business** . We may be unable to compete effectively against our competitors either because their products and services are superior or because they are more effective in developing or commercializing competing products and services. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more clinically or commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us. If we are unable to compete successfully

against current or future competitors, we may be unable to increase market acceptance for , and sales of , our tests, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline. **Our manufacturing, testing** ~~We currently perform our Cologuard~~ and ~~COVID- 19 tests in~~ laboratory facilities **are located** in Madison **and Marshfield** , Wisconsin ~~. We manufacture the Cologuard test in two facilities in Madison~~ , ~~Wisconsin. Our~~ **Redwood City, California, Kirkland, Washington, Phoenix, Arizona, and Trier, Germany, and our** headquarters are also located in Madison, Wisconsin. ~~We perform our Oncotype DX tests out of our clinical laboratory facilities in Redwood City, California. Redwood City is situated near active earthquake fault lines and we do not have a redundant facility where we can perform our Oncotype DX tests. We also operate laboratories in Phoenix, Arizona and Marshfield, Wisconsin, and provide a testing facility in Trier, Germany.~~ If our present, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, earthquakes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, it may render it difficult or impossible for us to perform our tests for some period of time , and our business could be severely disrupted. Our facilities and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The inability to perform our tests or the backlog of tests that could develop if any of our facilities become inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers **or rebuild our reputation** in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. ~~In order~~ **If our testing facilities become inoperable for any reason, we may not be able to transfer any or all testing to our other facilities and would need** to rely on a third party to perform certain of ~~our~~ **these** tests ~~, we~~ **. We** could use only another facility with established state licensure and CLIA accreditation, and for tests provided internationally, ISO 15189 accreditation, under the scope of which Oncotype ~~DX~~ tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find **an appropriately** ~~another CLIA or ISO 15189-~~ certified facility willing to comply with the required procedures, that this laboratory would be willing to perform the tests for us on commercially reasonable terms, or that it would be able to meet our quality or regulatory standards. **Alternatively,** ~~In order to establish~~ **establishing** a redundant ~~clinical reference laboratory outside of our Redwood City, California facilities~~ **facility** , ~~we~~ **for certain of our testing** would **require** ~~have to spend~~ considerable time and money ~~securing~~ **to secure** adequate space, ~~constructing~~ --- **construct** the facility, ~~recruiting~~ --- **recruit** and ~~training~~ --- **train** employees, and ~~establishing~~ --- **establish** the additional operational and administrative infrastructure necessary to support **this** ~~a second~~ facility. We **also** may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any **such** new ~~clinical reference laboratory~~ facility ~~opened by us~~ would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to resume operations. We purchase certain supplies **and products** from third- party suppliers ~~and manufacturers~~ . In some cases, due to the unique attributes of **certain** products that are incorporated into our tests **or otherwise used in our operations** , we maintain either a single- source supplier relationship or a very limited set of supplier relationships. Certain of our third- party suppliers possess exclusive intellectual property or otherwise may be the only party with the rights or expertise to provide us critical supplies **and / or products** . These third parties are independent entities subject to their own unique operational, regulatory compliance, and financial risks that are outside our control. These third parties may not be willing to enter or renew long- term supply arrangements with us or continue to supply us at all. Additionally, they may not perform their obligations in a timely and cost- effective manner , and they may be unwilling **or unable** to increase production capacity commensurate with demand for our tests or future products or services. Our relationships with suppliers may also be negatively affected by general supply chain material shortages worldwide, as suppliers struggle to keep pace with demand and manage their own supply chains. We may become dependent on additional single- or limited- source suppliers, or become increasingly dependent on existing suppliers, as we expand and develop our product and service pipeline. For example, our OncoExTra test is currently only validated to be performed on Illumina' s sequencing platform , and we are not aware of any other platform that we could use in the near future as a commercially viable alternative. Further, Illumina may be the only commercially viable supplier of certain equipment and reagents necessary for **some of our current tests and** future tests we may develop, including MCED ~~,~~ **and** MRD ~~, and recurrence monitoring~~ tests. **Since** ~~We currently procure Illumina equipment and reagents on a purchase order basis, without any long- term supply agreement. In~~ August 2021, Illumina **has owned** ~~completed its acquisition of~~ GRAIL, which is commercializing a MCED test against which certain of our planned tests would compete. Illumina' s ownership of GRAIL could incentivize Illumina to offer its sequencing products in a manner that advantages GRAIL over us and other competitors, including the potential that Illumina may be unwilling or unable to supply, or commit to supplying, us with sequencing equipment and reagents on commercially acceptable terms, or at all. ~~Although~~ Illumina has made an irrevocable standing offer to supply any customer with its sequencing products ~~on certain terms~~ **, which we have accepted. However** , that offer may not provide pricing or other terms necessary for us or others to successfully compete against GRAIL, including outside of the U. S **. On December 17, 2023, Illumina publicly announced its intention to divest GRAIL by the end of the second quarter of 2024, after various regulatory decisions in the U. S. and E. U. questioned whether Illumina' s ownership of GRAIL was consistent with antitrust laws. The timing and terms of such divestiture are uncertain and, even if it occurs as announced, it may not mitigate the risks associated with our use of Illumina' s products** . Although we expect to continue our efforts to validate alternative sequencing platforms on which we could run our OncoExTra tests or other future tests in a commercially viable manner, we may expend considerable time and efforts, endure delays to our test development and commercialization timelines, and be ultimately unsuccessful in our efforts to validate alternatives. Even if we validate an alternative sequencing platform, we may become substantially dependent on the supplier of that platform. Similarly, as an additional example, we rely on Hamilton Company (" Hamilton ") to provide us laboratory equipment and related supplies

(such as racking and pipette tips) necessary to perform certain critical ~~DNA analysis~~ steps in our clinical laboratory tests, including our Cologuard ~~, Oncotype DX,~~ and **precision oncology** ~~COVID- 19~~ tests. Although other companies may offer viable alternative platforms, we have invested significant capital, time and expertise to procure Hamilton machines and to optimize their use in our tests. **We** ~~Industry demand for Hamilton supplies has increased significantly since the onset of the COVID- 19 pandemic, and although we~~ have a long- term supply agreement with Hamilton, **which requires our exclusive use of certain Hamilton consumables and components with our Hamilton laboratory equipment. However,** it is possible that Hamilton could become unable or unwilling to continue ~~to provide~~ **providing** us with ~~certain~~ equipment and supplies on commercially acceptable terms, if at all. **If** ~~Hamilton may require us to exclusively use Hamilton consumables and components in connection with certain Hamilton laboratory equipment. Therefore, if~~ our access to certain Hamilton consumables and components became impacted, we may need to completely replace the Hamilton platform. Validating alternative vendors' offerings could be expensive, time- consuming, and unsuccessful. Further, because our Cologuard test is regulated by the FDA, we may also need FDA clearance or approval to replace certain Hamilton equipment and supplies with another vendor' s offerings. FDA approval or clearance may entail extensive new clinical and material costs and delays and may be ultimately unsuccessful. The loss of a critical supplier, the failure to perform by a critical supplier, the deterioration of our relationship with a critical supplier or any unilateral modification to the contractual terms under which we are supplied ~~materials~~ **certain supplies and / or products** could have a disruptive effect on our business, and could adversely affect our results of operations for an extended period of time, particularly if we are required to validate an alternative supplier. Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology (" IT ") systems, which support our operations, including at our clinical laboratories, and our research and development efforts. We ~~are dependent~~ --- **depend** on our IT systems to receive and process test orders, securely store patient health records and deliver the results of our tests. The integrity and protection of our own data, and that of our customers and employees, is critical to our business ~~. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve~~ . IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts from criminal hackers, hacktivists, state- sponsored intrusions, industrial espionage and employee malfeasance, breaches due to employee error and natural disasters. Moreover, despite network security and back- up measures, some of our servers are potentially vulnerable to physical or electronic break- ins, computer viruses, and similar disruptive problems ~~. High- profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyber- attacks targeting businesses such as ours~~ . Cyber- attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm **at** ~~. Computer hackers and others~~ **other companies** ~~routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data~~ . While we devote significant resources to **protect the security of our IT systems, including the personal data and other information that we receive and store, there can be no assurance that any** security measures ~~to protect~~ **will be effective against current** ~~our~~ **or future** ~~systems and data, these measures cannot provide absolute~~ security **threats** . We have experienced and expect to continue to experience attempted cyber- attacks of our IT systems ~~or~~ **and** networks. To date, none of these attempted cyber- attacks has had a material effect on our operations or financial condition. However, any such breach or interruption could compromise our networks and the information stored therein could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, unauthorized access, loss or disclosure could also disrupt our operations, including our ability to: • process tests, provide test results, bill payers or patients; • process claims and appeals; • provide customer assistance services; • conduct research and development activities; • collect, process and prepare company financial information; • provide information about our tests and other patient and healthcare provider education and outreach efforts through our website; and • manage the administrative aspects of our business ~~and damage to our reputation~~ . Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, similar U. S. state data protection regulations, ~~including~~ the ~~CCPA, the E. U.~~ GDPR, and other regulations, the breach of which could result in significant penalties **and damage to our reputation** . **In addition, disruptions to our business occurring as a result of** ~~System~~ **system** ~~upgrades~~ **updates** and enhancements ~~require significant expenditures and allocation of valuable employee resources. Differences in software and systems across our operations may create complexity and compatibility problems. As we complete acquisitions~~ , **such as our efforts** ~~it is necessary for us~~ to ~~integrate the acquired company' s information~~ **move our precision oncology tests to our** technology **and services platform,** ~~systems into our existing systems. Delays in integration or disruptions to our business from implementation of new or upgraded systems~~ could have a material adverse ~~impact~~ **effect** on our financial condition and operating results. There can be no assurance that our process of improving existing systems, developing new systems to support our expanding operations ~~,~~ ~~integrating new systems~~ , protecting confidential patient information, and improving service levels will not be delayed or ~~that~~ **will not give rise to** additional systems issues ~~will not arise~~ in the future. Although we carry insurance for this purpose, failure to adequately protect and maintain the integrity of our information systems and data, including as a result of a security breach, may result in significant losses that exceed our insurance coverage limits and have a material adverse effect on our financial position, results of operations and cash flows. We rely on courier delivery services to transport Cologuard collection kits to patients and samples for all of our tests back to laboratory facilities for analysis. If these delivery services are disrupted or become significantly more expensive, customer satisfaction and our business could be negatively impacted. In most cases, we ship Cologuard collection kits to patients, and patients ship samples to our Madison, Wisconsin laboratory facilities for analysis ~~,~~ by air and ground express courier delivery service. Additionally, medical providers typically ship samples for Oncotype testing to our laboratory facilities via air and ground express courier delivery service. Disruptions in delivery service, whether due to

