

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

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You should consider carefully the risks described below, as well as the other information in this Annual Report on Form 10 - K, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. You should consider all of the factors described as well as the other information in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and “ Management ’ s Discussion and Analysis of Financial Condition and Results of Operations ” when evaluating our business. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Condition A significant portion of our revenue comes from a small number of third- party payors. Our revenue for our test reports provided for patients covered by Medicare as a percentage of total revenue, was **49 % and 53 % and 57 %** for the years ended December 31, **2023 and 2022 and 2021**, respectively. Additionally, there ~~is was~~ a commercial payor from which ~~12-14 %~~ **12-14 %** of our revenue from patients were derived for the year ended December 31, ~~2022-2023~~. If our largest current payors were to significantly reduce, or cease to pay, the amount they reimburse for our products, or if they do not reach favorable coverage and reimbursement decisions for our products, or attempt to recover amounts they had already paid, it could have a material adverse effect on our business, financial condition and results of operations and cause significant fluctuations in our results of operations. Due to how we recognize revenue, our quarterly and annual revenues may not reflect our underlying business. We have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at the expected value using the ‘ ‘ most likely amount ’ ’ method under Accounting Standards Codification (‘ ‘ ASC ’ ’) Topic 606, Revenue from Contracts with Customers (‘ ‘ ASC 606 ’ ’). The amounts are ~~determined by~~ **estimated using** historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Determining variable consideration through a consideration of these factors involves a significant level of estimation uncertainty, and our estimations may turn out to be incorrect. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor. Variable consideration for ~~Medicare claims that for which there are not~~ **no existing positive covered coverage decisions by Medicare**, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e. g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. As a result of the timing and amount of adjustments for variable consideration, our operating results and comparisons of such results on a period- to- period basis may be difficult to understand and may not be meaningful. In addition, these fluctuations in revenue may make it difficult for us, for research analysts and for investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below expectations, the price of our common stock would likely decline. We have incurred significant losses since inception, and we may never achieve profitability. Since our inception, we have had a history of net losses. For the year ended December 31, ~~2022-2023~~, we had a net loss of \$ ~~67-57.1-5~~ **67-57.1-5** million, and as of December 31, ~~2022-2023~~, we had an accumulated deficit of \$ ~~160-218.9-4~~ **160-218.9-4** million. We cannot predict if we will achieve profitability in the near future or at all. We expect to incur losses in the future as we plan to invest significant additional funds toward the expansion of our commercial organization, the conduct of clinical utility and validity studies to support adoption of our products and the development or acquisition of additional products. We also expect ~~significant~~ increases in our stock- based compensation expense in future periods due to additional awards outstanding, attributable to increased headcount. Additionally, our performance could be affected by the impacts of **geopolitical and macroeconomic developments** ~~the ongoing COVID-19 pandemic~~, **such as** the invasion of Ukraine by Russia **and related sanctions or the Israel- Hamas war**, economic slowdowns, labor shortages, recessions or market corrections, **supply chain disruptions**, inflation and monetary policy shifts, **bank failures or other disruptions in the banking system or financing markets**, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments. Due to the requirements associated with being a public company, including those associated with no longer qualifying as **a smaller reporting company and becoming** an **accelerated filer** ~~emerging growth company~~, we expect to continue incurring significant additional legal, accounting and other expenses. We also expect that any acquisitions of businesses, assets, products or technologies will increase our expenses. These increased expenses will make it harder for us to achieve future profitability or generate positive cash flows. We may also incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this Annual Report on Form 10 - K,

adoption of our products, coverage of and reimbursement rates for our products from third- party payors, and future research and development activities. Our failure to achieve profitability in the future could cause the market price of our common stock to decline and make it more difficult or costly for us to raise additional capital. We are an early, commercial- stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. We are an early commercial- stage company and have a limited operating history. Our limited operating history may make it difficult to evaluate our current business and this makes predictions about our future success or viability subject to significant uncertainty. In particular, we intend to use a portion of our working capital to increase our headcount, including through the expansion of our laboratory testing operations, sales and marketing and research and development teams, which will increase our operating costs in a manner not historically reflected in our consolidated financial statements. These anticipated changes in our operating expenses may make it difficult to evaluate our current business, assess our future performance relative to prior performance and accurately predict our future performance. We will continue to encounter risks and difficulties frequently experienced by early commercial- stage companies, including those associated with increasing the size of our organization and the prioritization of our commercial, research and business development activities. If we do not address these risks successfully, our business could suffer. Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results. Accounting principles generally accepted in the United States of America (“ U. S. GAAP ”) is subject to interpretation by the Financial Accounting Standards Board (“ FASB ”), the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. Our quarterly and annual operating results and cash flows may fluctuate in the future, which could cause the market price of our stock to decline substantially. Numerous factors, many of which are outside our control may cause or contribute to significant fluctuations in our quarterly and annual operating results. ~~For example, following the onset of the COVID-19 pandemic in 2020 we experienced decreases in revenue and test report volumes.~~ These fluctuations may make financial planning and forecasting uncertain. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, comparing our operating results on a period- to- period basis may be difficult to understand and may not be meaningful. You should not rely on our past results as indicative of our future performance. In addition, a significant portion of our operating expense is relatively fixed in nature, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls could decrease our gross margins and cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our stock could fall substantially. This variability and unpredictability caused by factors such as those described above could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price. Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. If we fail to adequately staff our accounting and finance function or fail to maintain adequate internal control over financial reporting, any new or recurring material weaknesses could prevent our management from concluding our internal control over financial reporting is effective and could result in our auditor issuing an adverse opinion on our internal control over financial reporting. If we identify any future significant deficiencies or material weaknesses, the accuracy and timeliness of our financial reporting may be adversely affected, our ability to prevent material misstatements in our consolidated financial statements could be impaired, a material misstatement in our consolidated financial statements could occur and we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, which could cause our business to suffer and our stock price to decline. Since becoming a publicly traded company in 2019, we have increased the headcount of our accounting and finance functions to further support the demands placed upon us as a public company, including the requirements of the Sarbanes- Oxley Act of 2002 (“ Sarbanes- Oxley ”). We expect to continue expending significant time and resources related to our internal control over financial reporting, including by further expanding our finance and accounting staff over time, but there can be no assurance our efforts will be effective. We may need to raise additional capital to fund our existing operations, commercialize new products or expand our operations. We believe our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products will be sufficient to fund our operations for **at least the foreseeable future next 12 months**. If our available cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products are insufficient to satisfy our liquidity requirements including because of lower demand for our products, lower than currently expected rates of reimbursement from third- party payors or other risks described in this Annual Report on Form 10- K, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We ~~do not currently have any committed external source of funds.~~ In addition, we may seek

additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts for the DecisionDx- Melanoma, DecisionDx- SCC, MyPath Melanoma, DiffDx- Melanoma, DecisionDx-UM, TissueCypher and IDgenetix tests and address competitive developments among these or future commercial products;
- fund ongoing evidence development for our existing products as well as additional pipeline programs;
- expand our laboratory testing facility and related testing capacity;
- expand our technologies into other types of **dermatological skin cancer**, ocular cancer, gastrointestinal or mental health **disorders management and detection products**;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements with third- party payors;
- our rate of progress in, and cost of the sales, marketing, coverage and reimbursement activities associated with, establishing adoption of our lead product, DecisionDx- Melanoma, among our other products;
- the cost of expanding our laboratory operations and offerings, including our sales, marketing, coverage and reimbursement efforts;
- our rate of progress in, and cost of research and development activities associated with, diagnostic products in research and early development;
- the potential cost of, and delays in, the development of new products as a result of changes in regulatory oversight applicable to our products;
- acquisitions of businesses, assets, products or technologies;
- the duration and effects of elevated inflation;
- the effects on our operations of general political and economic conditions and evolving macroeconomic developments, including **geopolitical and macroeconomic developments the COVID-19 pandemic, such as the invasion of ongoing conflict between Ukraine by Russia and related sanctions or the Israel- Hamas war, public health crises**, economic slowdowns, labor shortages, recessions or market corrections, **supply chain disruptions, the duration and effects of elevated inflation and monetary policy shifts**, **bank failures or other disruptions in the banking system or financing markets**, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments; and
- the effect of competing technological and market developments.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or products, or grant licenses on terms that may not be favorable to us. Any disruptions to, or volatility in, the credit and financial markets or any deterioration in overall economic conditions may make any necessary debt or equity financing more difficult to obtain, more costly and / or more dilutive. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our commercialization, research and development efforts or grant rights to third parties to market and / or develop products that we would otherwise prefer to market and develop ourselves.

Risks Related to Our Business Our revenue currently depends primarily on sales of DecisionDx- Melanoma, and we will need to generate sufficient revenue from this and other products to grow our business. Our revenue in **2023 and 2022 and 2021** was primarily derived from the sale of our lead product, DecisionDx- Melanoma. While we also derive revenue from our other tests, we expect that the majority of our revenue for at least the next several years will be derived from sales of DecisionDx- Melanoma **as well as our other dermatologic tests**. We believe that our long- term commercial success, and ability to generate revenue, will depend on our ability to develop and market additional products, on our ability to increase market penetration for our existing and potential future products and on our ability to obtain favorable coverage and reimbursement policies from government payors, such as Medicare, and from private payors, such as insurance companies. Without positive coverage policies, our products may not be reimbursed and we may not be able to recognize revenue. If we are unable to increase sales and expand coverage and reimbursement for DecisionDx- Melanoma and our other tests, develop and commercialize other products, and successfully obtain coverage and adequate reimbursement for such products, our revenue and our ability to achieve profitability would be impaired, and the market price of our stock could decline substantially. Unfavorable U. S. and global economic conditions could adversely affect our business, financial condition, results of operations or cash flows. Our results of operations could be adversely affected by general conditions in the U. S. and global economies, the U. S. and global financial markets and adverse macroeconomic developments. U. S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including **public health crises such as the ongoing COVID- 19 pandemic, material shortages and related supply chain challenges, geopolitical and macroeconomic developments**, such as the **Israel- Hamas war and the ongoing conflict between Ukraine and Russia** and **increasing related sanctions, economic slowdowns, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, liquidity concerns, at, and failures of, banks and other financial institutions or other disruptions in the banking system or financial markets, rising interest rates and tightening of credit markets resulting from the conflict or the other evolving macroeconomic developments** responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate. A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on

our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U. S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. **Furthermore, the recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages that could materially harm our business and financial condition. In this regard, we continue to maintain our cash deposits with banking institutions, often in balances that exceed the current Federal Deposit Insurance Corporation insurance limits, and the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations, limit our access to additional capital on favorable terms, or at all, or delay our ability to access such funds or collect receivables, which could negatively affect our financial condition and our ability to pursue our business strategy.**

Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, UK and European Union (“EU”), along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability and / or supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia- Ukraine conflict has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. Further, a weak or declining economy could strain our suppliers, manufacturers and collaborators, possibly resulting in additional supply disruption for our product candidates. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. If economic conditions in Europe and other key markets for our business and the business of our suppliers, manufacturers and collaborators remain uncertain or deteriorate further, **including as a result of the COVID-19 pandemic or otherwise**, we could experience adverse effects on our business, financial condition, results of operations or cash flows. **Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. The COVID-19 pandemic, and federal, state and local government responses to these events, adversely impacted our business. Adverse impacts included reduced demand for our test reports, as well as disruptions to the business or operations of physicians and other healthcare providers who order our test reports and the third- party payors responsible for reimbursement for our tests, customers and other third parties with whom we conduct business. Following the onset of the COVID-19 pandemic, we experienced declines in orders and test report volume in certain periods. For example, in the second quarter of 2020, test reports delivered for our lead product, DecisionDx- Melanoma, decreased 18.5% compared to the second quarter of 2019. We believe these decreases in our test report volume were linked to delays and / or cancellations in patient visits, resulting in fewer diagnostic biopsies and thus a reduction in the number of diagnoses of cutaneous melanoma in response, as well as the cumulative impact on promotional responsiveness as a result of reduced sales calls per day and in- person sales calls during the COVID-19 pandemic. Similar future events, and responses to such events, could also adversely impact and disrupt our business, including, but not limited to:**

- decreased test report volume due to a decline in orders of our tests as patient visits for routine examinations and biopsies have been, and may continue to be, delayed and / or canceled;
- disruption of our sales and commercialization activities due to limitations on our ability to communicate with clinicians as a result of travel restrictions and hindered means of communicating with clinicians;
- delays or disruptions by third parties in the collection, preparation or delivery of the samples that we test;
- delays or difficulties in delivering test reports, interruptions in research and development and other limitations of key business activities due to members of our workforce becoming ill, compliance with applicable vaccination mandates and / or stay- at- home or other similar orders imposed by or that may be imposed by state and local governments, including at our Phoenix, Arizona; Pittsburgh, Pennsylvania; and Friendswood, Texas locations;
- delayed reimbursement from third- party payors, disruption in our supply channel and other adverse impacts on our business resulting from the negative effects a pandemic on our suppliers, service providers and other third parties on whom we rely; and
- delayed or postponed interactions with regulators and other important agencies and contractors, due to limitations in employee resources, travel restrictions or forced furlough of government employees. The receipt of government payments or other assistance during a public crisis or pandemic could generate negative publicity or other adverse impacts for our Company. Under legislation enacted (or that may be enacted) by the United States federal government in response to public health crises or pandemics, we could receive cash payments or other forms of assistance allocated to healthcare and other companies, the receipt of which could generate negative publicity, harm our reputation, trigger a review or audit by applicable government agencies and / or adversely impact our stock price. For example, during the COVID-19 pandemic we received \$1.9 million of government payments in the form of provider relief funds from HHS. Although we do not believe the receipt of these funds was perceived negatively by the public, we can provide no assurance regarding future public reactions to similar events. Further, the terms and conditions of such payments or other assistance may be subject to restrictive terms and conditions, which may be ambiguous or subject to further modification, interpretation and guidance issued by governments on an ongoing basis. In the event we fail to comply with any of the terms or

~~conditions associated with a payment we receive or if the terms and conditions or related interpretations change, we may be required to return it.~~ Billing for our products is complex and requires substantial time and resources to collect payment. Billing for clinical laboratory testing services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, including Medicare, Medicaid, private insurance companies, private healthcare institutions, and patients, all of which have different billing requirements. We generally bill third-party payors for products and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition. Several factors make the billing process complex, including:

- differences between the billing rates and reimbursement rates for our products;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare, Medicaid, Veterans Health Administration and TRICARE;
- risk of government audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and / or advanced notification;
- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical studies, including our registry studies, which can affect eligibility for payment;
- ongoing monitoring provisions of LCDs for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use ~~standard industry CPT billing~~ codes to bill for our products. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment we receive. As we introduce new products, we may need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting. Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, we may challenge the reason, low payment amount or payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received. Additionally, the ACA requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our products, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations. In addition to the complexities noted above, we rely upon a third-party software application in the administration of our billing and collection process. Any significant disruption in our billing operations or the discovery of a deficiency in the design of our billing process could adversely impact our ability to generate and send invoices, calculate revenues, track payments and collect our accounts receivable. Although to date we have not experienced any disruptions or identified any deficiencies with our billing process or billing system, there can be no assurances that any disruptions or deficiencies will not occur in the future. Additionally, any failure in the design or operation of our internal controls related to our billing and collection processes could adversely impact our ability to conclude on the effectiveness of our internal control over financial reporting and could cause our auditor to issue an adverse opinion on our internal control over financial reporting. We rely on third parties for sample collection, preparation and delivery. Any defects in sample collection or preparation by such third parties and any delays in delivery of such samples could cause errors in our test reports and affect our ability to deliver test reports in a timely manner or at all, which could significantly harm our business. The samples that we test are biopsied (if applicable), preserved, prepared and delivered to us by third parties, including dermatopathologists and laboratory facilities. As such, we rely on these third parties to prepare, label and deliver the samples that we test in compliance with applicable laws and guidelines, and in a timely manner. Therefore, the accuracy and correctness of the test reports that we deliver are dependent on proper chain of custody and appropriate methods of sample collection or preparation utilized by these third parties, and our ability to timely deliver reports is dependent upon the ability of these third parties to provide these samples to us in a timely manner. The ability of these third parties to provide these samples to us in a timely manner could be delayed by events beyond our control, including but not limited to operational problems, natural disasters and public health **epidemics crises**. Any errors in any part of the sample collection or preparation process could render us unable to process tests, or deliver test reports, or cause us to deliver incorrect test reports, potentially resulting in harm to patients whose clinicians implement a change in treatment decisions based upon our test report. If we are unable to timely deliver test reports, clinicians may be less likely to recommend and order our products and our revenues could be adversely affected. The occurrence of any of the foregoing could significantly harm our reputation and our results of operations, causing significant harm to our business. We rely on our database of samples for some of the development and improvement of our products. Depletion or loss of our samples could significantly harm our business. The development and validation of accurate products is a complex process that requires access to tissue specimens and long-term outcomes data. Our research and development efforts to improve our existing commercial products and develop new pipeline products may require the depletion of our existing database of samples. If our samples are lost or destroyed, or substantially depleted before we are able to generate meaningful data, we may be unable to improve our existing products, continue the development of pipeline products or validate product candidates. While we have historically been able to create and maintain a large sample bank to expand the clinical use of our products and develop new products, we may be unable

to do so in the future. If we were unable to maintain or replenish our sample bank, we may be unable to improve our products or develop new products. If **one or more of** our primary clinical laboratory ~~facility facilities~~ **becomes— become** damaged or inoperable or we are required to vacate our existing facility, our ability to conduct our laboratory analysis and pursue our research and development efforts may be jeopardized. We currently perform ~~most of~~ our testing and store our database of tumor samples at **both** our ~~primary~~ **Phoenix, Arizona and Pittsburgh, Pennsylvania** clinical laboratory ~~facility facilities~~ **in Phoenix, Arizona**. Our ~~facility facilities~~ and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, terrorism, burglary, public health crises (including restrictions that may be imposed on businesses by state and local governments under stay-at-home or similar orders and mandates **such as those imposed during the COVID-19 pandemic**) or other events, which may make it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform tests or to reduce the backlog of sample analysis that could develop if our ~~facility facilities~~ **becomes— become** inoperable, for even a short period of time, may result in the loss of revenue, loss of customers or harm to our reputation, and we may be unable to regain that revenue, those customers or repair our reputation in the future. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters and man-made disasters or other sudden, unforeseen and severe adverse events. In addition, the loss of our tissue samples due to such events could limit or prevent our ability to conduct research and development analysis on existing tests as well as tests in active pipeline development. While we have a business continuity plan in place, and ~~additional~~ **intentionally built out two clinical laboratory laboratories facilities in adjacent buildings in Phoenix, Arizona** to not only support our growth but to provide certain operational redundancy, our facilities and the equipment we use to perform our testing and research and development could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facilities, to locate and qualify a new facility, replace certain pieces of equipment or license or transfer our proprietary technology to a third-party, particularly in light of licensure and accreditation requirements. Even in the unlikely event that we are able to find a third party with ~~such~~ qualifications **enabling to enable** us to resume our operations, we may be unable to negotiate commercially reasonable terms. We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. Our current or future products may not achieve or maintain significant commercial market acceptance. We believe our ~~commercial~~ success is dependent upon our ability to continue to successfully **commercialize market and sell** our products, to continue to expand our current relationships and develop new relationships with healthcare providers, to expand and maintain coverage for our products, and to develop and commercialize new products. Our ability to achieve and maintain commercial market acceptance of our existing and future products will depend on a number of factors, including: • our ability to increase awareness of our products through successful clinical utility and validity studies; • the rate of adoption of our products by physicians and other healthcare providers; • our ability to achieve guideline inclusion for our products; • the timeliness with which we can provide our clinical reports to the ordering clinician; • the timing and scope of any regulatory approval for our products, if such approvals become required, and maintaining ongoing compliance with regulatory requirements; • our ability to obtain and maintain positive coverage decisions for our products from government and commercial payors; • our ability to obtain and maintain adequate reimbursement from third-party payors, such as Medicare, which accounted for **49 % and 53 % and 57 %** of our revenue from test reports for the years ended December 31, **2023 and 2022 and 2021**, respectively, with an additional third-party payor accounting for **12-14 %** of our revenue from test reports for the year ended December 31, **2022-2023**; • the impact of our investments in research and development and commercial growth; • negative publicity regarding our or our competitors' products resulting from scientific publications, or defects or errors in the products; and • our ability to further validate our products through clinical research and accompanying publications. We cannot assure you that we will be successful in addressing each of these factors or other factors that might affect the market acceptance of our products. If we are unsuccessful in achieving and maintaining market acceptance of our products, our business and results of operations will suffer. New product development involves a lengthy and complex process, and we may be unable to develop and commercialize, or receive reimbursement for, on a timely basis, or at all, new products. We continually seek to develop new product offerings, which requires us to devote considerable resources to research and development. Before we can commercialize a new pipeline product, we will need to expend significant resources in order to conduct substantial research and development, including clinical utility and validity studies, and further develop and scale our laboratory processes and infrastructure to accommodate additional products. For example, in 2021, we launched our innovative pipeline to develop a genomic test **, or series of genomic tests,** aimed at predicting response to systemic therapy in patients with moderate to severe psoriasis, atopic dermatitis and related inflammatory skin conditions. ~~We have~~ **With this launch, we** initiated our ~~IDENTITY Study~~, a **large 4,800 patient,** prospective, multi-center clinical study to develop and validate this inflammatory skin disease pipeline **program. We announced early discovery** test with the expectation of having initial validation and development data **from this study** in **October 2023 and in are targeting launching— launch of** this pipeline **test program** by the end of 2025. Our product development process takes time and involves a high degree of risk, and such development efforts may fail for many reasons, including failure of the product to perform as expected, failure to successfully complete analytic and clinical validation, or failure to demonstrate the clinical utility of the product. As we develop new products, we will have to make significant investments in research and development, marketing, selling, coverage and reimbursement activities. Typically, few research and development projects result in a commercialized product, and there can be no assurance that we will be able to successfully develop new products that can be commercialized. At any point, we may abandon development of a product or we may be required to expend considerable resources conducting research, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to

demonstrate the prospectively defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity or clinical utility, we might choose to abandon the development of the product, which could harm our business. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost. We may experience limits on our revenue if we are unable to increase and support adoption of our products by physicians and other healthcare providers. Physicians and other healthcare providers may be unwilling to adopt our products due to their reliance on existing traditional clinical and pathology staging criteria and our ability to generate revenue from our products would be significantly impaired if we were unable to educate physicians, healthcare providers, patients and third- party payors about the benefits and advantages of our products.