bad weather, natural disaster, labor disruptions, terrorist acts or threats, or for other reasons, can adversely affect customer satisfaction, specimen quality and our ability to provide our services on a timely basis. If the courier delivery services that transport Cologuard collection kits or other test samples institute significant price increases, our profitability would be negatively affected and we may need to identify alternative delivery methods, if possible, modify our service model, or attempt to raise our pricing, which may not be possible with regard to Medicare claims or commercially practicable with regard to commercial claims. **The success of our business substantially depends on the efforts of our senior management team and our qualified personnel and our ability to foster and maintain an inclusive and collaborative corporate culture.** Our success depends largely on the skills, experience, and performance of ~~key members of~~ our senior management team **,** ~~. Our executives are critical to directing~~ and ~~managing~~ **of the highly skilled personnel supporting** our ~~growth~~ **research** and development ~~in the future~~ **programs, commercial laboratory operations, sales efforts and information technology infrastructure** . ~~Our success is substantially dependent upon~~ **The loss of the service of any member of** our senior management **could significantly delay** ~~'s ability to lead our~~ **or** ~~company, implement successful~~ **prevent the achievement of our** corporate strategies and initiatives, **or adversely impact our ability to** develop key relationships ~~, including relationships with collaborators~~ and **commercialize our products and services. Also, facilitating seamless leadership transitions for key positions is a critical factor in sustaining the success of our organization. If our succession planning efforts are not effective, it could adversely impact our** business ~~partners, and successfully commercialize products and services~~ . **We face** ~~If we were to lose any of our senior management team, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Competition for desirable personnel is~~ intense ~~, and there can be no assurance that we will be able to attract and retain the necessary staff. Our research and development programs, commercial laboratory operations and information technology infrastructure depend on our ability to attract and retain highly skilled personnel. We may not be able to attract or retain qualified talent due to the~~ competition for ~~qualified~~ **certain highly technical or scientific** personnel **and experienced salespeople** among life science and technology businesses. We also **compete with** ~~face competition from~~ universities and public and private research institutions **for** ~~in recruiting and retaining~~ highly qualified scientific personnel. In addition, **as our sales efforts grow in size and complexity, we may not be able to successfully manage our dispersed** ~~our~~ **or** ~~success depends~~ **inside sales forces or our sales force may not be effective. Because of the competition for their services, we may be unable to hire, partner with or retain additional qualified sales representatives or marketing or medical affairs personnel, either as our employees or independent contractors or through independent sales or other third- party organizations. Market competition for commercial, marketing and medical affairs talent is significant, and we may not be able to hire or retain such talent** on **commercially reasonable terms** ~~our ability to attract and retain salespeople with extensive experience in primary care~~ , **if at all** ~~oncology, gastroenterology, women' s health, and urology and close relationships with healthcare providers and other hospital personnel~~ . All of our employees in the U. S. are at will, which means that either we or the employee may terminate their employment at any time. If we **fail** ~~are not able~~ to attract and retain ~~the~~ necessary personnel **or effectively manage leadership changes among key positions in our organization** , our business and operating results could be harmed. ~~Labor is a significant component of operating our~~ **In addition, recruiting and retaining talented and diverse personnel and fostering an inclusive culture focused on collaboration and partnership across the** business **are critical** ~~. A number of factors may adversely affect the labor force available~~ to ~~us or~~ **our success** ~~increase labor costs, including high employment levels, federal unemployment subsidies, increased wages offered by other employers, vaccine mandates and other government regulations and our responses thereto~~ . As ~~more employers offer remote work,~~ we **grow** ~~may have more difficulty recruiting for jobs that require on- site attendance~~ , ~~such as certain clinical laboratory and sales roles. Although~~ we ~~have not~~ **may face challenges in attracting and retaining qualified personnel with diverse backgrounds,** ~~experienced~~ **experiences** ~~any material labor shortage to date, we have observed an~~ **and skill sets** ~~overall tightening and increasingly competitive labor market. A sustained labor shortage or increased turnover rates within our employee base could lead to increased costs~~ , ~~such as increased overtime or financial incentives to meet demand and increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate our clinical laboratories and overall business. If we are unable to hire and retain employees capable of performing at a high level, or if mitigation measures we may take to respond to a decrease in labor availability have unintended negative effects, our business could be adversely affected. Additionally, the operations of our vendors and partners could also suffer from labor shortages, turnover, and labor cost increases~~ which could **harm** ~~result in supply chain disruptions and increases in the costs of the products and services we purchase, each of which could adversely affect~~ our ~~operations~~ **ability to execute our business strategy** . Inherent risks are involved in providing and marketing ~~cancer~~ **our** tests **, including our Cologuard test and our precision oncology tests,** and related services. Patients and healthcare providers rely on us to provide accurate clinical and diagnostic information that may be used to make critical healthcare decisions. As such, users of our tests may have a greater sensitivity to errors than users of some other types of products and services. We must maintain top service standards and FDA- mandated and other quality controls. Past or future performance or accuracy defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of our tests or mishandling of samples or test results (whether by us, patients, healthcare providers, courier delivery services, or others) can lead to adverse outcomes for patients and interruptions to our services. These events could lead to voluntary or legally mandated safety alerts relating to our tests or our laboratory facilities and could result in the removal of our products and services from the market or the suspension of our laboratories' operations. Insufficient quality controls and any resulting negative outcomes could result in significant costs and litigation, as well as negative publicity that could reduce demand for our tests and payers' willingness to cover our tests. Even if we maintain adequate controls and procedures, damaging and costly errors may occur. In connection with the commercialization of our tests, we have added, and expect to continue ~~to add~~ **adding,** personnel to certain areas of our business **,** including laboratory operations, quality assurance, and compliance. Our number of full- time employees has increased from 4, **800** ~~833,~~ as of December 31, 2020 ~~,~~ to 6, ~~278~~ **500** , as of

December 31, ~~2021~~ **2023** ~~and to 6, 300, as of December 31, 2022~~ . **As** ~~Further, as~~ we **continue to** build our commercialization **, marketing, and sales** efforts and expand research and development activities for **current and** new products and services, the scope and complexity of our operations is increasing significantly. **In addition,** ~~As a result of~~ our **acquisitions have contributed to the increasing complexity of operations, requiring significant changes to our corporate operations as we integrate other companies and their personnel to our systems. This** growth ~~,~~ **has also increased** our operating expenses and capital requirements ~~have also increased~~ , and we expect that they will continue to increase significantly. Our ability to manage our growth effectively requires us to expend funds to improve our operational, financial and management controls, reporting systems and procedures. As we **expand the commercialization of our current tests and** move **towards** ~~forward in~~ commercializing ~~our~~ **new** tests, we will also need to effectively manage our growing manufacturing, laboratory operations, and sales and marketing needs. We are continuing to ~~expand our current facilities and exploring~~ **explore** the need to add new facilities to support anticipated demand for our current and future tests. We face various risks in managing these expansion efforts, including financing, construction delays, budget management, quality control, design efficiency, and transition execution. If we are unable to manage our anticipated growth effectively, our business could be harmed. We undertake acquisition activities from time to time. For example, in ~~January~~ **September** ~~2021~~ **2023 ,** we acquired **Resolution Bioscience** ~~Thrive Earlier Detection Corporation~~ , ~~in April 2021 we acquired Ashion Analytics, LLC, in June 2021 we acquired PFS Genomics~~ Inc ~~. (" PFS Genomics "), in December 2021 we acquired PreventionGenetics, LLC, and in May 2022 we acquired OmicEra Diagnostics GmbH (" OmicEra ")~~ . Certain risks may exist as a result of these and other acquisition activities, including, among others ~~, that~~ : • ~~we may encounter~~ potential unknown liabilities and unforeseen increased expenses, delays **,** or unfavorable conditions in connection with the integration of the acquired businesses into our business; • ~~we may be unable to~~ **diversion of management' s attention and company resources from our existing operations of our business; • the issuance of dilutive securities, assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash in acquisitions; • difficulties in** ~~successfully~~ -- **successful** ~~integrate~~ **integration of** the **operations and information technology systems of** acquired businesses into our business; • ~~we may~~ **the potential** ~~lose~~ **loss of** key employees **, customers and strategic partners of ours and of acquired businesses** ; • ~~we may encounter potential unknown liabilities and unforeseen risks associated with contracts containing consent and / or other~~ -- **the inability** ~~provisions that may be triggered by the acquisitions; • we may be unable~~ to realize the anticipated benefits of the acquisitions or do so within the anticipated timeframe; • **negative impacts on our near- term financial results after an acquisition or on** our future **financial** results ~~will suffer~~ if we do not effectively manage our expanded operations; and • the market price of our common stock may decline as a result of the acquisitions. 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~~ **acquisition targets** , 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. We may also pursue strategic divestitures ~~from time to time~~ **that may prove distracting, unprofitable, or otherwise unsuccessful** . For example, in August 2022 we completed a divestiture of assets related to our **Oncotype DX Genomic Prostate Score test (" "** GPS test **")** to MDxHealth SA (" MDxHealth "). A successful divestiture depends on various factors, including our ability to effectively transfer liabilities, contracts, facilities and employees to the ~~purchaser~~ **buyer** , identify and separate the personnel, contracts **,** and assets, including intellectual property, to be divested from the ~~intellectual property~~ **portion of the business and assets** that we wish to keep **,** and reduce fixed costs previously associated with the divested assets or business. In exiting a business, we may still retain liabilities associated with ~~those~~ **that** ~~businesses~~ -- **business** and other indemnification obligations. We may also need to provide transition services to the buyer for an extended period of time following the closing, which may cause us to incur unanticipated costs and distraction. With respect to any divestiture, we may encounter difficulty finding potential ~~acquirers~~ **buyers** or other divestiture options on favorable terms **. We may agree to milestone or earnout- based consideration, the achievement of which will be outside our control, and which we may ultimately never receive** . Any divestiture could affect our profitability as a result of the gains or losses on such sale of a business or service, the loss of the operating income resulting from such sale or the costs or liabilities that are not assumed by the acquirer (i. e., stranded costs) that may negatively impact profitability subsequent to any divestiture. We may also be required to recognize impairment charges as a result of a divestiture. International expansion of our business exposes us to business, regulatory, labor, political, operational, financial, liability, compliance, payment collection, and economic risks associated with doing business outside of the U. S. **While we do not offer our Cologuard test outside of the U. S., we currently commercialize or plan to commercialize our Oncotype DX tests through employees in Canada, Japan, and a number of European countries, as well as through exclusive distribution agreements. We have provided our Oncotype tests in approximately 120 countries.** Our business strategy incorporates **continued** international expansion, which includes growing our direct sales and healthcare provider outreach and education capabilities outside of the U. S. and developing our relationships with payers and distributors in foreign markets. Doing business internationally involves a number of risks, including: • difficulties in complying with multiple, conflicting **,** and changing laws and regulations **,** such as tax laws, export and import restrictions, employment laws, privacy and data protection laws, regulatory requirements and other governmental approvals, permits and licenses **, including the changing regulation in Europe with regard to medical device and in vitro diagnostic regulations** ; • significant competition from local and regional product offerings **and the fact that products designed for U. S. markets may not be preferred by foreign authorities, payers, medical providers and patients; • restrictions or prohibitions of transmitting personal data, including patient data, from foreign jurisdictions to our**

centralized laboratories in the U. S. ; • difficulties in **staffing and** ~~complying with unclear product regulations in various jurisdictions, including the changing~~ **managing** ~~regulation in Europe with regard to medical device and in vitro diagnostic (" IVD ") regulations; • restrictions or prohibitions of transmitting personal data, including patient data, from~~ foreign **operations** ~~jurisdictions to our centralized laboratories in the U. S.~~ ; • difficulties in ~~staffing and~~ managing ~~foreign operations~~ **distributor relationships** ; • complexities associated with managing multiple payer reimbursement regimes, public payers **,** or patient self-pay systems; • logistics and regulations associated with shipping tissue samples, performing tests locally or complying with local regulations concerning the analysis of tissue, including infrastructure conditions and transportation delays; • limits in our ability to access or penetrate international markets if we are not able to process tests locally; • lack of intellectual property protection in certain markets; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, **lower margins resulting from smaller scale foreign operations,** the impact of local and regional financial crises on demand and payment for our tests **,** and exposure to foreign currency exchange rate fluctuations; • natural disasters, political and economic instability, including wars, strikes, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade **,** and other business restrictions; • staffing difficulties, funding restrictions, and other difficulties facing medical institutions and payers; • regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our sales force and distributors that may fall within the purview of the ~~U. S.~~ FCPA, its books and records provisions or its anti- bribery provisions, or similar anti- bribery or anti- corruption laws or regulations, such as the U. K. Anti- bribery Act and the U. K. Criminal Finances Act; **and** • complexity of compliance with local standard contractual requirements to access public customers and payers. Any of these factors could significantly harm our **current international operations or** future international expansion and ~~operations and~~ , consequently, our financial condition and results of operations **. The growth of our business is, and will continue to be, affected by changes in the overall global economy** . Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, **high** interest rates, ~~and~~ foreign currency exchange rates ~~and overall~~ **, weakness in general** economic conditions and ~~uncertainties~~ **threatened or actual recessions** , including those resulting from the current and future conditions in the global financial markets ~~. For instance~~ , ~~we experienced inflationary pressures in 2022~~ and **budgeting constraints of governmental entities** ~~expect such pressures to continue in 2023~~ . Cost inflation, including increases in raw material prices, labor rates, and transportation costs **,** may **continue to** impact our profitability. Our ability to recover these cost increases through price increases is significantly limited by the process by which we are reimbursed for our products and services by government and private payers. **In addition, disruptions in the U. S., Europe or other economies, including due to geopolitical conflict, could disrupt global markets, interrupt global supply chains, and have other potential inflationary or recessionary effects on the global economy.** The volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations. ~~Increasing~~ **The high** interest ~~rates~~ **rate environment** and reduced access to capital markets could also adversely affect the ability of our suppliers, distributors, licensors, collaborators, contract manufacturers and other commercial partners to remain effective business partners or to remain in business. The loss of a critical business partner, or a failure to perform by a critical business partner, could have a disruptive effect on our business and could adversely affect our results of operations. ~~On February 24~~ **Pandemics or disease outbreaks** , ~~2022~~ **such as the COVID- 19 pandemic** , ~~Russian forces launched~~ **have created and may continue to create** significant **volatility** ~~military action against Ukraine~~ , **uncertainty** and **economic** ~~sustained conflict and~~ disruption in the ~~region is possible~~ **markets in which we sell or plan to sell our current or future tests and in which we operate, and may negatively impact business and healthcare activity globally. For example, in response to the COVID- 19 pandemic, governments around the world imposed measures designed to reduce the transmission of COVID- 19, patients postponed visits to healthcare providers, certain healthcare providers temporarily closed their offices or restricted patient visits, healthcare provider employees became generally unavailable and there were disruptions in the operations of payers, suppliers and other third parties that are necessary for our tests to be administered** . The **extent to which fear of exposure to or actual effects of COVID- 19, new variants, disease outbreak, epidemic or a similar widespread health concern impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the speed and extent of geographic spread of the disease, the duration of the outbreak, travel restrictions, the efficacy of vaccination and treatment;** impact **on the U. S. and international healthcare systems, the U. S. economy and worldwide economy; the timing, scope and effectiveness of U. S. and international governmental response; and the impact on the health, well- being and productivity of our employees; and short- and long- term changes in the behaviors of medical professionals and patients resulting from any such pandemic, outbreak, epidemic or other health concern. Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition** to ~~Ukraine testing or prohibit testing for genetic predisposition to~~ certain conditions,particularly for those that have no known cure.Similarly,these concerns may lead patients to refuse to use,or clinicians to be reluctant to order,genetic tests even if permissible.These and other ethical,legal and social concerns may limit market acceptance of our genetic tests or reduce the potential markets for these tests,either of which could have an adverse effect on our business,financial condition or results of operations.The effects of global climate change present risks to our business.Natural disasters,extreme weather and other conditions caused by or related to climate change could adversely impact our supply chain,the courier delivery services we use,the availability and cost of raw materials and components,energy supply,water,transportation,or other inputs necessary for the operation of our business.Climate change and natural disasters could also **impact behaviors of medical providers or patients or** result in physical damage to our facilities as well as ~~actions taken by~~ **those of our suppliers, health care providers and** other ~~countries~~ **business partners** , ~~including new~~ **all of which could negatively impact** and **disrupt our business** ~~stricter sanctions imposed by Canada, the United Kingdom, the European Union, the United States.~~ and **operations. Our facilities and**