~~The COVID-19 crisis has impacted our in-person healthcare interactions, such as field-based sales and medical affairs, and we have had to convert visits, programs and projects to be performed online and by telephone. Although our in-person healthcare interactions have returned to more normal levels, they may become subject to restrictions or cancellations from time to time, due to the uncertainties surrounding the duration, extent and ongoing impacts of the COVID-19 crisis, possibly impacting the effectiveness of our efforts.~~

We will need to continue to educate physicians and pathologists about the benefits and cost- effectiveness of our products through published papers, presentations at scientific conferences, one- on- one marketing efforts by our sales force and one- on- one education by our medical affairs team. However, physicians and other healthcare providers may be reluctant to adopt our products in circumstances where our products are not incorporated into the current standard of care or practice guidelines. For example, while clinical utility of DecisionDx- Melanoma has been demonstrated in peer- reviewed publications, SLNB surgery is the most widely used pathology staging tool by clinicians for determining a cutaneous melanoma patient' s metastatic risk. Whether healthcare providers adopt DecisionDx- Melanoma as a complementary or triage diagnostic method relative to the SLNB surgery will depend on our ability to increase awareness of DecisionDx- Melanoma and its clinical validation. In addition, all of our testing services are performed by our certified laboratories located in Phoenix, Arizona ;and Pittsburgh, Pennsylvania, under CLIA rather than by local laboratory or pathology practices. Accordingly, it may be difficult for us to collect samples from pathologists, and pathologists may be reluctant to support our testing services. We rely on limited or sole suppliers for some of the reagents, equipment, chips and other materials used by our products, and we may not be able to find replacements or transition to alternative suppliers. We rely on limited or sole suppliers for certain reagents and other materials and components that we use for our products. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in laboratory operations could occur, we may not be able to deliver patient reports on a timely basis, or at all, and we may incur higher one- time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available. If our testing volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new products, we may experience supply issues as we ramp up test volume, or encounter additional disruptions to trade, commerce, pricing stability, credit availability and global supply chain continuity as a result of the invasion of Ukraine by Russia, particularly if we contract with suppliers with operations or commercial relationships in Eastern Europe or to the extent the conflict escalates to involve additional countries, further economic sanctions or wider military conflict. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents or other materials we require for our products, our business, financial condition, results of operations and reputation could be adversely affected. If our products do not meet the expectations of clinicians and patients, our operating results, reputation and business could suffer. Our success depends on clinician and patient confidence that we can provide reliable, high- quality information that will improve treatment outcomes, lower healthcare costs and enable better patient care. We believe that patients, physicians and other healthcare providers are likely to be particularly sensitive to defects and errors in our products, including if our products fail to accurately predict risk of metastasis with high accuracy from samples, and there can be no guarantee that our products will meet their expectations. As a result, the failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or reports. If we are unable to compete successfully, our business will suffer and we may be unable to increase or sustain our revenue or achieve profitability. We face competition from companies and academic institutions that have either developed or may seek to develop products intended to compete with our products. In addition, competitors may develop their own versions of our solutions in countries where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their solutions by clinicians in other countries. Some potential competitors may have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third- party payors. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their products than we do or sell their products at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Increased competition and cost- saving initiatives on the part of governmental entities and other third- party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well- established and well- financed companies. Certain potential competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to test development than we can. In

addition, companies or governments that control access to testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, our business will suffer and we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline. As we add new tests and services, we will face many of these same competitive risks for these new tests. **Impairment of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired, and intangible assets are measured at fair value upon the acquisition of a business for purposes of such calculations. As of December 31, 2023, our goodwill and other intangible assets balances were \$ 10. 7 million and \$ 106. 6 million, respectively. Goodwill is evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors could result in an impairment of goodwill or other intangible assets and, in turn, a charge to net income or loss. Any future charges could have a material adverse effect on our results of operations or financial condition. On June 2, 2023, a MAC finalized an LCD pursuant to which the DecisionDx- SCC test would no longer be covered by Medicare effective July 17, 2023. On June 5, 2023, our stock price decreased significantly and did not recover before June 30, 2023. In response to this trigger, we tested goodwill for impairment at June 30, 2023. We elected to bypass the optional qualitative assessment and proceeded directly to the quantitative assessment. In conducting our interim test, we concluded that our business consists of a single reporting unit. To measure the fair value of our reporting unit, we used a market approach whereby we calculated our total market capitalization on the impairment test date, based on the closing price of our common stock as reported on the Nasdaq Global Market, and applied a reasonable control premium. The control premium was based on an analysis of control premiums paid in recent acquisitions of companies in the same or similar industry as us. Our impairment test indicated that the fair value of our reporting unit exceeded its carrying value by 13 % and therefore no impairment was indicated. In July 2023, the MAC suspended the LCD and then posted a new draft LCD for comment that is substantially the same as the LCD that was to become effective. During the third quarter of 2023, we continued to monitor our market capitalization against the carrying value of our reporting unit and did not observe any significant changes since our impairment test at June 30, 2023. We have performed our annual impairment test, as of October 1, 2023, and we have not identified any additional indicators of impairment to date. Factors that could result in a future impairment of goodwill include declines in the price of our common stock, increased competition, changes in macroeconomic developments, unfavorable government or regulatory developments and changes in coverage or reimbursement conditions.** The sizes of the TAM for our current and future products have not been established with precision and may be smaller than we estimate. Our estimates of the TAM for the DecisionDx- Melanoma, DecisionDx- UM, DecisionDx- SCC, MyPath Melanoma, ~~DiffDx- Melanoma~~, TissueCypher and IDgenetix tests are based on a number of internal and third- party estimates, including, without limitation, the annual rate of patients with the applicable indications, the list price of our products relative to the reimbursement we expect to receive from third- party payors and the assumed prices at which we can sell our products in markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual TAM for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual TAM for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. The diagnostic testing industry is subject to rapid change, which could make our current or future products obsolete. Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current products and the other products we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of clinicians and patients on a timely and cost- effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our existing products and develop new products to keep pace with evolving standards of care. If we do not update our products to reflect new scientific knowledge about cancer biology, information about new cancer therapies or relevant clinical studies, our products could become obsolete and sales of our current products and any new products we develop could decline or fail to grow as expected. **Our business operations may subject us to disputes, claims, government investigations and lawsuits, which may be costly and time- consuming and could materially and adversely impact our financial position and results of operations. From time to time, we may become involved in disputes, claims, government investigations and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, financial arrangements with health care providers, regulatory compliance, product promotional practices, and documentation, coding and billing practices, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage, and acquisition or divestiture- related matters. Any dispute, claim, government investigation or lawsuit may divert management' s attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. For example, as described further in “ Item 3. Legal**

Proceedings,” on February 1, 2024 we received a subpoena from United States Department of Health and Human Services Office of Inspector General. This inquiry, and any potential resulting claim asserted against us, with or without merit, could be time-consuming, expensive to address and divert management’s attention and other resources. These claims also could subject us to significant liability for damages and harm our reputation. Our insurance and indemnities may not cover all claims that may be asserted against us. Additionally, the associated uncertainty could lead to increased volatility in our stock price and governmental enforcement action may result in substantial fines, penalties or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which would entail significant obligations and costs.

Risks Related to Reimbursement and Government Regulation We generally have limited reimbursement coverage for our products, and if third-party payors, including government and commercial payors, do not provide sufficient coverage of, or adequate reimbursement for, our products, our commercial success, including revenue, will be negatively affected. Our revenue depends on achieving broad coverage and adequate reimbursement for our products from third-party payors, including both government and commercial third-party payors. If third-party payors do not provide coverage of, or do not provide adequate reimbursement for, a substantial portion of the list price of our products, we may need to seek additional payment from the patient beyond any co-payments and deductibles, which may adversely affect demand for our products. Coverage determinations by a third-party payor may depend on a number of factors, including, but not limited to, a third-party payor’s determination of whether our products are appropriate, medically necessary or cost-effective. If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our products, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenues and our ability to succeed. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our products may decrease as we encounter pricing pressure from these competitors. Since each third-party payor makes its own decision as to whether to establish a policy to cover our products, enter into a contract with us and set the amount it will reimburse for a product, these negotiations are a time-consuming and costly process, and they do not guarantee that the third-party payor will provide coverage or adequate reimbursement for our products. In addition, the determinations by a third-party payor whether to cover our products and the amount it will reimburse for them are often made on an indication-by-indication basis. In cases where there is no coverage policy or we do not have a contracted rate for reimbursement as a participating provider, the patient is typically responsible for a greater share of the cost of the product, which may result in further delay of our revenue, increase our collection costs or decrease the likelihood of collection. Our claims for reimbursement from third-party payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming and expensive and may not result in payment. Third-party payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the third-party payors believe the funds were paid in error or determine that our products were medically unnecessary. If a third-party payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial third-party payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the third-party payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on current claims. We cannot predict when, or how often, a third-party payor might engage in these reviews and we may not be able to dispute these retroactive adjustments. Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating clinician. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. For these fully constrained claims, we generally recognize revenue in the period the uncertainties are resolved, if favorable. Due to potential future changes in Medicare coverage policies and appeal cycles, insurance coverage policies, contractual rates and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period. Although we are an in-network participating provider with some commercial third-party payors, including several Blue Cross Blue Shield plans, and certain large, national commercial third-party payors, including Aetna, other commercial third-party payors have issued non-coverage policies that currently categorize our tests as experimental or investigational. If we are not successful in obtaining coverage from third-party payors, in reversing existing non-coverage policies, or if other third-party payors issue similar non-coverage policies, this could have a material adverse effect on our business and operations.