our laboratory equipment would be costly to replace and could require substantial lead time to repair or replace. Although we believe we possess adequate insurance for ~~other -- the disruption of our business from causalities countries and companies and organizations against officials , individuals, regions, and industries in Russia and Ukraine, and actions taken by Russia in response to~~ such ~~sanctions, and each country' s~~ **insurance may not be sufficient to cover all of our** potential **losses** ~~response to such sanctions, tensions,~~ and **may not continue** ~~military actions could adversely affect the global economy and financial markets and thus could affect our business, operations, operating results and financial condition as well as the price of our common stock and our ability~~ to **be available to us** ~~raise additional capital when needed~~ on acceptable terms ~~. The extent and duration of the military action , sanctions and resulting market disruptions are impossible to predict, but could~~ **or at all. New or additional legal or regulatory requirements may** be ~~substantial~~ **enacted to reduce greenhouse gas emissions, mitigate the effects of climate change on the environment or address other corporate social responsibility and sustainability matters** . Any such **new or additional legal or regulatory requirements may increase the costs associated with, or disrupt, the development, manufacturing and** ~~disruptions --~~ **distribution of our tests or the performance of related services, which may adversely affect our business and financial results. In addition, any failure to adequately address stakeholder expectations with respect to corporate social responsibility and sustainability matters, including addressing climate change, may result in the loss of business, damage to our reputation, diluted market valuations, challenges in attracting and retaining talented employees and restrictions on certain aspects of our activities. Furthermore, our adoption of certain standards for our corporate social responsibility and sustainability efforts and related matters or mandated compliance to certain requirements could necessitate additional investments that could hinder our profitability. Artificial Intelligence (" AI ") is increasingly being** ~~caused --~~ **used across the global business landscape, including in the life sciences and healthcare industries. We have already employed certain AI technologies into our business to enhance our operations, products, technology, and services and expect our use of AI to increase as the technology rapidly evolves and improves. However, AI innovation presents risks and challenges that could impact our business. AI algorithms may be flawed. Datasets may be insufficient or contain biased information. Ineffective AI development and deployment practices** by **us or** ~~Russian military action or~~ **our commercial partners could** ~~resulting ---~~ **result in violations** ~~sanctions may magnify the impact~~ of **our confidentiality and privacy obligations or applicable laws and regulations, jeopardize our intellectual property rights, cause or contribute to unlawful discrimination, result in the misuse of personally identifiable information, including PHI, or give rise to significant cyber security risks, any of which could have a material adverse effect on our business, results of operations, and financial condition. We may also face increased competition from** other ~~risks~~ **companies that** are ~~developing~~ **employing AI** and ~~evolving~~ **related technologies** , **some of whom may develop more effective methods than we** and **any** ~~certain areas are subject to assumptions that could change over time and the extent and severity~~ of **our commercial partners have** ~~climate change impacts are unknown.In addition~~ , **which** ~~we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters.Any such matters~~ could have a material adverse ~~impact~~ **effect** on our ~~future~~ **business,** results of operations, **or** financial ~~position~~ **condition.In addition,uncertainties regarding developing legal** and ~~cash flows~~ **regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with U.S.and foreign laws concerning the use of AI and related technologies,the nature of which cannot be determined at this time** .From time to time,we are a party to or otherwise involved in legal proceedings,claims and government investigations and other legal matters,both inside and outside the ~~United States~~ **U.S.** ,arising in the ordinary course of our business or otherwise.We are currently involved in various legal proceedings and claims that have not yet been fully resolved,and additional claims may arise in the future.Legal proceedings in which we are currently involved include ~~an investigation by the~~ **those proceedings** ~~United States Department of Justice concerning Genomic Health' s compliance with the Medicare Date of Service billing regulations and~~ described in **Note 15 of the Notes to Consolidated Financial Statements included in Item 8 of** this Annual Report on Form 10- K. **Additionally,** ~~The broad and extensive impact of the COVID- 19 pandemic on virtually all aspects of our business and society has exacerbated many pre- existing risks to our business by making them -~~ **the distribution** ~~more likely to occur or more impactful when they do occur. Accordingly~~ , **sale** ~~you should consider the risks described in this risk factor in addition to~~ , **use** and ~~not in lieu of, the risks described elsewhere throughout these risk factors. The COVID- 19 pandemic has created significant, widespread and unprecedented volatility, uncertainty, and economic instability, disrupting broad aspects of the global economy, capital markets, our operations, our workforce and our supply chain. Many of these effects continue to varying degrees and further mutated variants and outbreaks globally or regionally continue to harm recovering consumer confidence and have led to renewed implementation of harsh preventative measures by local and regional governments and businesses. Therefore, comparing our financial~~ results for the reporting periods of 2022 to..... Additionally, the sale and use of our tests could lead to ~~product or professional~~ liability claims. Legal proceedings can be complex and take many months, or even years, to reach resolution, with the final outcome depending on a number of variables, some of which are not within our control. Litigation is subject to significant uncertainty and may be expensive, time- consuming, and disruptive to our operations. Although we will vigorously defend ourselves in such legal proceedings, their ultimate resolution and potential financial and other impacts on us are uncertain. For these and other reasons, we may choose to settle legal proceedings and claims, regardless of their actual merit. If a legal proceeding is resolved against us, it could result in significant compensatory damages, and in certain circumstances punitive or trebled damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief imposed on us. If our existing insurance does not cover the amount or types of damages awarded, or if other resolution or actions taken as a result of a legal proceeding were to restrain our ability to operate, our financial position, results of operations or cash flows could be materially adversely affected. Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent us from securing insurance coverage in the future. In addition, legal proceedings, and any adverse resolution thereof, can result in adverse publicity and damage to our reputation, which could adversely impact

our business. The amounts we record for legal contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions. While we have accrued for certain potential legal liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts accrued. ~~Additional information regarding certain legal matters in~~ **We must navigate complex healthcare regulations,** which **control how we conduct our business and how** we are **paid** ~~involved can be found in Note 15 to our Consolidated Financial Statements in Part II, Item 8. Healthcare reform laws, including the ACA, and the Protecting Access to Medicare Act of 2014 (" PAMA "), are significantly affecting the U. S. healthcare and medical services industry~~ . Existing legislation, and possible future legal and regulatory changes, including potential repeal or modification of the ACA ~~, elimination of penalties regarding the individual mandate for coverage, or approval of health plans that allow lower levels of coverage for preventive services~~ , could materially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs and devices, including our current and future products and services. The ACA has also been the subject of various legal challenges and if the plaintiffs in any case challenging the ACA are ultimately successful insurance coverage for our tests could be materially and adversely affected. Any change in reimbursement policy could result in a change in patient cost- sharing, which could adversely affect a provider' s willingness to prescribe and patient' s willingness and ability to use our tests and any other product or service we may develop. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payers from covering certain kinds of medical products and services, particularly newly developed technologies, like those we have developed in the past or we may develop in the future. We cannot predict whether future healthcare reform initiatives will be implemented at the federal or state level or the effect any such future legislation or regulation will have on us. The taxes imposed by new legislation, cost reduction measures and the expansion in the government' s role in the U. S. healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations. **The Protecting Access to Medicare Act of 2014 (" PAMA ")** presents significant uncertainty for future CMS reimbursement rates. Because Medicare currently covers a significant number of our patients, any reduction in the CMS reimbursement rate for our tests would negatively affect our revenues and our business prospects. Under PAMA, CMS reimbursement rates for clinical diagnostic laboratory tests are updated every three years or annually for clinical laboratory tests that are considered " advanced diagnostic laboratory tests. " There can be no assurance under PAMA that adequate CMS reimbursement rates will continue to be assigned to our tests. Congress could modify or repeal PAMA in the future or CMS could modify regulations under PAMA, and any such action could have the effect of reducing the CMS reimbursement rate for our tests. Further, it is possible that Medicare or other federal payers that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co- payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues. Coverage of our Cologuard test and other screening **or diagnostic** products that we may develop may also depend, in whole or in part, on whether payers determine, or courts and / **or legislative** or regulatory authorities determine, coverage is required under applicable federal or state laws mandating coverage of certain cancer screening **or diagnostic** services. For example, while we believe the ACA Mandate requires most health insurers to cover our Cologuard test for most patients between the ages of 45 and 75 without patient cost-sharing, some health insurers have disagreed and determined not to cover our Cologuard test and others may take that position in the future. Further, ~~if the ACA is repealed, replaced or overturned, or even if it is not,~~ states may decide to modify their laws, which may include repeal of those coverage mandates that we believe currently apply to our Cologuard test. **Our commercial success** ~~Outside of the U. S., we largely depend~~ **depends , in large part,** on ~~public or government- controlled or regulated payers for coverage of our Oncotype tests. In order to accommodate~~ the **availability** ~~unique characteristics~~ of ~~our Oncotype tests, public payers in certain non- U. S. markets have designed~~ reimbursement ~~frameworks specifically for our tests. These payers could decide to modify or discontinue these special frameworks, potentially leading to lower reimbursement prices or the impossibility of providing the test in the market. Existing reimbursement processes or changes to those processes could impose additional administrative burdens on us, such as complex public tendering procedures, or on ordering physicians, which could adversely affect the number of payers covering the test or the number of orders placed. Public payers could condition reimbursement of our tests upon performance of our tests locally or, even in laboratories owned or operated by the payers. Any such change would adversely affect our ability to continue to serve those patients through our centralized labs in the U. S. If payers, including managed care organizations, do not approve and maintain reimbursement for our tests~~ at adequate reimbursement rates ~~, our commercial success could be compromised. Our commercial success depends, in large part, on the availability of adequate reimbursement~~ for our current tests, including our flagship Cologuard and Oncotype tests and our products in development, from government insurance plans, managed care organizations and ~~private~~ **commercial** insurance plans. Although we received a positive coverage decision and what we believe is an adequate reimbursement rate from CMS for our Cologuard test, it is also critical that other third- party payers approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates. We also have received positive coverage determinations for our Oncotype DX breast cancer test for N-, ER patients from most third- party payers, but have less favorable coverage for our other Oncotype tests **. Additionally, successful commercialization of our newly developed products will also depend on our ability to obtain and maintain reimbursement from government insurance plans, managed care organizations, and commercial insurance plans at adequate reimbursement rates** . Healthcare providers may be reluctant to prescribe, and patients may be reluctant to complete, our tests if they are not confident that patients will be reimbursed for our tests. Third- party payers, both in the ~~United States~~ **U. S.** and internationally, are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for healthcare products and services. As a result, there is uncertainty surrounding the future level of reimbursement, if any, for our current tests and any new tests we may develop. Reimbursement by a third- party payer may depend on a number of factors, including a payer' s determination that tests using our technologies are ~~:~~ sufficiently sensitive and specific; not experimental or investigational; approved or recommended by the major guideline organizations; subject to