Palmetto, the MAC responsible for administering MolDX, the program that assesses molecular diagnostic technologies, issued a final LCD for DecisionDx–Melanoma, which became effective on December 3, 2018, and issued a final expanded LCD effective November 22, 2020. This LCD provides for coverage of DecisionDx–Melanoma for certain SLNB-eligible patients with cutaneous melanoma tumors with clinically negative sentinel node basins who are being considered for SLNB to determine eligibility for adjuvant therapy. The final expanded LCD also covers use of DecisionDx–Melanoma by clinicians for assessment of appropriate treatment plans, regardless of the decision to undergo or avoid the SLNB surgery. In the second quarter of 2021, Palmetto and the other MACs that participate in the MolDX program each released a revised draft LCD for DecisionDx–Melanoma. The draft LCD included commentary about two publications regarding the clinical utility of GEP tests and included an assessment stating that the new data is not sufficient to change the coverage criteria. There was an open public comment

period, and we submitted comments in support of Medicare coverage. The comment period ended on August 8, 2021. Palmetto issued a final LCD on May 19, 2022 with Noridian issuing the same on June 16, 2022. The final LCDs did not result in any change in coverage. Separately, Palmetto issued a final LCD for DecisionDx-UM effective July 10, 2017. This LCD provides for coverage of DecisionDx-UM to determine metastatic risk in connection with the management of a patient's newly diagnosed UM and to guide surveillance and referral to medical oncology for those patients. We worked with Palmetto to obtain these positive coverage decisions through the submission of a detailed dossier of analytical and clinical data to substantiate that the tests meet Medicare's medical necessity requirements. Per their joint operating agreement, Noridian, the MAC responsible for administering claims for laboratory services performed in Arizona, has adopted the same coverage policy as Palmetto for DecisionDx-UM and DecisionDx-Melanoma. Separately, we also have received Medicare coverage for our MyPath Melanoma, DecisionDx-SCC, TissueCypher and IDgenetix tests. The process to obtain Medicare coverage is lengthy, time-consuming, has changed over time, may change in the future and requires significant dedication of resources, and as we develop or acquire new products, we may be unsuccessful in receiving Medicare coverage for those products or in maintaining our current Medicare coverage. On a periodic basis, CMS requests bids for its MAC services, and MAC jurisdictions have changed in the past. A change in our MAC, or future changes in the MolDX program, the elimination of the program, or a change in the administrator of that program, may affect our ability to obtain/maintain Medicare coverage and reimbursement for products for which we have coverage, obtain Medicare coverage for products for which we do not yet have coverage, or obtain Medicare coverage for any products we may launch in the future, or delay payments for our tests. Additionally, MACs that currently provide coverage for our products may periodically reevaluate their coverage decisions and decide to withdraw coverage based on a number of factors that we may not be able to predict or control. Accordingly, current Medicare coverage of our tests or a history of coverage by Medicare is no guarantee of future Medicare coverage. We have received positive coverage decisions and receive Medicare reimbursement for our DecisionDx- Melanoma, DecisionDx- UM, MyPath Melanoma tests, and IDgenetix. Our DecisionDx- SCC and TissueCypher tests receive Medicare reimbursement as well. If coverage for one or more of our products is withdrawn, our business could be adversely impacted. On June 2, 2023, Novitas posted a finalized oncology biomarker LCD pursuant to which the DecisionDx- SCC test would no longer be covered by Medicare effective July 17, 2023. However, on July 6, 2023, Novitas suspended the final version of the LCD and announced its intent to post a new proposed LCD for comment and presentation at an open meeting. On July 27, 2023, Novitas posted a nearly identical proposed oncology biomarker LCD that continues to intend to rely upon evidentiary reviews sourced from three databases: ClinGen, OncoKB and NCCN. The proposed LCD also recommends non- coverage for our DecisionDx- SCC test. The comment period for the proposed LCD ended on September 9, 2023. We cannot predict whether this LCD will be finalized as proposed or what the timing of any final LCD might be. Under Medicare, payment for products like ours is generally made under the CLFS with payment amounts assigned to specific procedure billing codes. Medicare reimbursement rates for our tests are subject to change and may decrease from those currently in effect. For example, in February 2023, MolDX notified us that as part of its annual CPT code updates IDgenetix should shift billing to a different multi- test generic gene sequencing CPT code and continue using the IDgenetix Z- Code beginning in March 2023. The New CPT Code is currently contractor priced at As a result of this change, the Medicare reimbursement rate for the IDgenetix multi- gene panel decreased from approximately \$ 1, 500 to \$ 917 while it goes through per test. We subsequently obtained a test- specific PLA CPT code which became effective October 1, 2023. In November 2023, CMS posted its final CLFS determination which crosswalks our PLA 's Gapfill pricing process in 2023. The New CPT Code code does not describe all to an existing PLA code at a rate of the components of the IDgenetix \$ 1, 336 per test. We effective January 1, 2024 therefore, do not believe the New CPT Code, in conjunction with the IDgenetix Z- Code, provides additional specificity and thus we believe the New CPT Code is not appropriate for IDgenetix. In April 2014, Congress passed the PAMA which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, certain laboratories are required to report to CMS commercial third- party payor payment rates and volumes for each test they perform. CMS uses this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We bill Medicare for our products, and therefore we are subject to reporting requirements under PAMA. In the second quarter of 2020, we submitted our technical assessment dossier for DecisionDx- SCC to Palmetto. The dossier was accepted as complete in the third quarter of 2020. In early 2021, we submitted our technical assessment dossier for DiffDx- Melanoma. The dossier was accepted as complete in the first quarter of 2021. In June 2022, Palmetto and Noridian each posted a draft LCD that would provide coverage criteria for DiffDx- Melanoma, and each of the comment periods closed during the third quarter of 2022. We believe the LCD for DiffDx- Melanoma will be finalized by the end of the second quarter of 2023. However, there is no assurance that any draft or final LCD will match our expectations, be posted in a timeframe consistent with our historical experience or will be posted at all. Regarding DecisionDx- SCC, no draft LCD has been posted by Palmetto or Noridian to date. In the second quarter of 2022, following the completion of a requested medical review and pricing of our DecisionDx- SCC test by Novitas, we obtained a PLA code and began receiving reimbursement from Novitas for DecisionDx- SCC at a rate of approximately \$ 3, 800 per test. In November 2022, CMS set our rate of reimbursement for DecisionDx- SCC at \$ 3, 873 per test. DecisionDx- SCC will go through CMS' s Gapfill pricing process in 2023, which we expect to conclude in late 2023. We expect our current rate of \$ 3, 873 per test to be maintained through the Gapfill process and for the Gapfill rate to go into effect in 2024. On June 9, 2022, Novitas posted a draft oncology biomarker LCD that proposes to rely upon evidentiary reviews sourced from three databases for all oncology biomarker tests: ClinGen, OncoKB and NCCN. We believe the purpose of the proposals in this draft LCD are to streamline future reviews. Two of the databases do not review GEP tests and NCCN has not yet, to our knowledge, reviewed DecisionDx- SCC. If finalized as proposed, then DecisionDx- SCC would not be included as a covered test in the associated billing and coding article. The

comment period for the draft LCD ended on September 6, 2022. We cannot predict whether this draft LCD will be finalized as proposed or what the timing of any final LCD might be. If we are unable to obtain and maintain adequate reimbursement rates from commercial third- party payors, this may adversely affect our Medicare rate. It is unclear what impact new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations or cash flows. The U. S. federal government continues to show significant interest in pursuing healthcare reform and reducing healthcare costs. Similarly, commercial third- party payors may seek to reduce costs by limiting coverage or reducing reimbursement for our products. Any government- adopted reform measures or changes to commercial third- party payor coverage and reimbursement policies could cause significant pressure on the pricing of, and reimbursement for, healthcare products and services, including our products, which could decrease demand for our products, and adversely affect our sales and revenue. In addition, some third- party payors have implemented, or are in the process of implementing, laboratory benefit management programs, often using third- party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence- based guidelines for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it could have a negative impact on our revenue in the short term. It is possible that third- party payors will resist reimbursement for the products that we offer, in favor of less expensive products, may require pre- approval for our products or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our products. We expect to continue to focus substantial resources on increasing coverage and reimbursement for our current products and any future products we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of third- party payors for our products. However, we cannot predict whether, under what circumstances, or at what payment levels third- party payors will cover and reimburse our products. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our products, our ability to generate revenue could be harmed and our future prospects and our business could suffer. Our products are currently marketed as laboratory developed tests, and any changes in regulations or the FDA' s enforcement discretion for laboratory developed tests, or violations of regulations by us, could adversely affect our business, prospects, results of operations or financial condition. The diagnostics industry is highly regulated, and we cannot assure you that the regulatory environment in which we operate will not change significantly and adversely in the future. In many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics that are designed, manufactured and used within a single laboratory. These tests are referred to as LDTs. We currently market our products as LDTs. The FDA has adopted a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively require premarket review of LDTs or otherwise impose its requirements applicable to other medical devices on LDTs. **However, On October 3, 2023, the FDA has stated issued proposed regulations under which its- its intention to modify would phase out its enforcement discretion approach policy with respect to LDTs over a period of four years. Although the proposed regulation The FDA could ultimately modify its- is subject current approach to LDTs in a way that period of notice and comment, if finalized as proposed, we would be subject our products marketed as LDTs to the enforcement of additional regulatory requirements. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require required premarket review of and regulate LDTs. If and when such changes to the regulatory framework occur, we could obtain 510 (k) or PMA for the first time certain of our tests by October 1, 2027. We would also be subject to enforcement of regulatory requirements as a manufacturer such as registration and listing requirements, medical device reporting requirements and the requirements of the FDA' s Quality System Regulation. We may be required to conduct clinical trials prior to continuing to sell our existing products or launching any other products we may develop. This may increase the cost of conducting, or otherwise harm, our business. Moreover, even Even if the FDA does not modify its policy of enforcement discretion, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements. While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, we cannot assure you that the FDA will agree with our determination. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition. If the FDA begins to actively regulate our diagnostic products, we may be required to obtain premarket clearance under Section 510 (k) of the FDCA or a PMA. The process for submitting a 510 (k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer, and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510 (k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will be cleared or approved by the FDA through either the 510 (k) clearance process or the PMA process on a timely basis, or at all. Moreover, there can be no assurance that any cleared or approved labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our products. If premarket review is required for some or all of our products, the FDA may require that we stop selling our products pending clearance or approval, which would negatively impact our business. Even if our products are allowed to remain on the market prior to clearance or approval, demand or reimbursement for our products may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our products, or from other pipeline products. If the FDA imposes significant changes to the regulation**