applicable federal or state coverage mandates; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost- effective. Moreover, coverage determinations and reimbursement rates are subject to change, and we cannot guarantee that even if we initially achieve adequate coverage and reimbursement rates for our tests, they will continue to apply in the future or remain adequate as we face increases in operating costs, such as labor and supply costs that are subject to inflation ~~. As noted above~~ , **and government and** ~~under PAMA, our Medicare reimbursement rates will be subject to adjustment based on our volume- weighted median~~ commercial **payers may cause us to accept lower prices** ~~reimbursement rate. Any reduction in our Medicare reimbursement rates could significantly and adversely affect our business prospects, financial condition, and results of operations~~ . Even where a third- party payer agrees to cover one of our tests, other factors may have a significant impact on the actual reimbursement we receive from that payer. For example, if we do not have a contract with a given payer, we may be deemed an " out- of- network " provider by that payer, which could result in the payer allocating a portion of the cost of the test to the patient, notwithstanding any applicable coverage mandate. We may be unsuccessful in our efforts to enter into, or maintain, a network contract with a given payer, and we expect that our network status with a given payer may change from time to time for a variety of reasons, many of which may be outside our control. To the extent one of our tests is out of network for a given payer, healthcare providers may be less likely to prescribe that test for their patients and their patients may be less likely to comply with those prescriptions that are written. Also, some payers may **mandate** ~~require that they give~~ prior authorization ~~for~~ **or** ~~a test before they are willing to pay for it or review claims post- service to ensure the service was medically appropriate for specific patients. Prior authorization and~~ other medical management practices ~~may require~~ that ~~we, patients, or healthcare providers provide the payer with extensive medical records and other information. Prior authorization and other medical management practices~~ impose ~~a~~ significant additional ~~cost~~ **costs** on us, may be difficult to comply with given our position as a laboratory that generally does not have direct access to patient medical records, may make healthcare providers less likely to prescribe our tests for their patients, and may make patients less likely to comply with healthcare provider orders for our tests, all or any of which may have an adverse effect on our revenues. Under Medicare billing rules, payment for..... to expand internationally will be compromised. The majority of our international Oncotype DX breast and colon cancer test revenues come from payer reimbursement, **including from public or government- controlled or regulated payers,** payments from our distributors, and patient self- pay. ~~In many countries~~ **Obtaining reimbursement from public payers** outside of the U. S. **generally involves complex requirements that we may** ~~, various coverage, pricing and reimbursement approvals are required for our tests to~~ be ~~available~~ **unable** to **satisfy** ~~patients in significant volume. We expect that it will take several years to establish broad coverage and reimbursement for our tests with payers in countries outside of the U. S., and our efforts may not be successful~~ . Even if public or private reimbursement is obtained, it may **be discontinued,** cover competing tests, or the reimbursement may be limited to a subset of the eligible patient population or conditioned upon local performance of the tests or other requirements we may have difficulty satisfying. Reimbursement levels outside of the U. S. may vary considerably from the domestic reimbursement amounts we receive. In addition, because we generally rely on distributors to obtain reimbursement for our tests in certain countries outside of the U. S., to the extent we do not have direct reimbursement arrangements with payers, we may not be able to retain reimbursement coverage in those countries if our agreement with a distributor is terminated or expires, if a distributor fails to pay us or if other events prevent payment. We ~~may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union and elsewhere. We and certain laboratories with whom we collaborate~~ are subject to **CLIA, a** federal ~~and state laws~~ **law** ~~and~~ **that** ~~regulations~~ **regulates** ~~regarding the operation of~~ clinical laboratories **that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease** . ~~Federal~~ CLIA ~~requirements~~ **regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance** and ~~laws of certain~~ **inspections. Any testing subject to CLIA regulation must be performed in a CLIA certified laboratory. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial payers, for our tests. In addition, some** states, including **California and** New York, ~~impose certification~~ **require that we hold licenses or permits to test samples from patients in those states, even if our laboratory facilities are not located in those states, and as a result we are also required to maintain standards related to those states' licensure** requirements ~~for clinical~~ **to conduct testing in our** laboratories ~~and establish standards for quality assurance and quality control, among other things~~ . **Failure** ~~Some state laws restrict laboratory marketing activities, which may adversely affect our ability to market our laboratory services. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing~~ to comply with applicable **clinical laboratory licensure** requirements ~~.~~ **may result in a range of enforcement** ~~Sanctions~~ -- **actions** ~~available under~~ **, including suspension, limitation or revocation of our** CLIA ~~include prohibiting~~ **certification and / or state licenses, imposition of** a **directed** ~~laboratory from running tests, requiring a laboratory to implement a corrective~~ plan **of action** , ~~and imposing~~ **on- site monitoring,** civil monetary penalties **, criminal sanctions, inability** ~~. If we or our third party partners fail~~ to ~~meet any applicable requirements of~~ **receive reimbursement from Medicare, Medicaid and commercial payers, as well as significant adverse publicity. Any sanction imposed under** CLIA **, its implementing regulations,** or state **or foreign** ~~law~~ **laws** ~~, that~~ **or regulations governing clinical laboratory licensure or our** failure **to renew our CLIA certification, a state or foreign license or accreditation,** could **have a material** ~~adversely~~ -- **adverse** ~~affect~~ **effect on** ~~any payer consideration of our current or our business~~ ~~future technologies~~ , **financial condition** ~~prevent their approval entirely,~~ and ~~/~~ **results of operations. Even if we were able to bring** ~~or~~ **our laboratory back into compliance, we could** ~~interrupt the commercial sale and / or marketing of any products and services and otherwise cause us to~~ incur significant ~~expense~~ **expenses and potentially lose revenue in doing so** . ~~As a condition~~ **We may also be subject to laboratory regulations in foreign jurisdictions as we seek to expand international utilization** of ~~the FDA approval of~~ our ~~Cologuard test~~ **tests or as such jurisdictions adopt new licensure requirements** , ~~we were~~ **which may** ~~required~~ - **require review of our tests in order** to ~~conduct a~~ **offer them or may have**

other limitations such as restrictions on the transport of specimens necessary for us to perform our tests that may limit our ability to make our tests available outside of the U. S. Complying with licensure requirements in new jurisdictions may be expensive, time- consuming and subject us to significant and unanticipated delays. Manufacturers of medical devices must comply with various regulatory requirements under the FDCA and regulations thereunder, including, but not limited to, quality system regulations, unless they are exempt, facility registration, product listing, labeling requirements, and certain post- **market surveillance** ~~approval study. The post- approval study concluded in 2020 and final results were submitted to FDA in late 2020. There is a risk that the FDA may modify or withdraw the approval of our Cologuard test if the results of this post- approval study are not satisfactory. We anticipate feedback from FDA in 2023 on the acceptance of these data to close the post- approval order. Our manufacturing and laboratory facilities are periodically subject to inspection by the FDA and other governmental agencies to ensure they meet production and quality~~ requirements ~~. Operations at these facilities could be interrupted or halted if the FDA or other governmental agency deems the findings of such inspections unsatisfactory. Further, failure to comply with FDA or other regulatory requirements regarding the development, marketing, promotion, manufacturing and distribution of our tests could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, restrictions on labeling and promotion, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution~~ . If we do not meet applicable regulatory or quality standards, our products may be subject to recall, and, under certain circumstances, we may be required to notify applicable regulatory authorities about a recall. In 2017, we recalled one of the components of our Cologuard test kit and circumstances may arise that cause us to recall other products or components used in connection with our Cologuard test. Any such recalls could have an adverse effect on our ability to provide the Cologuard test, which in turn would adversely affect our financial condition. ~~Delays in obtaining regulatory clearances or approvals for new medical devices, or improvements to or expanded indications for our current offerings, could prevent, delay or adversely impact future product commercialization. Although the FDA has historically exercised enforcement discretion with regard to certain types of tests — commonly referred to as laboratory developed tests or LDTs — that are developed by laboratories certified pursuant to federal Clinical Laboratory Improvement Amendments, we may develop new tests that are regulated by the FDA as medical devices.~~ Unless otherwise exempted **or subject to enforcement discretion** , medical devices **, which include screening and diagnostic tests,** must receive either FDA regulatory approval or clearance before being marketed in the U. S **. Our Cologuard test is regulated by the FDA as a medical device and we may develop new tests that are deemed medical devices and require FDA clearance or approval** . The FDA determines whether a medical device will require either regulatory approval or clearance based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. The process to obtain either regulatory approval or clearance will likely be costly, time- consuming, and uncertain. **The** ~~However, we believe the~~ regulatory approval process is generally more challenging than the clearance process. Even if we design a product that we expect to be eligible for the regulatory clearance process, the FDA may require that the product undergo the regulatory approval process. There can be no assurance that the FDA will ever permit us to market any new product that we develop. Even if regulatory approval or clearance is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new medical device. FDA regulatory approval or clearance is ~~not just required for new medical devices we develop, but would~~ also ~~be~~ required for certain enhancements we may ~~seek to~~ make to our Cologuard test or future FDA- approved or- cleared tests. For example, **our next generation Cologuard test will require** FDA approval **before it can be marketed and we are in the process of seeking that approval. FDA approval** or clearance may **also** be required to make changes to the processes, equipment, reagents, and other consumables used in connection with a test. The FDA **’** ~~’~~ s **approval** pathway ~~to approve or clear changes to tests~~ can be time- consuming and costly and **there can be no assurance that** the FDA ~~rely~~ **will ultimately approve any premarket approval submitted by us in a timely manner or at all.In addition** , ~~which could negatively impact our business.The ability of~~ the FDA **’ s ability** to review and clear or approve new products or changes to existing products can be affected by a variety of factors,including government budget and funding levels,statutory,regulatory,and policy changes,the FDA’ s ability to hire and retain key personnel and accept the payment of user fees, ~~federal government shutdowns,~~ and other events that may otherwise affect the FDA’ s ability to perform routine functions.Average review times at the agency have fluctuated in recent years as a result. ~~If a~~ **In addition,** prolonged government ~~shutdown~~ **shutdowns** ~~occurs,~~ or ~~if~~ global health concerns **may** ~~continue to~~ prevent or delay the FDA or other regulatory authorities from conducting,at all or in a timely manner,their regular inspections,reviews,or other regulatory activities (including pre- submission engagements) ~~,it could significantly impact~~ **.Any such delay in** the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions ~~,which could have~~ could ~~ultimately reject~~ **have a material adverse effect on** our **business** ~~proposed changes~~ . Delays in receipt of, or failure to obtain, clearances or approvals could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA clearance or approval for a new or enhanced product, the FDA may condition, withdraw, or materially modify its clearance or approval. **The** ~~If the~~ FDA **may** ~~were to~~ change its position with respect to its regulation of the laboratory developed tests we offer or may seek to offer in the future, ~~we could~~ **causing us to** incur substantial costs and time delays associated with meeting requirements for pre- market clearance or approval or we could experience decreased demand for or reimbursement of our tests. **Our Oncotype tests, OncoExTra test, and certain other tests we offer are regulated as LDTs and we may seek to commercialize certain of our products in development as LDTs. LDTs are clinical laboratory tests that are developed and validated by a laboratory for its own use.** The FDA **historically** has **taken** ~~regulatory responsibility over, among other~~ -- **the position** ~~areas, instruments, test kits, reagents, and other medical devices used by clinical laboratories to perform diagnostic testing. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, frequently develop internal LDTs to provide diagnostic results to customers. LDTs are subject~~

~~to CMS oversight through its enforcement of CLIA. The FDA has also claimed regulatory authority over all LDTs, but indicates~~ that it has **the authority to regulate such tests as medical devices under the FDC Act but has for the most part** exercised enforcement discretion ~~with regard to most LDTs offered by CLIA- certified laboratories,~~ and has not **required clearance, de novo classification,** ~~subjected these tests to the panoply of FDA rules and regulations governing medical devices. IVDs like our -~~ **or approval of** ~~Cologuard test are regulated as medical devices by the FDA. We believe that our Oncotype tests are not diagnostic kits and also believe that they are~~ LDTs **prior** ~~that are subject~~ to **marketing** ~~regulation under CLIA and applicable state laws. As a result, we believe our Oncotype products fall within the scope of FDA' s exercise of enforcement discretion and should not be subject to FDA oversight or review under current FDA guidelines. Packaging requirements for receipt of tumor tissue for our Oncotype products may be subject to regulation under Department of Transportation, International Air Transport Association, and other state, regional, or local laws~~ . At various times since 2006, the FDA has issued documents outlining its intent to require varying levels of FDA oversight of many LDTs, including our tests. **In October 2023, the FDA announced a proposed rule seeking to regulate LDTs as medical devices under the FDCA. The comment period for the FDA' s proposed rule closed in December 2023 and the FDA has indicated its desire to issue a final rule on LDTs in April 2024 or shortly thereafter. Even if FDA does not finalize its proposed rule, the U. S. Congress may enact statutory changes that could alter or eliminate FDA' s current LDT enforcement policy.** It is **therefore** unclear ~~whether the~~ **at this time what form that final regulation may take, or if** FDA will **finalize the** ~~proceed with rulemaking to regulate~~ **regulation at all** ~~LDTs in the future. In addition, legislative proposals addressing oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time to time in the future~~ . It is ~~possible~~ **also unclear** ~~that~~ **what** ~~legislation will~~ **additional obligations might** be ~~enacted~~ **placed on us as we continue to offer LDTs in light of FDA' s renewed interest in greater oversight** into ~~law~~ **this class of tests and the potential** ~~or~~ **for** ~~guidance could be issued~~ **legislative changes. Action** by the FDA ~~which may result in increased regulatory burdens for -~~ **or** ~~us~~ **Congress** to ~~continue to offer~~ **phase out the FDA' s current policy of enforcement discretion over LDTs may materially impact our development and commercialization of LDTs, including** our Oncotype tests ~~or to develop and introduce new LDTs~~ . If pre- market review is required for our current LDTs, ~~our business could be negatively impacted in the U. S. until such review is completed and clearance or approval is obtained, and~~ the FDA could require that we stop selling our tests pending pre- market clearance or approval **and** ~~. If~~ our **business could be negatively impacted in** ~~Oncotype tests are allowed to remain on the market but there --~~ **the U. S. until such review** is **completed and clearance** ~~uncertainty about the regulatory status of such tests, if they are labeled investigational by the FDA,~~ or **approval is obtained** ~~if labeling claims the FDA allows us to make are more limited than the claims we currently make, orders or reimbursement may decline~~ . The regulatory approval process may involve, among other things, successfully completing additional clinical studies and submitting a pre- market clearance notice or filing a pre- market approval application with the FDA. Such pre- market clinical testing could delay the commencement or completion of other clinical testing, significantly increase our test development costs, delay commercialization of any future LDTs, and interrupt sales of our current LDTs. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval. If pre- market review is required by the FDA, there can be no assurance that our LDTs will be cleared or approved on a timely basis, if at all, nor can there be assurance that the labeling claims cleared or approved by the FDA will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our LDTs. ~~Ongoing compliance with~~ **If our Oncotype 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 the** FDA **,** ~~regulations with respect to our -~~ **or if labeling claims** ~~current LDTs would increase~~ the **FDA allows** ~~cost of conducting our business, and subject~~ us to ~~inspection by and the regulatory requirements of the FDA, for example registration and listing and medical device reporting, and penalties in the event we fail to comply with these requirements. We may also decide voluntarily to pursue FDA pre- market --~~ **make** ~~review of~~ **are more limited than the claims we currently make, orders** ~~our -~~ **or reimbursement** ~~LDTs if we determine that doing so would be appropriate. We cannot predict the ultimate timing or form of final FDA guidance, legislation or regulation of LDTs and the potential impact on our existing tests, our tests in development or the materials used to perform our tests. While we qualify all materials used in our LDTs according to CLIA regulations, we cannot be certain that the FDA will not enact rules or guidance documents that could impact our ability to purchase certain materials necessary for the performance of our LDTs, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used 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. Changes in funding or disruptions at FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to perform normal business functions on which the operation of our business~~ may **decline** rely, which could negatively impact our..... a material adverse effect on our business . We are subject to regulation in the ~~United States~~ **U. S.** by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the ~~United States~~ **U. S.** , including: • Federal, state, and local laws regarding the use, storage, handling and disposal of medical and hazardous waste, as well as regulations relating to the safety and health of laboratory employees; • the Federal Anti- Kickback Statute and state anti- kickback prohibitions and EKRA; • the Federal Physician Self- Referral Law, commonly known as the Stark Law, and the state equivalents; • the HIPAA ~~and ,~~ the CCPA **,** including expansions and amendments pursuant to the California Privacy Rights Act **, and other state privacy laws; • Federal, state, and local consumer protection laws governing communications, including the Telephone Consumer Protection Act (" TCPA ") and the Controlling the Assault of Non- Solicited Pornography and Marketing Act (" CAN- SPAM Act ")** ; • the Medicare civil money penalty and exclusion requirements; • the Federal False Claims Act civil and criminal penalties and state equivalents; and • the FCPA, the United Kingdom Anti- Bribery Act, the GDPR and other national or provincial laws protecting personal information, the E. U. Medical Device and In Vitro Diagnostic

Device Regulations, and national laws restricting industry interaction with healthcare professionals, all of which may or will apply to our international activities **. We have adopted policies and procedures designed to comply with these laws. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the U. S. may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations** . The U. S. Attorney' s Offices have increased their scrutiny over the healthcare industry in recent years. The U. S. Congress, **U. S. Department of Justice (" DOJ ")** , Office of Inspector General of the Department of Health and Human Services, and Department of Defense have all issued subpoenas and other requests for information to conduct investigations of **,** and commenced **,** civil and criminal litigation against healthcare companies related to financial arrangements with healthcare providers, regulatory compliance, product promotional practices, and documentation, coding and billing practices. In addition, the Federal False Claims Act and state equivalents have led to whistleblowers filing numerous qui tam civil lawsuits against healthcare companies, in part, because a whistleblower can receive a portion of any amount obtained by the government through such a lawsuit. 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, **qui tam litigation or** governmental enforcement action may result in substantial **damages (including treble damages),** fines, **civil and criminal** penalties **, payment of attorney' s fees** 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. As described further in Note 15 of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10- K, **in September 2023,** we ~~are currently responding~~ **entered into settlement agreements with the United States, acting through the U. S. DOJ, with respect** to (1) a civil investigative demand initiated by the U. S. DOJ concerning Genomic Health **, Inc.** ' s **(" Genomic Health ")** compliance with the Medicare **Laboratory** Date of Service billing regulations **prior to our acquisition of Genomic Health in 2019** and (2) **a** qui tam **lawsuit alleging** ~~civil investigation related to allegations that we offered or gave gift cards to patients in exchange for returning the Cologuard screening test, in violation~~ **violations** of the Federal Anti-Kickback Statute and False Claims Act **for offering gift cards to patients in exchange for returning the Cologuard screening test, for which Niles Rosen M** . **D., the petitioner in the qui tam lawsuit, was also a party to the settlement agreement. The settlement agreement between Genomic Health and the U. S. DOJ required us to pay $ 32. 5 million, which was paid in September 2023 and the settlement agreement with the U. S. DOJ and Dr. Rosen required us to pay $ 13. 8 million plus legal fees, which was paid in October 2023. Any such actions or litigation in the future could result in** ~~Adverse~~ **adverse penalties or** outcomes ~~from these investigations could include our being required to pay treble damages, incur civil and criminal penalties, paying attorney' s fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions~~ that could materially and adversely affect our business, financial condition and results of operations. **Our business is subject** ~~We have adopted policies and procedures designed~~ to **various** ~~comply~~ **complex** ~~with these~~ laws ~~. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws~~ and regulations ~~is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any~~ applicable ~~penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required~~ to **providers** ~~refund payments received by us, and we could lose the ability to bill for our tests, we could be prohibited from participating in public procurement, and we could be required to curtail or cease our operations. Any~~ of **clinical diagnostic products** ~~the foregoing consequences could seriously harm our business~~ and **services** ~~our financial results~~ . As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state, local and foreign laws and regulations governing various aspects of our business. In particular, the clinical laboratory and healthcare industry is subject to significant governmental certification and licensing regulations, as well as federal, state and foreign laws regarding: • test ordering and billing practices; • marketing, sales and pricing practices; • health information privacy and security, including HIPAA and comparable state and foreign laws; • insurance, including foreign public reimbursement; • anti- markup legislation; and • consumer protection. We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the Federal Trade Commission, or FTC, and advertising of laboratory services is regulated by certain state laws. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC or state law requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for **medical** devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. In particular, the entry into application of the E. U.' s In Vitro Diagnostic Device Regulation will impose new requirements and create new compliance risks. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA, FTC and state regulation. We incur various costs in complying and overseeing compliance with these laws and regulations. The growth of our business and sales organization, the acquisition of additional businesses or products and services

and our expansion outside of the U. S. may increase the potential of violating these laws, regulations or our internal policies and procedures. Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments , and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests and planned development of products in our pipeline has been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations. If we , or our partners ~~, including our German laboratory partner~~ , fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, any such partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business. ~~Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the tests we perform, and delays in submitting claims could have an adverse effect on our revenue.~~ Billing for diagnostic and laboratory services is a complex process. ~~Laboratories~~ **We** bill many different payers including patients, private insurance companies, Medicare, Medicaid, and employer groups, all of which have different billing requirements. We are continuing to work with third- party payers to cover and reimburse our tests. If we are unsuccessful, we may not receive payment for the tests we perform for patients on a timely basis, if at all, and we may not be able to provide services for patients with certain healthcare plans. ~~In the past, failures to submit claims to insurers timely have required us to record downward adjustments to our revenue. Despite efforts to improve our billing systems and prevent recurrences of these failures, future failures to timely submit claims could result in further downward adjustments to revenue. We may have to litigate to enforce coverage obligations under Medicare laws and laws that mandate coverage for certain screening or diagnostic tests or to enforce contractual coverage obligations. Such litigation may be costly, may divert management attention from other responsibilities, may cause payers, including those not directly involved in the litigation, to resist contracting with us, and may ultimately prove unsuccessful for a variety of reasons. We may face lawsuits by government or commercial payers if they believe they have overpaid us for our test services or as a result of other circumstances. We may face write- offs of doubtful accounts, disputes with payers and patients, and long collection cycles.~~ We may face patient dissatisfaction, complaints or lawsuits, including to the extent our tests are not fully covered by insurers and patients become responsible for all or part of the price of the test. As a result, patient demand for our tests could be adversely affected. To the extent patients express dissatisfaction with our billing practices to their healthcare providers, those healthcare providers may be less likely to prescribe our tests for other patients, and our business would be adversely affected. Even if payers ~~do~~ agree to cover our tests, our billing and collections process may be complicated by the following and other factors, which may be beyond our control: **• complex and disparate reimbursement rules and requirements;** • disputes among payers as to which payer is responsible for payment; • disparity in coverage among various payers or among various healthcare plans offered by a single payer; • payer medical management requirements, including prior authorization requirements; • differing information and billing requirements among payers; • failure by patients or healthcare providers to provide complete and correct billing information; and • limitations and requirement for patient billing, including those related to deductibles, co- payments, and co- insurance originating from contracts with commercial payers. ~~Sometimes~~ **For example** ~~Under these circumstances~~ , ~~where~~ **pursuant to certain CMS rules (** the **" Medicare Laboratory** ~~date~~ **Date** of ~~service~~ **Service billing regulation "),subject to certain exceptions issued by CMS,we cannot bill Medicare directly for some tests provided** for Medicare **beneficiaries in some situations involving certain hospital patients** ~~billing purposes is the date the specimen was collected~~ and **instead must** ~~such date is within 14 days of inpatient discharge,we are required to~~ bill hospitals for such tests. **In these circumstances** ~~We refer to this rule~~ , **only** ~~as it has been in effect and most recently amended as of January 1,2018,as~~ the **hospital may bill** Medicare **for such tests** ~~Date of Service billing regulation~~ .These billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our tests,and could discourage providers from ordering our tests for Medicare patients or even non-Medicare patients.In addition,changes in Medicare billing rules and processes could result in delays in receiving payments or receiving payments that are less than the original invoice.When hospitals disclaim responsibility for or delay payment of our bills for tests affected by the Medicare **Laboratory** Date of Service ~~rule~~ **billing regulation** ,and when our collection efforts are unsuccessful,we may be forced to accept payments from hospitals that are less than the original invoice or we may be unable to collect from hospitals at all **despite diligent efforts** . **Similarly** ~~Our inability to successfully~~ , when we have a contract with a commercial payer to cover our tests, we are not permitted to bill patients insured by that payer for amounts beyond deductibles, co- payments, and co- insurance as prescribed in the coverage agreement between the payer and the patients. Therefore, when such contracted payers do not pay us our full, contracted rate for a test, for example, for failure to satisfy prior- authorization or other payer medical management requirements, we may not be permitted to collect the balance from the patient and our business is adversely impacted. ~~The uncertainty~~ **In the past, failures to submit claims to insurers timely have required us to record downward adjustments to our revenue. Despite efforts to improve our billing systems and prevent recurrences** of ~~receiving payment~~ **these failures, future failures to timely submit claims could result in further downward adjustments to revenue. As a result of the above, we may face write- offs of doubtful accounts, disputes with payers and patients, and long collection cycles. We also may face lawsuits by government or commercial payers if they believe they have overpaid us** for our ~~tests~~ **test** ~~and complex laboratory~~ **services or as a result of other circumstances. For example, as described in Note 15 of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10- K, in September 2023, Genomic Health, entered into a settlement agreement with the United States, acting through the U. S. DOJ, to resolve a civil investigation concerning Genomic Health' s compliance with the Medicare Date of Service** billing **regulation prior to** ~~processes could negatively affect~~ our ~~business and our operating results~~ **acquisition of Genomic Health in 2019. This settlement agreement required us to pay $ 32. 5 million, which was paid in October, 2023** . Some of our activities may subject us to risks under federal and state laws prohibiting " kickbacks " and false or fraudulent claims. In addition to FDA marketing and promotion restrictions, several other types of state and federal healthcare fraud and abuse laws have been

applied in recent years to restrict certain marketing practices in the healthcare product and service industry and to regulate billing practices and financial relationships with healthcare providers, hospitals and other healthcare providers. These laws include a federal law commonly known as the Medicare / Medicaid anti- kickback law, and several similar state laws, which prohibit payments intended to induce healthcare providers or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices and providers of laboratory services by limiting the kinds of financial arrangements, including sales programs, that may be used with hospitals, healthcare providers, laboratories and other potential purchasers or prescribers of medical devices and laboratory services. ~~Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payers that are false or fraudulent, or are for items or services that were not provided as claimed.~~ In **addition, the Eliminating Kickbacks in Recovery Act of** 2018 ~~, Congress passed EKRA as part of the Substance Use- Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Similar to the Medicare / Medicaid anti- kickback law, EKRA~~ imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) unless a specific exception applies. ~~However~~ **Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment** , ~~unlike~~ the **language in** ~~Medicare / Medicaid anti- kickback law,~~ EKRA is ~~not limited~~ **broadly written and can apply** to **laboratory** services covered ~~by federal~~ **under public** or ~~state healthcare programs~~ **private payer arrangements. EKRA permits the DOJ to issue regulations clarifying EKRA' s exceptions or adding additional exceptions,** but **it has not done so** ~~applies more broadly to services covered by " healthcare benefit programs, " including commercial insurers~~ . As ~~currently drafted, EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. In addition, while the Medicare / Medicaid anti- kickback law includes certain exceptions that are widely relied upon in the healthcare industry, not all of those same exceptions apply under EKRA. Because EKRA is~~ a **result** ~~relatively new law~~ , there is no agency guidance and limited court precedent to indicate how **,** and to what extent **,** it will be applied and enforced. We cannot assure you that our relationships with healthcare providers, sales representatives, hospitals, customers, or any other party will not be subject to scrutiny or will survive regulatory challenge under EKRA **. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payers that are false or fraudulent, or are for items or services that were not provided as claimed** . Additionally, to avoid liability under federal false claims laws, we must carefully and accurately code claims for reimbursement, proactively monitor the accuracy and appropriateness of Medicare claims and payments received, diligently investigate any credible information indicating that we may have received an overpayment, and promptly return any overpayments. Medicare payments are subject to audit, including through the Comprehensive Error Rate Testing (" CERT ") program, and payments may be recouped by CMS if it is determined that they were improperly made. Currently, a significant percentage of our revenues are generated by payments from Medicare. The federal anti- kickback statute and certain false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing and billing practices are constantly evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. Our failure to comply with applicable laws could result in various adverse consequences that could have a material adverse effect upon our business, including the exclusion of our products and services from government programs and the imposition of civil or criminal sanctions. Some of our activities may subject us to risks under ~~foreign laws prohibiting " kickbacks " as well as~~ the Foreign Corrupt Practices Act **and similar anti- bribery laws in non- U. S. jurisdictions** . Many countries in which we **or our distributors** offer our tests have regulations prohibiting providers, as well as medical and in vitro diagnostic device manufacturers, from offering or providing a benefit to a healthcare professional in order to induce business. In situations involving healthcare providers employed by public or state- funded institutions or national healthcare services, violation of local anti- corruption or anti- gift laws may also constitute a violation of the ~~U. S.~~ FCPA. The FCPA prohibits any U. S. individual, business entity or employee of a U. S. business entity from offering or providing, directly or through a third party, including the distributors we rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws ~~. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls~~ . We are also required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its anti- bribery provisions. Other countries, including the U. K. and other Organisation for Economic Co- operation and Development (" OECD ") Anti- Bribery Convention members, have similar extraterritorial anti- corruption laws. Any violation of these laws, or allegations of such violations, **by us or any of our commercial partners** could disrupt our operations, involve significant management distraction, cause us to incur significant costs and expenses, including legal fees, and result in a material adverse effect on our business. We could also suffer severe penalties, including criminal and civil penalties, debarment from public procurement, disgorgement and other remedial measures. **We are subject to a number of foreign, federal and state laws and regulations protecting the use, disclosure, and confidentiality of certain patient health and personal information, including patient records, and restricting the use and disclosure of that protected information, including state breach notification laws, the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, the European Union' s General Data Protection Regulation,**