of LDTs it could reduce our revenues or increase our costs and adversely affect our business, prospects, results of operations or financial condition. We conduct business in a heavily regulated industry, and failure to comply with federal, state and foreign laboratory licensing requirements including those established by CMS and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions. The diagnostics industry is highly regulated, and the laws and regulations governing the marketing of diagnostic tests are extremely complex. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation: • federal and state laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and / or regulatory agencies enforcing those laws and regulations; • federal and state fraud and abuse laws; • federal and state laboratory anti- mark- up laws; • coverage and reimbursement levels by Medicare, Medicaid, other governmental payors and private insurers; • restrictions on coverage of and reimbursement for tests; • federal and state laws governing laboratory testing, including CLIA, and state licensing laws and accreditation requirements; • federal and state laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including LDTs; • federal, state and local laws governing the handling and disposal of medical and hazardous waste; • federal and state Occupational Safety and Health Administration rules and regulations; and • HIPAA and similar state health data privacy laws. In particular, the FDCA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Our products are considered by the FDA to be subject to regulation as medical devices, and marketed under FDA's policy of enforcement discretion for LDTs. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices manufactured between the United States and international markets. CLIA Certifications We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. Any testing subject to CLIA regulation must be performed in a CLIA- certified or accredited lab. CLIA certification or accreditation is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial third- party payors, for our products. CAP maintains a clinical laboratory accreditation program. While not required for the operation of a CLIA- certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. CAP accredited laboratories are surveyed for compliance with CAP standards every two years in order to maintain accreditation. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our products and the results of our operations. Therefore, to maintain our CLIA accreditation, we have elected to be subject to survey and inspection every two years by CAP. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time. We have a current CLIA accreditation under the CAP program to conduct our tests at our clinical reference laboratories in Phoenix, Arizona. The most recent CAP inspection of our Phoenix, Arizona laboratories occurred in October 2022. We currently have a CLIA certificate of registration for our Pittsburgh, Pennsylvania laboratories **laboratory** which expires in February 2024. In November 2022, our Pittsburgh, Pennsylvania passed CAP inspection and received CAP accreditation. ~~We have since applied for, and are currently waiting to receive, our updated CLIA accreditation for our Pittsburgh, Pennsylvania laboratories.~~ In addition, certain states require our laboratories to be licensed in specific states in order to test specimens from those states. Accordingly, our laboratories are licensed by California, Maryland, Pennsylvania, Rhode Island and New York. Other states do not currently require additional licensure **but** they may adopt similar requirements in the future. Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out- of- state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future. In order to test specimens from New York, LDTs must be approved by the NYSDOH on a test- by- test basis before they are offered. Our laboratory director and laboratory operations must also be separately qualified and approved through the state of New York. DecisionDx- Melanoma, DecisionDx- CMSeq, DecisionDx- UM, DecisionDx- PRAME, DecisionDx- UMSeq, DecisionDx- SCC, MyPath Melanoma, **and** DiffDx- Melanoma **and** IDgenetix **have each been approved. We have been given conditional approval for IDgenetix from the NYSDOH while we work our way through the formal approval.** In July 2022, we submitted TissueCypher for review by the NYSDOH and ~~expect a response in~~ **had been given clearance to test New York state patients by the first quarter of New York's Clinical Laboratory Evaluation Program while our applications were under review. On September 12, 2023, we received our Clinical Laboratory Permit from NYSDOH for our Pennsylvania laboratory.** Our laboratory director has been qualified by the NYSDOH. We are subject to periodic inspection by the NYSDOH and are required to demonstrate ongoing compliance with the NYSDOH regulations and standards. Our most recent inspection was in October 2022 and we were deemed to be compliant with the NYSDOH regulations and standards. To the extent the NYSDOH had identified any instances of non- compliance, and we were unable to remedy such non- compliance, the State of New York could withdraw approval for our products to test samples from New York state. We will need to seek the NYSDOH approval of any future LDTs we develop and want to offer for clinical testing to New York residents, and there can be no assurance that we will be able to obtain such approval. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our products or such jurisdictions adopt new licensure requirements, which may require review of our products in order to offer them or may have other limitations such as restrictions

on the transport of human tissue samples necessary for us to perform our tests that may limit our ability to make our products available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays. Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA accreditation and / or state licenses, imposition of a directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA accreditation, or a state or foreign license, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so. Doing business with the public sector, including the U. S. government, subjects us to risk of audits, investigations, sanctions and penalties. We have entered into, and may enter into in the future, contracts with the U. S. government or other governmental entities, and this subjects us to statutes and regulations applicable to companies doing business with the government. For example, we have a U. S. Federal Supply Schedule contract with the Veterans Health Administration covering our ~~skin cancer~~ **covering all of our tests with the exception of DecisionDx- UM**. Government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits (or increase our losses) and expose us to liability for failure to comply with these terms and conditions. Such requirements may include mandatory socioeconomic compliance requirements, including labor requirements, non-discrimination and affirmative action programs and environmental compliance requirements. Being a government contractor also subjects us to reviews, audits and investigations regarding our compliance. If we fail to comply with our obligations associated with being a government contractor, our contracts may be subject to termination, and we may be subject to financial and / or other liability under our contracts, which could adversely affect our results of operations. The FDA may modify its enforcement discretion policy with respect to LDTs in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business. If the FDA changes or ends its policy of enforcement discretion with respect to LDTs, **whether by finalization of regulations initial proposed on October 3, 2023, or otherwise**, and our products become subject to the FDA's requirements for premarket review of medical devices, we may be required to cease commercial sales of our products and conduct clinical trials prior to making submissions to the FDA to obtain premarket clearance or approval. If we are required to conduct such clinical trials, delays in the commencement or completion of clinical trials could significantly increase our product development costs and delay commercialization of any currently marketed testing that we may be required to cease selling or the commercialization of any future tests that we may develop. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health. Even if we were able to obtain FDA clearance or approval for one or more of our products, if required, a diagnostic test may be subject to limitations on the indications for which it may be marketed or to other regulatory conditions. In addition, such clearance or approval may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the test. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approvals. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. **Furthermore, government funding of the FDA other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other government agencies may impact the ability of such agencies to timely review and process our regulatory and other submissions, which could have a material adverse effect on our business.** Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the

preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become **becomes** available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and marketing efforts. Further, others, including healthcare providers or payors, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the topline or interim data that we report differ from actual results, or if others, including healthcare providers or payors, disagree with the conclusions reached, our ability to commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our products. In March 2010, the ACA became law. This law substantially changed the way healthcare is financed by both government and commercial third- party payors, and significantly impacted our industry. Among other things, the ACA required medical device manufacturers to pay a sales tax equal to 2.3 % of the price for which such manufacturer sells its medical devices, and began to apply to sales of taxable medical devices after December 31, 2012, but was suspended in 2016. Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the medical device tax and “Cadillac” tax on high- cost employer- sponsored health coverage and, effective January 1, 2021, also eliminated the health insurer tax. Since 2016, there have been efforts to repeal all or part of the ACA, and the previous administration and the U. S. Congress have taken action to roll back certain provisions of the ACA. For example, on June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “ individual mandate ” was repealed by Congress. Further, there have been a number of health reform measures by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures of the Biden administration will impact the ACA and our business. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2 % per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until ~~2031~~ **2032**, unless additional Congressional action is taken. ~~Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester.~~ We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial third- party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our products, the coverage of or the amounts of reimbursement available for our products from third- party payors, including government and commercial payors. We are subject to numerous federal and state healthcare statutes and regulations, and complying with laws pertaining to our business is an expensive and time- consuming process. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties and a material adverse effect to our business and operations. Physicians, other healthcare providers and third- party payors play a primary role in the recommendation of our products. Our arrangements with healthcare providers, third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that affect the business and financial arrangements and relationships through which we market and sell our products. The laws that affect our ability to operate include, but are not limited to: • the AKS, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “ remuneration ” has been broadly interpreted to include anything of value, such as specimen collection materials or test kits. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, however these are drawn narrowly. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and monetary penalties of up to \$ 100, 000 for each violation, plus up to three times the remuneration involved, imprisonment of up to ten years and exclusion from government healthcare programs. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA; • the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties and exclusion from the federal healthcare programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA; • federal civil and criminal false claims laws, such as the FCA, which can be enforced by private citizens through civil qui tam action, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented through distribution of template medical

necessity language or other coverage and reimbursement information, false, fictitious or fraudulent claims for payment or approval by the federal government, including federal healthcare programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Private individuals can bring FCA “ qui tam ” actions, on behalf of the government and such individuals, commonly known as “ whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs; • the EKRA prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal healthcare programs to include private insurance (i. e., it is an “ all payor ” statute). For purposes of EKRA, the term “ laboratory ” is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal AKS exceptions and safe harbors, and others that materially differ; • HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information as well as their covered subcontractors. Failure to comply with the HIPAA’s obligations can result in civil monetary penalties, and, in certain circumstances, criminal penalties. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U. S. federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions; • state laws that prohibit other specified practices, such as billing physicians for tests that they order or providing tests at no or discounted cost to induce physician or patient adoption; insurance fraud laws; waiving coinsurance, ~~co-payments~~ **payments**, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other third- party payors employing, exercising control over or splitting professional fees with licensed professionals in violation of state laws prohibiting fee splitting or the corporate practice of medicine and other professions; • federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and information regarding physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations. We believe that we are exempt from these reporting requirements. We cannot assure you, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business; • the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other part; • state and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, which may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non- governmental third- party payors, including private insurers; and • federal, state, local and foreign laws that govern the privacy and security of health information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health- related and other personal **information data**, many of which differ from each other in significant ways and **may often are not be** pre- empted by HIPAA, thus complicating compliance efforts. As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the OIG and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from patients. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories. We have entered into consulting and scientific advisory board arrangements, speaking arrangements and clinical research agreements with physicians and other healthcare providers, including some who could influence the use of our products. Because of the complex and far- reaching nature of these laws, regulatory agencies may view these transactions as prohibited

arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of our products to be in violation of applicable laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with physicians, as well as our financial assistance programs, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. Responding to investigations can be time and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations is costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. We are subject to certain U. S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations and may become subject to their similar foreign equivalents. We can face serious consequences for violations. U. S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations prohibit, among other things, companies and their employees, agents, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect that we may engage in non-U. S. activities over time. We expect to rely on third-party suppliers and / or third parties to obtain necessary permits, licenses, and patent registrations. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We are subject to stringent and changing state, federal, local, foreign, and other privacy and security laws, regulations ~~and~~ rules, contractual obligations, **industry standards**, policies and other obligations, and our failure to comply or perceived failure to comply with those obligations could result in regulatory investigations or actions; litigation **(including class claims) and mass arbitration demands**; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of our business, we collect, store, use, transmit, disclose, or otherwise process ("Process") confidential, proprietary, and sensitive data, including PHI, personal ~~information-data~~, credit card and other financial information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payors and other parties. Our data processing activities may subject us to numerous data privacy and security obligations, such as laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the Processing of personal ~~information-data~~ by us and on our behalf. In the United States, numerous federal, state, and local governments have enacted data privacy and security laws, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. **Additionally, In the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted several comprehensive privacy laws governing that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning the their Processing of personal information-data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), as amended by which provides California residents certain rights relate to their personal information, the California Rights Privacy Act of 2020 ("CPRA") (collectively, effective January 1, 2023, which will expand the "CCPA"). applies including by applying to personal information-data of consumers, business representatives and employees who are and establishing a new regulatory agency to implement and enforce the law; and the California residents Confidentiality of Medical Information Act, which restricts the use and requires businesses to provide specific disclosure disclosures of health information in privacy notices and honor requests of such individuals to exercise certain privacy**

rights. The CCPA provides for fines of up to \$ 7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other personal information states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. Although these states, like the CCPA, and the CPRA exempt some personal information data processed in the context of clinical trials, these developments CCPA and CPRA, to the extent applicable to our business and operations, may increase compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, other U. S. states have enacted or proposed privacy laws, further complicating **complicate our** compliance efforts **and costs and increase legal risk for us and the third parties upon whom we rely**. Outside the United States, there are also an increasing number of laws, regulations, industry standards and other obligations concerning privacy and data security. For ~~including for~~ example, we may be subject to the EU European Union's General Data Protection Regulation ("EU") 2016 / 679 ("EU GDPR") and the UK United Kingdom's GDPR ("UK GDPR") (collectively, "**GDPR**"). Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Our employees and personnel use, or may use, generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. In addition ~~the ordinary course of business~~, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries ~~due to data localization requirements or limitations on cross-border data flows~~. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the United States in compliance with law, such as the EEA ~~and standard contractual clauses~~, the UK's ~~standard contractual clauses~~ **International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework)**, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. In addition, privacy advocates and industry groups have proposed, and may in the future propose, standards with which we are legally or contractually bound to comply. In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. For example, we are subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from \$ 5,000 to \$ 100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We rely on vendors to process payment card data, and those vendors may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance. More generally, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, the CCPA, and the CPRA, may require our customers to impose specific contractual restrictions on their service providers. Additionally, we publish privacy policies and other statements regarding data privacy and security, and, if these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we could experience adverse consequences. Obligations related to data privacy and security **(and consumers' data privacy expectations)** are quickly changing in an increasingly stringent fashion, creating regulatory uncertainty as to the effective future legal framework. These obligations may be subject to varying applications and interpretations, which may be inconsistent or conflicting among jurisdictions, creating complex compliance issues for us and our clients. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal ~~information data~~ on our behalf. In addition, these obligations may require us to change our business model or to take on more onerous obligations in our contracts. Although we endeavor to comply with all applicable obligations, we may, at times, fail or be perceived to have failed to do so. Moreover,