the U. K. Data Protection Act and the U. K. GDPR, and the California Consumer Privacy Act, among others. HIPAA extensively regulates the use and disclosure of individually identifiable health information, known as " protected health information, " and require covered entities, including health plans and most health care providers, to implement administrative, physical and technical safeguards to protect the security of such information. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay and notification must also be made to the U. S. Department of Health & Human Services, Office for Civil Rights (the " OCR ") and, in certain situations involving large breaches, to the media. Various U. S. state laws and regulations may also require us to notify affected individuals and state agencies in the event of a data breach involving individually identifiable information. Violations of the HIPAA privacy and security regulations may result in criminal and civil penalties. The OCR enforces the regulations and performs ~~Compliance~~ **compliance audits. In addition to enforcement by OCR, state attorneys general are authorized to bring civil actions seeking either injunction or damages in response to violations that threaten the privacy of state residents. We follow and maintain a HIPAA compliance program, which we believe complies** with **the HIPAA** privacy ~~laws~~ and **security** regulations ~~may increase~~ **, but there can be no assurance that OCR** ~~our~~ **or** ~~costs~~ **other regulators will agree** . The HIPAA privacy ~~,~~ **regulations and** security ~~and breach notification~~ regulations **have** ~~, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses~~ and **will continue** ~~disclosures of protected health information (" PHI ") by health plans, healthcare providers and healthcare clearinghouses, in addition~~ to **impose significant costs** ~~setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework~~ on ~~a variety of subjects, including: • the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities; • a patient' s rights to access, amend and receive an accounting of certain disclosures of PHI; • requirements to notify individuals if there is a breach of their PHI; • the contents of notices of privacy practices for PHI; • administrative, technical and physical safeguards required of entities that use~~ **us in order** ~~or receive PHI; and • the protection of computing systems maintaining electronic PHI. We have implemented practices intended to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law. We are required~~ to comply with **these standards. We also remain subject to** ~~federal privacy, security and breach notification regulations as well as varying~~ state privacy **- related** ~~, security and breach notification~~ laws ~~and regulations~~ , ~~which may be~~ **such as the CCPA, that are** more ~~stringent~~ **restrictive** than ~~federal HIPAA requirements. In addition, for healthcare data transfers from other~~ -- **the** ~~countries relating to citizens of those countries, we must comply with the laws of those countries. The federal~~ privacy regulations ~~restrict our ability to use~~ **issued under HIPAA. These laws vary and could impose additional penalties. We utilize** ~~or~~ **our** ~~disclose~~ patient **adherence program** ~~identifiable data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the healthcare industry. HIPAA provides for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Computer networks are always vulnerable~~ to **communicate** ~~breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI~~ with ~~third parties~~ - **patients** who are **existing** ~~legally obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third parties' computer networks. Any wrongful use or disclosure of PHI by us or such third parties, including disclosure due to data theft or unauthorized access to our~~ - **or potential users of** ~~or~~ **our** ~~our third parties' computer networks,~~ **products and services for various business purposes. These activities** could subject us to **laws, rules and regulations relating to communications with consumers, such as the CAN- SPAM Act and the TCPA. Despite our compliance efforts, we could face allegations that we have violated these laws, rules and regulations as we have in the past. Even if such allegations are without merit, we could face liability and harm to our reputation. We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U. S. laws, including in particular the laws of Europe. For instance, the GDPR applies across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant** fines ~~or~~ **for non- compliance** ~~penalties that could adversely affect our business and results of operations~~ . ~~Although~~ **The GDPR also requires companies processing personal data of individuals residing in** the ~~HIPAA statute~~ **European Union to comply with EU privacy** and ~~regulations~~ **data protection rules, even if we** do not **have** ~~expressly provide for~~ a ~~private right of damages, we~~ **physical presence in the European Union. Noncompliance** could ~~also incur damages under state~~ **result in the imposition of fines, penalties, or orders to stop noncompliant activities. These** laws **and regulations, in addition** to **similar laws and regulations being enacted by** ~~private parties for the wrongful use or disclosure of confidential health information or~~ other **states** ~~private personal information. Our employees, independent contractors, consultants, commercial partners,~~ and **counties** ~~vendors may engage in misconduct or other improper activities~~ . ~~including~~ **impose stringent cybersecurity standards and potentially significant non-** ~~noncompliance~~ --- **compliance penalties, involve the expenditure of significant resources, the investment of significant resources and the investment of significant time and effort to comply. As these laws and regulations continue develop in the United States and internationally, we may be required to expend significant time and resources in order to update existing processes or implement additional mechanisms as necessary to ensure compliance** with **such cybersecurity laws** ~~regulatory standards and requirements~~ . We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to ~~:~~comply with the rules and regulations of the CMS, FDA, and other comparable foreign regulatory authorities; provide true, complete and accurate information to such regulatory authorities; comply with manufacturing and clinical laboratory standards; comply with healthcare fraud and abuse laws in the

~~United States~~ **U. S.** and similar foreign ~~fraudulent misconduct~~ laws; or report financial information or data accurately or to disclose unauthorized activities to us. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing, and other abusive practices, as well as off- label product promotion. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of participant recruitment for clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We ~~have adopted~~ **maintain a global compliance program, including** a code of business conduct and ethics **and processes and systems for reporting, reviewing and remediating allegations of potential non- compliance or other misconduct** , but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Even if it is later determined after an action is instituted against us that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters. We expect to rely on third parties **,** such as contract research organizations, medical institutions and clinical investigators to conduct studies **of our technologies that may be** ~~, including the post- approval studies~~ required by the FDA ~~for~~ - **or other U. S.** ~~our~~ - **or** ~~Cologuard test~~ **foreign regulatory bodies** . Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. Our reliance on **these** third parties ~~that we do not control~~ will not relieve us of our requirement to prepare, and ensure our compliance with, various procedures required under good clinical practices, even though third- party contract research organizations may prepare and comply with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, **the study data may be invalidated,** and we may not be able to obtain a required regulatory approval. We are subject to ~~increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations. As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to~~ tax in multiple U. S. tax jurisdictions and in foreign tax jurisdictions as we continue to expand internationally. ~~The~~ **As we grow, the** development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in **,** or interpretations of **,** tax rules and regulations in the jurisdictions in which we do business or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are subject to the examination of our tax returns by federal, state and foreign tax authorities, which could focus on our intercompany transfer pricing methodology as well as other matters. If our tax strategies are ineffective or we are not in compliance with domestic and international tax laws, our financial position, operating results and cash flows could be adversely affected. ~~Our business is subject to complex and evolving laws, as well as customer and patient expectations, regarding data privacy, protection and security. The interpretation and application of consumer, health related and data protection laws in the U. S., Europe and elsewhere are often uncertain, contradictory and in flux. In order to mitigate concerns about overseas data transfers and to comply with provisions of the GDPR and its predecessor regulations, we self- certified with the Department of Commerce for compliance with the U. S.- E. U. Privacy Shield. However, the Court of Justice of the European Union invalidated the U. S.- E. U. Privacy Shield program in its July 2020 Schrems II decision. Although we are taking other measures to ensure compliance with the GDPR, the changing legal landscape could cause us to incur substantial costs or change our operations and compliance procedures, all of which may adversely affect our business. If we fail to comply with the GDPR, recently enacted state privacy laws, and other applicable data privacy, protection and security laws, or if we fail to satisfy customer or patient concerns or customer contractual requirements regarding data handling, we could be subject to class action litigation, government injunctions, or other enforcement actions including a prohibition on processing patient data at our centralized laboratories in the U. S. or sites outside the U. S., as well as private litigation, civil, administrative, or criminal penalties, reduced orders, loss of national markets, and adverse publicity. We are subject to changing rules and regulations promulgated by a number of governmental and self- regulatory organizations, including the SEC and Nasdaq, as well as evolving investor expectations around corporate governance and environmental and social practices and disclosures. These rules and regulations continue to evolve in scope and complexity, and many new requirements have been created in response to laws enacted by the U. S. and foreign governments, making compliance more difficult and uncertain. The increase in costs to comply with such evolving expectations, rules and regulations, as well as any risk of noncompliance, could adversely impact us.~~ Risks Relating to Product Development, Commercialization, and Sales of our Products **The success** ~~To grow our business as planned, we must continue to enhance our sales, marketing and customer support capabilities, which will involve developing and administering our commercial infrastructure and / or collaborative commercial arrangements and partnerships. We must also maintain satisfactory arrangements for the manufacture and distribution~~ of ~~our tests and operate CLIA- certified lab facilities to process our tests and provide patient results. Since 2019, when we had a single commercialized product,~~ our Cologuard test, ~~we have significantly expanded our operations and product offerings both organically and through acquisitions, and we have limited experience managing a sales force, customer support operation and operating manufacturing and clinical laboratory operations for multiple products in multiple locations with divergent regulatory requirements. We may encounter difficulties retaining and managing the specialized workforce these activities require. We may~~