despite our efforts, our personnel or third parties upon whom we rely on may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Failure or perceived failure to comply with these obligations could result in significant consequences, including but not limited to government enforcement actions (~~which could include civil~~ **e. g. criminal investigations, and administrative fines, penalties, audits, inspections, and similar**), ~~private litigation~~ **(including class- action claims) and mass arbitration demands**, additional reporting requirements and / or oversight, bans on processing personal ~~information- data~~ **information- data**, and orders to destroy or not use personal ~~information- data~~ **information- data**. **In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations**. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: **inability to process personal data or to operate in certain jurisdictions**, increase our cost of providing our services, decrease demand for our services, reduce our revenue, interrupt our business operations **(including our clinical trials)**, limit our ability to develop our services, expenditure of time and resources to defend any claim or inquiry, **and adverse publicity, or substantial changes to our business model or operations**. Ethical, legal and social concerns related to the use of genetic information could reduce demand for our products. Genetic testing has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities have, through the Genetic Information Nondisclosure Act of 2008, and could further, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Ethical and social concerns may also influence governmental authorities to deny or delay the issuance of patents for technology relevant to our business. While we do not currently perform genetic tests for genetic predisposition to certain conditions, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, our genomic tests or genetic tests for somatic mutations even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our products or reduce the potential markets for our products, either of which could have an adverse effect on our business, financial condition, or results of operations. **Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance (“ ESG ”) matters, may expose us to reputational and other risks. Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or that are perceived to have not responded appropriately, may suffer from reputational damage, which could result in the business, financial condition and / or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and / or third- party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation.**

Risks Related to Intellectual Property If we are unable to obtain and maintain sufficient intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize diagnostic tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired. We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection as well as nondisclosure, confidentiality and other contractual restrictions to protect our brands and proprietary tests and technologies, 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. In addition, we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. As is the case with other life science companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely or jointly with others or in- license from others, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing life sciences patents is costly, time- consuming and complex, and we may fail to apply for patents on important tests, services and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent portfolio as of December 31, ~~2022~~ **2023** includes ~~15~~ **16** issued U. S. patents and ~~ten~~ **13** pending U. S. patent applications, with foreign counterparts. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable tests or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our future patented technologies. We may not be successful in defending any such challenges made against our patents or patent applications. Any successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. Even if our patents are held valid and enforceable, they may still be found insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may have to challenge the patents or patent applications of third parties, such as to counter infringement or unauthorized use. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to enjoin the other party from using the technology at issue on the grounds that our patents do

not cover the technology in question. Even if we prevail against an infringer in a U. S. district court or foreign trial- level court, there is always the risk that the infringer will file an appeal and the initial court judgment will be overturned at the appeals court and / or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. The outcome of patent litigation or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business. The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the life sciences field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA sequences. In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests are particularly uncertain. Various courts, including the U. S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third- party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to life science technologies, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition, and our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time- consuming and expensive. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative: • others may be able to develop and / or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue; • we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed; • we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive tests for sale in our major commercial markets; • third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license; • parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property; • we may not develop or in- license additional proprietary technologies that are patentable; • we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business and results of operations. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other life sciences companies, our success is heavily dependent on intellectual property, particularly patents relating to our research programs and products. Obtaining and enforcing patents in the life sciences industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or the USPTO rules and regulations could increase these uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy- Smith America Invents Act (" AIA "), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The AIA includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent in USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. For applications filed after March 15, 2013 that do not claim the benefit of applications filed before that date, the AIA transitioned the United States from a first to invent system to a first- inventor- to- file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The U. S. Supreme Court has ruled on several

patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Our in- licensed intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as ‘ ‘ march- in’ ’ rights, certain reporting requirements and a preference for U. S.- based companies, and compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. Intellectual property rights that have been in- licensed pursuant to the License Agreement with WUSTL have been generated through the use of U. S. government funding, and are therefore subject to certain federal regulations. As a result, the United States federal government may retain certain rights to intellectual property embodied in our current or future product candidates under the Bayh- Dole Act. These federal government rights include a ‘ ‘ nonexclusive, nontransferable, irrevocable, paid- up license’ ’ to use inventions for any governmental purpose. The Bayh- Dole Act also provides federal agencies with ‘ ‘ march- in rights.’ ’ March- in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a ‘ ‘ nonexclusive, partially exclusive, or exclusive license’ ’ to a ‘ ‘ responsible applicant or applicants’ ’ if it determines that (1) adequate steps have not been taken to commercialize the invention, (2) government action is necessary to meet public health or safety needs or (3) government action is necessary to meet requirements for public use under federal regulations. If the patent owner refuses to do so, the government may grant the license itself. The U. S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States, and the License Agreement requires that we comply with this requirement. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or future in- licensed intellectual property is also generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Issued patents covering our products and related technologies could be found invalid or unenforceable if challenged. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications (including licensed patents) have been, are being or may be challenged at a future point in time in an opposition, nullification, derivation, reexamination, inter partes review, post- grant review or interference action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. Any successful third- party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could harm our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future diagnostic tests. We may not be aware of all third- party intellectual property rights potentially relating to our products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases (e. g., U. S. applications for which a request not to publish has been filed), not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we have and may have to participate in interference proceedings, derivation proceedings or other post- grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post- grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Therefore, the validity, enforceability and scope of our patents in the United States and other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction. Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties. The life sciences industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our potential competitors in both the United States and abroad, may have substantially greater resources and are likely to make substantial investments in patent portfolios and competing technologies, and may apply for or obtain patents that could prevent, limit or otherwise interfere with our ability to make, use and sell our products. Numerous third- party patents exist in fields relating to our products and technologies, and it is difficult for industry participants, including us, to identify all third- party patent rights relevant to our products and technologies. Moreover, because

some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products and technologies. Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation. From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our products, components of our products, and / or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or technologies do not infringe those third parties' patents;
- we may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products or technologies;
- if a competitor files patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our products or technologies infringe their patent or other intellectual property rights, we will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products and technologies; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our products or technologies infringe or misappropriate its patent or other intellectual property rights and / or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force us to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the diagnostic test or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party's attorneys' fees;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the diagnostic test or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such test or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our products and technologies so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with applicable third party, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims if our claims are held invalid or otherwise unenforceable.

Third parties may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact our business, cause delays, or prohibit us from marketing or otherwise commercializing our products and technologies. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows. We depend on information technology systems that we license from third parties. Any failure of such systems or loss of licenses to the software that comprises an essential element of such systems could significantly harm our business. We depend on information technology systems for significant elements of our operations, such as our Laboratory Information Management System, including test validation, specimen tracking and quality control, our bioinformatics analytical software systems, our test report generating systems and billing systems. Essential elements of these systems depend on software that we license from third parties. If we are unable to maintain the licenses to this software or our software providers discontinue or alter the programs on which we rely, it could render our test reports unreliable or hinder our ability to generate accurate test reports, among other things. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. We rely on licenses from third parties, and if we lose these licenses or are not able to obtain licenses to third-party technology on reasonable grounds or at all, then we may not be able to continue to commercialize existing diagnostic tests, be subjected to future litigation and may not be able to commercialize new diagnostic tests in the future. We are party to certain royalty-bearing license agreements that grant us rights to use certain intellectual property, including patents and patent applications, in certain specified fields of use. Although we intend to develop products and technologies through our own internal research, we may need to obtain additional licenses from

others to advance our research, development and commercialization activities. Our license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us. In the future, we may identify third- party technology we may need, including to develop or commercialize new diagnostic tests or services. In return for the use of a third party' s technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of the cost of our products or services and affect our margins. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercialized test. The in- licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in- license or acquire third- party intellectual property rights for technologies that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in- licensing or acquisition of third- party intellectual property rights for technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may not be able to obtain necessary or strategic licenses to patents or patent applications, and our business may suffer if we are unable to enter into these licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize tests and technology covered by these license agreements. If these in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, tests identical to ours and we may be required to cease our development and commercialization activities. For example, we license certain intellectual property from WUSTL that is incorporated into DecisionDx- UM. In 2022-2023, we provided over 1, 700-600 test reports for DecisionDx- UM. If the License Agreement were terminated, we would be unable to continue to issue test reports and thus sales of DecisionDx- UM. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Moreover, disputes may arise with respect to any one of our licensing agreements, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our products, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. If we do not prevail in such disputes, we may lose any of such license agreements. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected diagnostic tests, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. Our failure to maintain such licenses could have a material adverse effect on our business, financial condition and results of operations. Any of these licenses could be terminated, such as if either party fails to abide by the terms of the license, or if the licensor fails to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable. Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products or services, which could adversely affect our ability to offer our products or services, our ability to continue operations and our financial condition. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own tests or products and may also export infringing tests or products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products. Our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to life science technologies, which could make it difficult for us to stop the infringement of our patents in such countries. We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce our patent rights could result in

substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may not be able to stop a competitor from marketing and selling in foreign countries tests, products and services that are the same as or similar to our products and technologies, in which case our competitive position in the international market would be harmed. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed. In addition to pursuing patents on our technology, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We take steps to protect our trade secrets, in part, by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and once disclosed, we are likely to lose trade secret protection and may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We do and may employ individuals who previously worked with universities or other companies, including potential competitors. We could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer or competitor. Although, we are currently not subject to any such claims. While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Therefore, we could be required to obtain a license from such third-party employer to commercialize our products or technology. Such a license may not be available on commercially reasonable terms or at all. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We have not yet registered certain of our trademarks in all of our potential markets, although we have registrations for, among others, DecisionDx, DiffDx- Melanoma, DecisionDx- UM, DecisionDx- Melanoma, DecisionDx- SCC, MyPath Melanoma, TissueCypher and IDgenetix in the United States. Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely

affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in- licensed patents, trade secrets or other intellectual property as an inventor or co- inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our ~~or our~~ licensors' ownership of our owned or in- licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, right to use, or right to exclude others from using, intellectual property that is important to our products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications must be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, such as failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we, or our licensors, fail to maintain the patents and patent applications covering our products and technologies, potential competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time. Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent term has expired, we may be open to competition from competitive tests or products. Given the amount of time required for the development, testing and regulatory review of potential new tests or products, patents protecting such tests or products might expire before or shortly after such tests or products are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing tests or other products similar or identical to ours.

Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business We are highly dependent on the services of our key personnel. We are highly dependent on the services of our key personnel, including Derek J. Maetzold, our President and Chief Executive Officer. Although we have entered into agreements with our key personnel regarding their employment, they are not for a specific term and each may terminate their employment with us at any time, though we are not aware of any present intention of any of these individuals to leave us. Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our laboratory facilities and office spaces located in Phoenix, Arizona; Pittsburgh, Pennsylvania; and our corporate headquarters in Friendswood, Texas. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified salespeople. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. ~~This competition has become exacerbated by the increase in employee resignations currently taking place throughout the United States as a result of the COVID-19 pandemic, which is commonly referred to as the "great resignation."~~ We may also experience employee turnover as a result of the ongoing " great resignation. " In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing stockholders. All of our employees are at- will, which means that either we or the employee may terminate their employment at any time. ~~The~~ **With respect to equity compensation, as of December 31, 2022, we have granted awards in excess of the number of shares authorized for issuance under our** 2019 Equity Incentive Plan (the " 2019 Plan ") ~~. Although the 2019 Plan~~ provides for automatic increases in the number of shares authorized for issuance annually through January 1, 2029, **however**, there can be no assurances that these increases will be adequate to support our requirements for future equity awards or that we will be able to obtain approval from

our stockholders in the future should we require authorization for the issuance of additional shares. **For example, for the year ended December 31, 2022, we had granted awards in excess of the number of shares authorized for issuance under our 2019 Plan. As of December 31, 2023, there were 366, 432 shares available for grant under the 2019 Plan.** In December 2022, our board of directors adopted a separate equity plan, the 2022 Inducement Plan (the “ Inducement Plan ”), to be used exclusively for grants of awards as an inducement material to new employees entering into employment with us, **which was subsequently amended in November 2023 to increase the shares reserved under the plan.** However, the Inducement Plan cannot be used to grant ongoing equity awards to existing employees. If we are unable to provide adequate or competitive equity compensation, we may have to adjust other elements of our compensation packages and may encounter difficulties attracting and retaining personnel. Our employees, clinical investigators, consultants, speakers, vendors and any current or potential commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, clinical study investigators, consultants, speakers, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: federal laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information; manufacturing standards; federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad; sexual harassment and other workplace misconduct; or laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, 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 comply with these laws or regulations. 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 civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy. We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, human resources, laboratory operations, customer support and sales administration systems, processes and controls. Failure to effectively manage our anticipated growth could lead us to over- invest or under- invest in development, operational and administrative infrastructure, result in weaknesses in our infrastructure, systems, or internal controls, give rise to operational mistakes, losses, loss of customers, productivity or business opportunities, and result in loss of employees and reduced productivity of remaining employees. We also anticipate further growth in our business operations. For example, since May 2021, we have completed the acquisitions of Myriad MyPath Laboratory, Cernostics and AltheaDx, each of which we expect will contribute to our future growth. These acquisitions and other future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue increasing our headcount and hire more specialized personnel in the future as we grow our business and expand our product offerings. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, and sales and marketing staff and improve and maintain our technology to effectively manage our growth. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed. In addition, our anticipated growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new diagnostic tests and services. As we commercialize additional ~~diagnostic and prognostic~~ tests, we may need to incorporate new equipment, implement new technology systems, automate or otherwise improve the efficiency of our operational processes or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher costs, declining quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business. **In July 2023, we elected to temporarily pause accepting additional TissueCypher orders to focus on scaling efforts and to work through a significant backlog of orders. In September 2023, we resumed accepting new orders for testing in a phased approach consistent with continued scaling activity aimed at accommodating current demand and future growth. As of mid- October 2023, we completed the pre-existing backlog orders. However, there can be no assurance that our efforts will be successful, which could damage our reputation and the prospects for our business.** We may not be able to maintain the quality or expected turnaround times of our products, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations. If our management is unable to effectively manage our anticipated growth, our expenses may increase more than expected, our revenue could decline or grow more slowly than expected and we

may be unable to implement our business strategy. The quality of our products and services may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers. We have engaged in, and may continue to engage in, strategic transactions, such as the acquisition of businesses, assets, products or technologies, which could be disruptive to our existing operations, divert the attention of our management team and adversely impact our liquidity, cash flows, financial condition and results of operations. From time to time, we may consider strategic opportunities and engage in transactions such as acquisitions of businesses, assets, products or technologies, as well as technology licenses or investments in complementary businesses. For example, in May 2021, December 2021 and April 2022, we completed the acquisitions of the Myriad MyPath Laboratory, Cernostics and AltheaDx, respectively. These and any other strategic acquisition transactions may entail numerous operational and financial risks, including:

- delays, difficulties and higher than expected costs associated with integration activities, such as those involving operational processes, regulatory and licensure compliance, personnel and information technology systems;
- difficulties in scaling and growing the operations of acquired businesses in a cost- efficient manner;
- disruption of our existing business operations and diversion of management’ s time, focus and attention;
- decreases in our liquidity and operating cash flows, increases in our overall operating costs, substantial amounts of amortization expense, increased capital expenditure requirements and non- recurring charges, including possible impairments of acquired assets and losses on the remeasurement of contingent consideration;
- incurrence of substantial debt or dilutive issuances of equity securities, the assumption of additional liabilities, exposure to unknown liabilities and being subject to disputes with the former owners of an acquired businesses;
- inability to retain key personnel of any acquired businesses; and
- failure to realize any of the anticipated revenues, synergies, efficiencies or other benefits of a transaction within our estimated time frame or at all.

With regard to our acquisitions of the Myriad MyPath Laboratory, Cernostics and AltheaDx, actual results may differ materially from our plans and expectations. For example, there can be no assurances regarding our ability to successfully scale and integrate the MyPath Melanoma, TissueCypher and IDgenetix tests into our commercial offerings and the ability of the combined strengths of Castle, the Myriad MyPath Laboratory, Cernostics or AltheaDx to position us for continued growth and success as a leader in the diagnostics space. Further, there are inherent execution and business risks associated with managing the integration and growth objectives of more than one acquisition at the same time and such circumstances may have the effect of heightening the operational and financial risks related to acquisitions noted above and the other risks described in this “ Risk Factors ” section .

In July 2023, we elected to temporarily pause accepting additional TissueCypher orders to focus on scaling efforts and to work through a significant backlog of orders. In September 2023, we resumed accepting new orders for testing in a phased approach consistent with continued scaling activity aimed at accommodating current demand and future growth. As of mid- October 2023, we completed the pre- existing backlog orders. However, there can be no assurance that we will be successful in our efforts .

We are unable to predict the timing, size or nature of any future transactions, whether they will be completed or financed on favorable terms, if at all, or what the impact of those transactions might be on our financial results, including if such transactions are not effectively and profitably integrated into our business. Our failure to successfully complete the integration of any business that we acquire could have an adverse effect on our prospects, business activities, cash flows, financial condition, results of operations and stock price. Additionally, our ability to successfully integrate, manage and derive financial and other benefits from any acquired business, asset, product or technology cannot be assured given our limited historical experience with such transactions. Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income and taxes may be subject to limitations. As of December 31, ~~2022~~ **2023** , we had federal net operating loss (“ NOL ”) carryforwards of approximately \$ ~~207.197.21~~ **21** million, of which \$ ~~106.92~~ **10** million will begin to expire in 2029 if not utilized to offset taxable income, and \$ ~~101.105~~ **11** million may be carried forward indefinitely. Also, as of December 31, ~~2022~~ **2023** , we had state NOL carryforwards of \$ 114. ~~03~~ **3** million, which begin to expire in 2028 if not utilized to offset state taxable income. Under the legislation known as the Tax Cuts and Jobs Act of 2017 (“ TCJA ”), as modified by the Coronavirus Aid, Relief, and Economic Security Act (“ CARES Act ”), federal NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80 % of taxable income. In addition, under Sections 382 and 383 of the **IRC- Internal Revenue Code** , and corresponding provisions of state law, if a corporation undergoes an ‘ ‘ ownership change ’ ’ (which is generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period), the corporation’ s ability to use its pre- change NOL carryforwards and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. For example, with respect to the NOLs we obtained in our acquisitions of Cernostics and AltheaDx, \$ 36, 347, 000 of NOLs are expected to expire unused as a result of Section 382 limitations. We have experienced ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the TCJA, the CARES Act and the IRA enacted many significant changes to the U. S. tax laws. Further guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U. S. tax expense. Effective January 1, 2022, the TCJA eliminated the option to deduct research and development expenses for tax

purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, it could harm our future operating results by effectively increasing our future tax obligations. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and development activities inside or outside the United States. If our information technology systems ~~or data~~, or those of third parties upon which we rely, **or our data** are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of business, we and the third parties upon which we rely (such as contractors and consultants) **Process-process** proprietary, confidential, and sensitive information (including but not limited to intellectual property, proprietary business information and personal **information-data**). Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our proprietary, confidential, and sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent, continue to increase, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including threat actors, traditional computer “hackers,” organized criminal threat actors, personnel (such as through theft or misuse), hacktivists, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. **We** ~~Despite the implementation of security measures designed to protect against a security incident, we~~ and the third parties upon which we rely (such as our contractors and consultants) are vulnerable to a variety of evolving threats including but not limited to service interruptions, system malfunction, natural disasters, terrorism, war, public health crises, telecommunication and electrical failures, malware (including as a result of advanced persistent threat intrusions), malicious code **(such as viruses and worms)**, ransomware, supply chain attacks, credential harvesting, denial-of-service attacks, **(such as credential stuffing)**, **personnel misconduct or error**, social engineering **attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), attacks enhanced or facilitated by AI,** and other **similar** ~~attempts to affect service reliability and threaten threats the confidentiality, integrity and availability of our proprietary, confidential and sensitive information-~~. In particular, **severe** ransomware attacks have become increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. **Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.** We manage and maintain our applications and information utilizing a combination of on-site systems, managed data centers, and cloud-based data centers, ~~and we are increasingly dependent upon information technology systems, infrastructure and information to operate our business-~~. It is critical that we do so in a secure manner to maintain the confidentiality, availability and integrity of such information. We also have outsourced elements of our operations to third parties, including third-party service providers and technologies to help operate critical business systems to Process proprietary, confidential and sensitive information, and as a result we **also** manage a number of third-party contractors who have access to our proprietary, confidential and sensitive information **including information related to our clinical trials**. Our ability to monitor these third parties’ cybersecurity information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Additionally, supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services. **While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents, including affected individuals, regulators, customers, and investors. Such disclosures are costly, and the disclosures or failure to comply could lead to adverse consequences.** Any of the previously