~~seek to partner with others to assist us with any or~~ **our Precision Oncology** ~~all of these functions. For example, we rely on a third- party partner to operate our German laboratory that is expected to perform a portion of our international tests. However, we may be unable to find appropriate third parties with whom to enter into these arrangements or maintain successful relationships with third parties once established. To achieve commercial success for our current and future products and services, we must continue to develop and maintain our sales, marketing and medical affairs organizations to effectively explain to healthcare providers the reliability, effectiveness and benefits of our current and future products and services as compared to alternatives. Our sales efforts have grown in size and complexity, and we may not be able to successfully manage our dispersed or inside sales forces or our sales force may not be effective. Because of the competition for their services, we may be unable to hire, partner with or retain additional qualified sales representatives or marketing or medical affairs personnel, either as our employees or independent contractors or through independent sales or other third- party organizations. Market competition for commercial, marketing and medical affairs talent is significant, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all. Establishing and maintaining sales, marketing, and medical affairs capabilities will be expensive and time- consuming. Our expenses associated with maintaining our sales force may be disproportional compared to the revenues we may be able to generate on sales of current and future products or services. The success of our Cologuard test, our Oncotype~~ tests, and any other screening or diagnostic product or service we offer or develop will depend on the degree of market acceptance by healthcare providers, patients, healthcare payers, and others in the medical community. Our products and services may not gain market acceptance by healthcare providers, healthcare payers, and others in the medical community. The degree of market acceptance of our Cologuard test, our ~~Oncotype~~ **precision oncology** tests, and other products and services that we offer will depend on a number of factors, including: • demonstrated performance and utility; • price; • the availability and attractiveness of alternative tests; • the willingness of healthcare providers to prescribe our products and services; • the ease of use of our ordering process for healthcare providers; and • adequate third- party coverage or reimbursement. Our assumptions regarding the market opportunity for our products or services may not prove true. For example, we estimate the potential market opportunity for our Cologuard test assuming, among other things, the size of the screening population, the adoption rate in the screening population and a three- year screening interval. Although ACS guidelines and others recommend a three- year screening interval for our Cologuard test and CMS has determined that Medicare will cover the test at this interval, the label for our Cologuard test does not specify a three- year interval and healthcare providers, healthcare payers, the FDA, and other regulators and opinion leaders could recommend a different interval. Further, patients may not adhere to any recommended testing interval. Securing influential recommendations, inclusion in healthcare guidelines, and inclusion in quality measures are keys to our healthcare provider and payer engagement strategies. These guidelines, recommendations, and quality metrics may shape payers' coverage decisions and healthcare providers' cancer screening procedures. The USPSTF, a panel of primary care providers and epidemiologists and other national experts funded by the U. S. Department of Health and Human Services' Agency for Healthcare Research and Quality, makes influential recommendations on clinical preventive services. USPSTF updates its screening recommendations periodically, approximately every five to eight years. The USPSTF' s most recent recommendation statement for colorectal cancer screening gave an " A " grade to colorectal cancer screening starting at age 50 and continuing until age 75 and gave a " B " grade to colorectal cancer screening for ages 45 to 49. Any update to the USPSTF recommendations that may have the effect of reducing screening, that does not include FIT- DNA in a favorable manner, or that adds new technologies could have a material adverse effect on our business. Maintaining a high USPSTF recommendation for our Cologuard test may have certain potentially significant implications. For example, the ACA mandates that certain non-grandfathered health insurers cover evidence- based items or services that have in effect a rating of " A " or " B " in the current recommendations of USPSTF without imposing any patient cost- sharing. Similarly, federal regulations require that Medicare Advantage plans cover " A " or " B " graded preventive services without patient cost- sharing. Following the updated 2016 USPSTF recommendation statement, CMS issued an updated Evidence of Coverage notice for Medicare Advantage plans that affirms such plans must include coverage of our Cologuard test every three years without patient cost- sharing. While we believe the ACA Mandate requires certain health insurers to cover our Cologuard test for individuals between the ages of 45 and 75 without patient cost- sharing, some health insurers have disagreed. Enforcement of the ACA Mandate is difficult and depends on state, federal, or other third- party enforcement actions that we do not control. Further, a court or regulatory agency may agree with arguments that have been made, or that may in the future be made, by insurers and determine that the ACA Mandate does not require that they cover our Cologuard test or **future tests we may develop or** may otherwise interpret the ACA Mandate in a manner unfavorable to us. Also, Congress may modify or repeal all or part of the ACA, and any such modification or repeal may repeal or limit the ACA Mandate for preventive services. Additionally, the ACA has also been the subject of various legal challenges and, if the plaintiffs are successful in any such challenges, insurance coverage for our Cologuard test **or future tests we develop** could be materially and adversely affected. If **for any of these reasons** the ACA Mandate **ceases** ~~for preventive services is repealed, overturned or modified, if the ACA Mandate is determined not~~ to require coverage of our Cologuard test ~~, if the ACA Mandate is~~ **or future tests we may develop or we are** otherwise ~~interpreted in a manner unfavorable to us, or if we are~~ unable to ~~influence or~~ secure effective enforcement of **such** ~~the ACA Mandate~~ **mandate** ~~, even if it is held to require coverage of our Cologuard test~~ , our business prospects may be adversely affected. The healthcare industry in the ~~United States~~ **U. S.** has experienced a trend toward cost containment and value- based purchasing of healthcare services. Some government and private payers are adopting pay- for- performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies, or patient outcomes. Payers may look to quality measures such as the NCQA, HEDIS, and the CMS Medicare Advantage Star Ratings to assess quality of care. These measures are intended to provide incentives to service providers to deliver the same or better results while consuming fewer resources. Our Cologuard test has been included in NCQA' s HEDIS measures since 2017 and in CMS' s Medicare Advantage Star Ratings since 2018. If for some reason our Cologuard test was removed from or not included in HEDIS, the Star

Ratings, or other quality metrics, payers may be less inclined to reimburse our Cologuard test at adequate levels, if at all, which could adversely impact our business. Additionally, if our Cologuard test was removed from or not included in HEDIS, the Star Ratings, or other quality metrics, healthcare providers may not earn quality credit for prescribing our Cologuard test and therefore may be less inclined to do so. If our Cologuard test fails to maintain its current position within any updated USPSTF colorectal cancer screening recommendations, our Cologuard test may, as a result, become excluded from the HEDIS measures and the Star Ratings. We **expect** ~~are seeking~~ to **incur significant expenses on development efforts** ~~increase our Cologuard test's specificity by substituting new biomarkers and~~ to **improve our current products and** develop a pipeline for future products and services, **but such** ~~including multi- cancer early detection, molecular residual disease, recurrence monitoring, and hereditary cancer tests. We expect to incur significant expenses on these development~~ efforts ~~, but they~~ may not be successful. Developing new or improved cancer tests is a speculative and risky endeavor. Candidate products and services that may initially show promise may fail to achieve the desired results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. Results from early studies or trials are not necessarily predictive of future clinical study or trial results, and interim results of a trial are not necessarily indicative of final results. From time to time, we may publicly disclose then- available data from clinical studies before the studies are complete, and the results and related findings and conclusions may be subject to change following the final analysis of the data related to the particular study or trial. As a result, such data should be viewed with caution until the final data are available. Additionally, such data from clinical studies are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and / or follow- up continues and more patient data become available. Significant adverse differences between initial or interim data and final data could significantly harm our reputation and business prospects. Any cancer screening **or diagnostic** test we develop will need to demonstrate in clinical studies a high level of accuracy. Because cancer screening tests seek to identify relatively rare occurrences, if in a clinical study a candidate product or service fails to identify even a small number of cancer cases, the sensitivity rate may be materially and adversely affected and we may have to abandon the candidate product or service. Any cancer diagnostic test we develop will need to address an unmet medical need with accurate performance and utility. We may need to explore a number of different biomarker combinations, alter our candidate products or platform technologies, and repeat clinical studies before we identify a potentially successful candidate. We may need to acquire, whether through purchase, license or otherwise, technologies owned by third parties, and we may not be able to acquire such technologies on commercially reasonable terms or at all. **We also require human sample types, such as blood, tissue, and stool for our research and product development, which may not be available to us on a timely basis or commercially reasonable terms. Our inability to negotiate access to such clinical samples or the ability of other laboratories or our competitors to secure access to these samples before us could limit or delay our ability to research, develop and commercialize future products.** Product development is expensive, may take years to complete, and can have uncertain outcomes. Failure can occur at any stage of development. If, after development, a candidate product or service appears successful, we may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances or approvals before we can market it ~~. The FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development, and clinical study expenditures~~ . There can be no guarantee that the FDA would clear or approve any future product or service we may develop. Even if the FDA and other regulatory authorities clear or approve a new product or service we develop, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially viable. In developing a test, we must make numerous assumptions regarding the commercial viability of a test, including with respect to healthcare providers' and patients' interest in a test, payers' willingness to pay for a test, our costs to perform a test, and availability and attractiveness of competing offerings. Frequently, we must make those assumptions many years before a test is ready for clinical use. If we determine that any of our current or future development programs is unlikely to succeed, we may abandon it without any return on our investment into the program. We may need to raise significant additional capital to bring any new products or services to market, which may not be available on acceptable terms, if at all. As of December 31, ~~2022~~ **2023** , we have entered into exclusive distribution agreements for the sale of our Oncotype tests with distributors covering dozens of countries. We may enter into other similar arrangements to distribute our tests in other countries in the future. We intend to continue **growing** ~~to grow~~ our business internationally, and to do so we may need to attract additional distributors to expand the territories in which we sell our tests. Despite contractual obligations, distributors may not commit the necessary resources to market and sell our tests to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to enter into or maintain arrangements with distributors to market our tests in particular geographic areas, we may not realize long- term international revenue growth. Additionally, local laws may make it very difficult or costly for us to terminate or replace distributors, and local public procurement law may complicate providing our centralized laboratory services through a distributor. Furthermore, our revenue from distributors could be negatively impacted as a result of changes in business cycles, business or economic conditions, coverage determinations, reimbursement rates, changes in foreign currency exchange rates that make our tests more expensive in our distributors' local currencies, or other factors that could affect their ability to pay us for tests on a timely basis or at all. ~~Access to human sample types, such as blood, tissue, and stool is necessary for our research and product development. Acquiring samples from individuals with clinical diagnoses or associated clinical outcomes through purchase or clinical studies is necessary. Lack of available samples can delay development timelines and increase costs of development. Generally, the agreements under which we gain access to human samples are non- exclusive. Other companies may compete with us for access. Additionally, the process of negotiating access to samples can be lengthy and it may involve numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership, and research parameters. If we are not able to negotiate access to clinical samples with research institutions, hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our~~

~~ability to research, develop and commercialize future products will be limited or delayed. Finally, we may not be able to conduct or complete clinical studies on a timely basis if we are not able to enroll sufficient numbers of patients in such studies, and our failure to do so could have an adverse effect on our research and development and product commercialization efforts.~~ The development and commercialization of our products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. We have collaborative and licensing arrangements with Mayo Foundation for Medical Education and Research, under which Mayo provides us with certain exclusive and non- exclusive intellectual property rights and ongoing product development and research and development assistance. In addition, we have licensing agreements with ~~Hologic, Inc., Johns Hopkins University, Ludwig Institute for Cancer Research, Translational Genomics Research Institute, and others~~ **other partners that** ~~. Such arrangements~~ provide us with intellectual property and other business rights crucial to our product development and commercialization. We have incorporated licensed technology into our Cologuard test and expect to **continue relying on, and** ~~incorporate~~ **incorporating ,** licensed technology into our pipeline products. Our dependence on licensing, collaboration, and other similar agreements with third parties may subject us to a number of risks. There can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties will be continued on materially similar terms and will not be breached or terminated early. Any failure to obtain or retain the rights to necessary technologies on acceptable commercial terms could require us to re- configure our products and services, which could negatively impact their commercial sale or increase the associated costs, either of which could materially harm our business and adversely affect our future revenues and ability to achieve sustained profitability. **In addition,** ~~We expect to continue and expand our reliance on collaborative and licensing arrangements. Establishing~~ **establishing** new strategic collaborations and licensing arrangements is difficult and time- consuming. Discussions with potential collaborators or licensors may not lead to the establishment of collaborations on favorable terms, if at all. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be limited. Potential collaborators or licensors may reject collaborations with us based upon their assessment of our financial, regulatory, or intellectual property position or other factors. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service. In addition, the success of the projects that require collaboration with third parties will be dependent on the continued success of such collaborators. There is no guarantee that our collaborators will continue to be successful and, as a result, we may expend considerable time and resources developing products or services that will not ultimately be commercialized. We may be subject to substantial costs and liability or be prevented from using technologies incorporated in our screening or diagnostic tests as a result of litigation or other proceedings relating to patent or other intellectual property rights. Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners, or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the non- invasive early detection of cancer and pre- cancer ~~,~~ as well as in the guidance of cancer treatment decisions, and is designed to maximize our patent protection against third parties. We have filed patent applications that we believe cover the methods we have designed and use in our Cologuard test to detect colorectal cancer and pre- cancer, our Oncotype tests to provide prognosis and guide treatment decisions, and for pipeline cancer tests still in development. In order to protect or enforce our patent and other intellectual property rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time consuming and divert the attention of our management and key personnel from our business. Additionally, such actions could result in challenges to the validity, enforceability, or applicability of our patents. Because the U. S. Patent and Trademark Office (" USPTO ") maintains patent applications in secrecy until a patent application publishes or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by our partners or us. Additionally, there may be third- party patents, patent applications, and other intellectual property relevant to our technologies that may block or compete with our technologies. From time to time we have received correspondence from third parties alleging to hold intellectual property rights that could block our development or commercialization of products. While none of these inquiries to date have had any material effect on us, we may receive inquiries in the future that could have a material effect on our business. Even if third- party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits to the extent necessary to conduct our business according to our strategic plan or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may only be available on unacceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition, and results of operations ~~. Also, patents and patent applications owned by us may become the subject of interference proceedings in the USPTO to determine priority of invention, which could result in substantial cost to us as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding~~ . We rely on patent protection as well as a combination of trademark, copyright, and trade secret protection and other contractual restrictions to protect our proprietary technologies and other intellectual property rights, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property, which may not be entirely successful, if at all. Additionally, certain of our patents began to expire in 2018. This loss of intellectual property protection may permit third parties to use certain intellectual property assets previously exclusively reserved for our use. We cannot assure you that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for any such patents to be issued. Further, we cannot assure you that other parties will not challenge

any patents issued to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We have been in the past, and may be in the future, the subject of ~~opposition~~ **pre- or post- grant** proceedings ~~relating to~~ **challenges at the USPTO** ~~our~~ **or international** ~~patents~~ **patent offices to determine priority of invention or validity of a patent, which could result in substantial cost to us as well as a possible adverse decision as to the priority of invention or validity of the patent involved. An adverse decision in any such challenge may result in the loss of rights under a patent or patent application** . We cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third- party challenge to our patents could result in co- ownership of such patents with the third party or the unenforceability or invalidity of such ~~patents. Furthermore, in the life sciences field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of isolated DNA and / or methods for analyzing or comparing DNA. Such decisions may adversely impact our ability to obtain new patents and facilitate third- party challenges to our existing~~ patents. Even where we have valid patents, third parties may be able to successfully design their products and services around those patents, such that their products and services do not infringe our patents. We may face competition internationally in jurisdictions where we do not have intellectual property protection. Our business may be adversely affected to the extent third parties are able to develop or commercialize competing products and services that do not infringe our patents. We may also be adversely affected to the extent third parties develop or commercialize competing products or services in countries where we did not apply for patents, where our patents have not issued, or where our intellectual property rights are not recognized or are poorly enforced. We depend on trademarks to establish a market identity for our company and our products and services. To maintain the value of our trademarks, we may have to file lawsuits against third parties to prevent them from using trademarks confusingly similar to or dilutive of our registered or unregistered trademarks. We also may not obtain registrations for our pending or future trademark applications, and might have to defend our registered trademarks and pending applications from challenges by third parties. Enforcing or defending our registered and unregistered trademarks might result in significant litigation costs and, if we are unsuccessful, might result in damages, including the inability to continue using certain trademarks ~~. If patent regulations or standards are modified, such changes could have a negative impact on our business~~ . From time to time, the U. S. Supreme Court, other federal courts, the U. S. Congress, or the USPTO may change the standards of patentability and validity of patents within the cancer screening and diagnostics space, and any such changes could have a negative impact on our business. There have been several cases involving " gene patents " and diagnostic claims that have been considered by the U. S. Supreme Court that have affected the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions. Additionally, in December 2014 and again in 2019, the USPTO published revised guidelines for patent examiners to apply when examining process claims that narrow the scope of patentable subject matter. While these guidelines may be subject to review and modification by the USPTO over time, we cannot assure you that our patent portfolio will not be negatively impacted by the decisions mentioned above, rulings in other cases, or changes in guidance or procedures issued by the USPTO. Additional substantive changes to patent law, whether new or associated with the America Invents Act — which substantially revised the U. S. patent system — may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact these substantive changes will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries, and our ability to enforce or defend our issued patents, all of which could have a material adverse effect on our business. ~~We~~ **As a public company, we** are **subject to the Sarbanes- Oxley Act of 2002 and the related rules and regulations promulgated by the SEC, which** ~~required~~ **require us, among other things,** to ~~assess our~~ **maintain effective disclosure controls and procedures and** internal control over financial reporting ~~on an annual basis and any future adverse results from such assessments could result in a loss of investor confidence and have an adverse effect on our stock price~~ . **Maintaining** ~~Pursuant to the Sarbanes- Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10- K a report by our management regarding the effectiveness~~ ---- **effective** ~~of our~~ **disclosure controls and procedures and** internal control over financial reporting ~~. The report includes, among other things,~~ **is necessary for us to produce reliable financial statements** ~~an~~ **and** ~~assessment~~ **to prevent fraud. In addition, we are required to disclose publicly for each fiscal year the conclusion** of **our management as to** the effectiveness of our internal control over financial reporting **and to report any material weaknesses identified by management. The Sarbanes- Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm. Although we determined that our internal control over financial reporting was effective** as of ~~the end of~~ **December 31, 2023, we must continue to monitor and assess our internal control over financial reporting. If we identify material weaknesses in our internal control over financial reporting** ~~our~~ **or if we are unable** ~~fiscal year, including a statement as~~ to ~~whether~~ **assert that** our internal control over financial reporting is effective ~~. This assessment must include disclosure of~~ **when required in the future, or if our independent registered public accounting firm is unable to express** ~~any~~ **an** ~~material weaknesses in~~ **opinion as to the effectiveness of** our internal control over financial reporting ~~identified by management. While we believe our internal control over financial reporting is currently effective~~ , **investors** ~~the effectiveness of our internal controls in future periods is subject to the risk that our controls~~ may ~~become inadequate because of changes in conditions. Establishing, testing, and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments, and would increase our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could~~ lose ~~investor~~ confidence in the accuracy and completeness of our financial reports ~~, which could have an~~ **and the market** ~~adverse effect on our stock~~ price ~~. As a result of our international operations, we receive a portion of our revenues and pay a portion of our expenses in currencies other than the U. S. dollar, such as the Euro, the Swiss franc, the British pound and the Canadian dollar. In addition, many of our distribution~~

~~agreements contain clauses requiring regular U. S. dollar price re- adjustments to account for fluctuations in the exchange rate between the U. S. dollar and the local currency. As a result, we are at risk from exchange rate fluctuations between such foreign currencies and the U. S. dollar, which could adversely affect our results of operations. Additionally, the volume of our international orders may be negatively impacted by a strong U. S. dollar. For the year ended December 31, 2022, approximately 5. 6 % of our revenues came from foreign denominated currencies. If the U. S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses. We may not be able to offset adverse foreign currency impact with increased revenues. We enter into forward contracts to mitigate the impact of adverse movements in foreign exchange rates related to the re- measurement of monetary assets and liabilities and hedge our foreign currency exchange rate exposure. Even with this strategy in place to mitigate balance sheet foreign currency risk, we will not eliminate our exposure to foreign exchange rate fluctuations on our financial results. Delaware law, our charter and bylaw documents, and certain provisions of our convertible notes could impede or discourage a takeover or change of control that stockholders may consider favorable. As a Delaware corporation, we are subject to certain anti- takeover provisions. Under Delaware law, a corporation may not engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Accordingly, our board of directors could rely on Delaware law to prevent or delay an acquisition of our company. In addition, certain provisions of our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions include the following: • Our board of directors is divided into three classes serving staggered three- year terms. • Only our board of directors can fill vacancies on the board. • Our stockholders may not act by written consent. • There are various limitations on persons authorized to call a special meeting of stockholders and advance notice requirements for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders. • Our board of directors may issue, without stockholder approval, shares of undesignated preferred stock. These types of provisions could make it more difficult for a third party to acquire control of us, even if the acquisition would be beneficial to our stockholders. Certain provisions of our outstanding convertible notes we issued in 2018, 2019, and 2020 could make it more difficult or more expensive for a third party to acquire us. Upon the occurrence of certain transactions constituting a " fundamental change, " as such term is defined in the indenture for the notes, holders of the convertible notes will have the right, at their option, to require us to repurchase all of their convertible notes or any portion of the principal amount of such convertible notes in integral multiples of $ 1, 000. We may also be required to increase the conversion rate in the event of a " make- whole fundamental change, " as such term is defined in the indenture for the notes. In addition, the indenture and the convertible notes will prohibit us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the convertible notes and the indenture. These and other provisions in the indenture could deter or prevent a third party from acquiring us. Our bylaws provide, subject to certain exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or stockholders. Our bylaws provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for any claims, including any derivative actions or proceedings brought on our behalf, (1) that are based upon a violation of a duty by a current or former director or officer or stockholder in such capacity or (2) that may be brought in the Court of Chancery pursuant to the Delaware General Corporation Law. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares~~ of our common stock ~~shall be deemed to have notice of and to have consented to the provisions of our bylaws described above. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision that is contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations. As of December 31, 2022, we had federal, state, and foreign net operating loss carryforwards (" NOLs ") of approximately $ 475. 2 million, $ 70. 9 million, and $ 7. 2 million, respectively. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the " Code "), a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change NOLs to offset future taxable income. An ownership change is generally defined as a greater than 50 % change in equity ownership by value over a specified time period (generally three years). Given the Code' s broad definition, an ownership change~~ could be **adversely affected** ~~the unintended consequence of otherwise normal market trading in our stock that is outside our control. An ownership change under Section 382 of the Code could also be triggered by certain strategic transactions. Additionally, tax law limitations may result in our NOLs expiring before we have the ability to use them. Pursuant to the Tax Cuts and Jobs Act (H. R. 1) of 2017, federal NOLs arising in tax years beginning after December 31, 2017 have an indefinite carryover period and may only be used to offset 80 % of current year taxable income. For these reasons, even if we attain profitability, our ability to utilize our NOLs may be limited, potentially significantly so~~ . The market price for our common stock ~~varied between a high of $ 84. 46 and a low of $ 29. 27 in the twelve- month period ended December 31~~ , ~~2022. Our stock price is likely~~ -- **like** ~~to~~ **the securities of many other companies in the life sciences industry, has been highly volatile and could** continue to be volatile and subject to significant price and volume fluctuations in response to **various** ~~market and other~~ factors, **many of which are beyond our control. Such factors** ~~including~~ **include** those listed in this " Item 1A. Risk Factors " section **as well as** ~~and other, unknown factors. Among numerous other factors, our stock price also may be affected by~~ : • comments by securities analysts regarding our business or prospects; • our quarterly operating performance; • our issuance of common stock or other securities; • our inability to accurately forecast future performance; • our

inability to meet analysts' expectations; • **announcements by us** ~~our~~ **or** ~~entering into merger, acquisition, or~~ **our** ~~other similar~~ **competitors, including strategic actions, management changes, and material** transactions; **and** • general **financial, domestic, international, economic, and market conditions, including overall** fluctuations in the ~~stock~~ **U. S. equity and credit** ~~market~~ **markets , which may be unrelated** or ~~in~~ **disproportionate to** the ~~stock prices~~ **operating performance** of **particular** companies ~~in the life sciences or healthcare diagnostics industries; and • general conditions and publicity regarding the life sciences or healthcare diagnostics industries~~ . **In** ~~Consequently,~~ the ~~current~~ **past, companies whose securities have experienced periods of volatility in** market price **have been subjected to securities class action or derivative litigation. In this regard, sharp drops in the market price** of our common stock ~~may not be indicative of future market prices~~ , **could** ~~and we may be unable to sustain or increase the value of an investment in our common stock. Further, sharp drops in the market price of our common stock, such as we experienced at certain times in our history, may~~ expose us to **claims and litigation alleging violations of the** securities ~~class- action litigation~~ **laws or other related claims** . Such litigation could result in substantial expenses and diversion of management' s attention and corporate resources, which would seriously harm our business, financial condition, and results of operations ~~. We have never paid cash dividends and do not intend to do so. We have never declared or paid cash dividends on our common stock. We currently plan to use any cash proceeds from our operations to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors~~ . Our balance sheet includes goodwill and intangible assets that represent ~~69~~ **66** % of our total assets at December 31, ~~2022~~ **2023 , which are** ~~. These assets consist~~ primarily ~~of goodwill and identified intangible assets~~ associated with our acquisitions. On at least an annual basis, we assess whether there have been impairments in the carrying value of goodwill. In addition, we review intangible assets for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. If the carrying value of the asset is determined to be impaired, then it is written down to fair value by a charge to operating earnings. An impairment of a significant portion of goodwill or intangible assets could have a material negative effect on our results of operations. ~~From time to time we may carry high levels of cash and marketable securities. As of December 31, 2022, we had $ 632. 1 million in combined cash and marketable securities. Our management currently expects to deploy our cash and marketable securities primarily to expand our Cologuard and Oncotype operations and commercialization activities, to fund our product development efforts, and for general corporate purposes, including working capital and possible acquisitions. However, our management has broad discretion to pursue other objectives, we may raise additional capital, and we may use our current and future resources for other purposes. Our management might not effectively deploy our cash and marketable securities which could have an adverse effect on our business.~~ We have a significant amount of indebtedness. As of December 31, ~~2022~~ **2023** , we had total indebtedness of $ 2. ~~26~~ **39** billion, including $ 2. ~~21~~ **34** billion in aggregate principal and interest due under our ~~1. 0 %, 0. 375 %, and 0. 375 %~~ convertible senior notes ~~due in 2025, 2027, and 2028~~ and $ 50. 0 million in borrowings under our Securitization Facility. We also had $ ~~2~~ **4** . ~~9~~ **4** million of letters of credit issued under our Revolver. This level of debt could have significant consequences on our future operations, including: • increasing our vulnerability to adverse economic and industry conditions; • making it more difficult for us to meet our payment and other obligations; • making it more difficult to obtain any necessary future financing for working capital, capital expenditures, debt service requirements, or other purposes; • requiring the dedication of a substantial portion of any cash flow from operations to service our indebtedness, thereby reducing the amount of cash flow available for other purposes, including capital expenditures; • placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital than we have; and • limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete. Any of the above- listed factors could have an adverse effect on our business, financial condition, and results of operations and our ability to meet our payment obligations under our indebtedness. Our ability to meet our payment and other obligations under our indebtedness depends on our ability to generate significant cash flow in the future. This, to some extent, is subject to general economic, financial, competitive, legislative, and regulatory factors as well as other factors that are beyond our control. We cannot assure you that our business will generate cash flow from operations, or that future borrowings will be available to us, in an amount sufficient to enable us to meet our payment obligations under our indebtedness and to fund other liquidity needs. If we are not able to generate sufficient cash flow to service our debt obligations, we may need to refinance or restructure our debt, sell assets, reduce or delay capital investments, share- settling the convertible notes or seek to raise additional capital ~~and~~ **, any** of which ~~such~~ events could have an adverse effect on our business, financial condition, and results of operations or be highly dilutive to our shareholders. Our credit facilities contain certain customary representations, warranties, affirmative covenants and negative covenants, events of default as well as termination events which would permit the lenders to terminate upon the occurrence of certain specified events, including, among others, failure to pay amounts when due, certain defaults on other material indebtedness, certain judgments, a change of control and bankruptcy and insolvency events. A breach of any covenant in our credit facilities or the agreements and indentures governing any other indebtedness that we may have outstanding from time to time would result in a default under that agreement or indenture after any applicable grace periods. A default, if not waived, could result in **(i)** acceleration of the debt outstanding under the agreement and ~~in~~ **(ii)** a default with respect to, and an acceleration of ~~,~~ the debt outstanding under **,** other debt agreements. If that occurs, we may not be able to make all of the required payments or borrow sufficient funds to refinance such debt. Even if new financing were available at that time, it may not be on terms that are acceptable to us or terms as favorable as our current agreements. If our debt is in default for any reason, our business, results of operations and financial condition could be materially and adversely affected.