identified or similar threats could cause a disruption or security incident, which could result in unauthorized, unlawful, or accidental loss of, damage to, modification of, destruction of, alteration of, encryption of, disclosure of, access to, or acquisition of our information and could interrupt our **or ability to provide our information technology services. While we have not experienced any such system systems failure, accident or material those of the third parties upon whom we rely. A security incident could disrupt our ability (and to date, we cannot assure you that of the third parties upon whom we rely) to provide our services. We may expend significant resources our or modify our business activities (including our clinical research activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protection** protect efforts and our investment in information technology systems have or will prevent security incidents. We take steps to detect and sensitive information remediate vulnerabilities but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents, including affected individuals, the Secretary of the HHS, states Attorneys General and others. Such disclosures are costly, and the disclosures or failure to comply could lead to adverse consequences. If we or a third party upon whom we rely experience a security incident or are perceived to have experienced a security incident, we may experience government enforcement actions **(for example, investigations, fines, penalties, audits, and inspections)**, additional reporting requirements and / or oversight, restrictions on Processing data (including personal information data), litigation **(including class action claims)**, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, **diversion of management attention**, interruptions in our operations, and other harms. Such consequences may disrupt our operations (including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business), damage our reputation, negatively impact our ability to grow our business, and others. For example, we maintain a tumor specimen database comprised of over 60, 000 samples. Some of these samples were used to develop and validate DecisionDx- Melanoma, and, of those, some are currently being used to improve upon the test and some will be used in the future. If we were to lose this database, our ability to further validate, improve and therefore maintain and grow sales of DecisionDx- Melanoma could be significantly impaired. Our contracts may not contain limitations of liability, and there can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable privacy and security obligations. Additionally, while we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, information loss, regulatory actions or material adverse impacts arising out of our privacy and security practices, Processing or security incidents we may experience, or that such coverage will continue to be available on commercially reasonable terms or at all. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. **Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel' s, or vendors' use of generative AI technologies.** Product or professional liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of our products. We face an inherent risk of product and professional liability exposure related to our products. The marketing, sale and use of our products could lead to the filing of product liability claims were someone to allege that our products identified or reported inaccurate or incomplete information, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. If we cannot successfully defend ourselves against claims that our products caused injury or otherwise failed to function properly, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in: • decreased demand for our current tests any tests that we may develop, and the inability to commercialize such tests; • injury to our reputation and significant negative media attention; • reluctance of experts willing to conduct our clinical studies; • initiation of investigations by regulators; • significant costs to defend the related litigation and diversion of management' s time and our resources; • substantial monetary awards to study subjects or patients; • product recalls, withdrawals or labeling, or marketing or promotional restrictions; and • loss of revenue. We currently carry product liability insurance. However, the amount of this insurance may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States. While we currently accept orders from customers outside of the United States, our historical business strategy has been directed toward customers within the United States. Our long- term business strategy contemplates potential international expansion. Doing business internationally involves a number of risks, including: • multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • limits in our ability to penetrate international markets if we are not able to perform tests locally; • logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays; • difficulties in staffing and managing foreign

operations; • failure to obtain regulatory approvals for the commercialization of our products in various countries; • complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property; • complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and • regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions, or its anti-bribery provisions. Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, UK and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and / or supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not operate in Russia or Ukraine, as the adverse effects of this conflict continue to develop and potentially spread, both in Europe and throughout the rest of the world, our business and results of operations may be adversely affected, particularly to the extent this conflict escalates to involve additional countries, further economic sanctions or wider military conflict. Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. Requirements associated with being a public company, **including those associated with no longer qualifying as a smaller reporting company and becoming an accelerated filer,** will continue to increase our costs as well as divert significant company resources and management attention. We are subject to the reporting requirements of the Exchange Act or the other rules and regulations of the SEC and any securities exchange relating to public companies. Sarbanes- Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes- Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations. For example, during 2022, the SEC adopted new rules covering pay versus performance disclosures, "clawback" policies and insider trading plans. Future changes in regulations and disclosure obligations may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis. **We will be subject to the reporting deadlines of an accelerated filer effective December 31, 2023. Beginning with our Quarterly Report on Form 10- Q for the three months ended March 31, 2024, we will no longer qualify as a smaller reporting company and we will be unable to take advantage of scaled disclosure requirements. We** expect the rules and regulations applicable to public companies will continue to increase our legal and financial compliance costs and to make some activities more time- consuming and costly. If we are unable to comply with these requirements on a timely basis or if the attention of our management and personnel is diverted from other business concerns, it could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss or decrease our net income, and may require us to reduce costs in other areas of our business or increase the prices of our products. In addition, as we expand, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our business could be adversely impacted

by inflation. In 2021, the rate of inflation in the United States began to increase and then rose to levels not experienced in over 40 years, but began subsiding in the second half of 2022. We are experiencing inflationary pressures, primarily in **increased** personnel costs and **with price increases for** certain lab supplies. We anticipate **possible** inflationary impacts on other cost areas in the future. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and the extent to which the rate of inflation were to further increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents and marketable investment securities may be further diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payors may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows. Our business could be adversely affected by natural disasters, public health **epidemics crises** and other events beyond our control. Although we maintain crisis management plans, our business operations are subject to interruption by natural disasters and other events and catastrophes beyond our control, including, but not limited to, earthquakes, floods, fires, tornadoes, hurricanes, power or other utility outages, telecommunications failures and public health crises. Further, ~~outbreaks of epidemic diseases, such as the~~ **ongoing conflict between Ukraine and COVID-19 pandemic discussed above, or Russia's invasion of Ukraine in February 2022**, or the fear of **such similar** events, could provoke responses, including government- imposed travel restrictions that could impede the mobility and effectiveness of our sales force, disrupt our operations or those of our suppliers and service providers. The ultimate impact of any of these or similar events is highly uncertain and could have a material adverse impact on our operations.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile or may decline regardless of our operating performance, and you may lose all or part of your investment. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our operating performance and the performance of other similar companies;
- our success in marketing and selling our products;
- reimbursement determinations by third- party payors, **including MACs**, and reimbursement rates for our products;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to product development and clinical studies for our products;
- our ability to achieve product development goals in the timeframes we announce;
- announcements of clinical study results, regulatory developments, acquisitions, strategic alliances or significant agreements by us or by our competitors;
- the success or failure of our efforts to acquire, license or develop additional tests;
- recruitment or departure of key personnel;
- general economic conditions and market conditions specific to our industry;
- interest rates and the rate of inflation;
- the extent and duration of the impacts on our operations of general political and economic conditions, including the **COVID- Israel - 19 pandemic Hamas war**, the **invasion of ongoing conflict between Ukraine by and** Russia, economic slowdowns, recessions or market corrections, and effects of elevated inflation, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments;
- trading activity by a limited number of stockholders who together beneficially own a significant percentage of our outstanding common stock;
- ~~general investor interest in emerging growth stocks;~~ **the size of our market float; and** • any other factors discussed in this Annual Report on Form 10- K. **For example, on June 5, 2023 our stock price decreased 49 % after Novitas published a final LCD that would have impacted Medicare coverage for our DecisionDx- SCC test**.

In addition, the stock market in general, and diagnostic and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. In the past, stockholders of other companies have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business. If there are substantial sales of shares of our common stock, the price of our common stock could decline. The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. Shares held by directors, executive officers and other affiliates are subject to volume limitations under Rule 144 under the Securities Act. Certain of our stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We have registered shares of common stock that we have issued and may issue under our employee equity incentive plans. As a result, these shares will be able to be sold freely in the public market upon issuance. The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares. We have broad discretion in the use of working capital and may not use it effectively or in ways that increase our share price. We cannot specify with any certainty the particular uses of working capital, but we currently expect such uses will include: funding selling and marketing activities, including expansion of our sales force to support the ongoing commercialization of current and future products; research and development related to the continued support of our current products, as well as the development of our product pipeline; and other general corporate purposes, including acquisitions and the costs associated with being a public company. The failure by our management to apply our working capital effectively could adversely affect our business and financial condition. Pending its use, we may invest working capital in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our

common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas. We have and may continue to enter into related party transactions that create conflicts of interest, or the appearance of conflicts of interest, which may harm our business and cause our stock price to decline. We have entered into related party transactions that create conflicts of interest between our interests and the interests of our directors and executive officers. For example, we employ three children and a brother-in-law of Derek J. Maetzold, our President and Chief Executive Officer, three children and a son-in-law of Kristen M. Oelschlager, our Chief Operating Officer, and the son of Tobin W. Juvenal, our Chief Commercial Officer, in each case in non-officer positions. Additionally, Derek J. Maetzold and Daniel M. Bradbury, the **chairperson-chair** of our board of directors, each served on the board of directors of AltheaDx, a commercial-stage molecular diagnostics company that we acquired in April 2022. Further, each of the following individuals was a direct or indirect beneficial owner of AltheaDx securities and received consideration in the transaction: Mr. Bradbury; Mr. Maetzold; Thomas Sullivan, John Maetzold and Peter Maetzold, immediate family members of Mr. Maetzold; Frank Stokes, our Chief Financial Officer; Tobin Juvenal, our Chief Commercial Officer; Kristen Oelschlager, our Chief Operating Officer; and Joshua Albers and Allysa Topel, immediate family members of Ms. Oelschlager. These types of related party arrangements are required to be disclosed in our public filings based on certain criteria. We may engage in other transactions in the future involving our executive officers, directors and their family members and / or entities which they control or are affiliated, which could cause individuals in our management to seek to advance their economic interests or the economic interests of certain related parties above ours. Although we have a written policy on related party transactions that involves independent review and oversight by the audit committee of our board of directors, there can be no assurances that conflicts of interest will not exist, or that we will be able to adequately address or mitigate any actual or perceived conflicts of interest, and stockholders, analysts, proxy advisory firms, the news media and other parties may view these transactions as representing conflicts of interest or as otherwise inappropriate, which may result in negative public perception and reputational harm, and could impair our ability to enter into new customer relationships or attract and retain employees. Potential, perceived and actual conflicts of interest could cause investors to question the independence of our management, the adequacy and effectiveness of our disclosure controls and procedures or the integrity of our corporate governance procedures and compensation practices, which could have a material adverse effect on the trading price of our common stock and our business, financial condition and results of operations. We are a smaller reporting company and we cannot be certain if the scaled disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors. **As Effective as of June 30, 2022, we requalified as a smaller reporting company as defined in the Exchange Act, we have. We began to take taken** advantage of certain of the scaled disclosures available to smaller reporting companies **beginning. Revenue exceeded \$ 100. 0 million for the year ended December 31, 2022 and the market value of our common stock held by non-affiliates exceeded \$ 250. 0 million as of June 30, 2023. Therefore, effective with** our Quarterly Report on Form 10- Q for **our second quarter the three months ended June 30- March 31, 2022-2024 and, we will no longer qualify as a smaller reporting company and will not be able permitted** to take advantage of these **the** scaled disclosures. **Until** for so long as **the then** market value of our voting and non-voting common stock held by non-affiliates is less than \$ 250. 0 million measured on the last business day of our second fiscal quarter, **we** or our annual revenue is less than \$ 100. 0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$ 700. 0 million measured on the last business day of our second fiscal quarter. We cannot predict if investors will find our common stock less attractive because **of we will rely on** these scaled disclosures. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We do not intend to pay dividends for the foreseeable future. We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval. Based upon shares outstanding as of December 31, **2022-2023**, our executive officers, directors and the known holders of more than 5 % of our outstanding common stock, in the aggregate, beneficially owned approximately **32-43** % of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including

the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial. Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws: • permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control); • provide that the authorized number of directors may be changed only by resolution of the board of directors; • provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock; • provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; • divide our board of directors into three classes; • require that any action to be taken by our stockholders must be effected at a duly called annual or special meetings of stockholders and not be taken by written consent; • provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice; • do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); • provide that special meetings of our stockholders may be called only by the chairperson of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; • provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and • provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former

directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. ~~88~~