Risk Factors Comparison 2024-03-01 to 2023-03-06 Form: 10-K

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The following is a summary of the principal risks that could adversely affect our business, operations and financial results. This summary does not address all of the risk that we face and should be read in conjunction with the entire Risk Factors section below beginning at " Risks Related to Our Business and Industry " within this Item 1A. **"** Risk Factors. **"** • We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we achieve profitability, we may not be able to sustain it ~~.~~ **;** • Our audited financial statements include a statement that there is a substantial doubt about our ability to continue as a going concern and a continuation of negative financial trends could result in our inability to continue as a going concern ~~.~~ **;** • The commercial success of our current and future diagnostic tests and services **and our revenue growth** depends upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies ~~.~~ **;** • We may encounter difficulties in managing our growth, which could disrupt our operations ~~.~~ **;** • If we fail to retain sales and marketing personnel and, as we grow, fail to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests in a cost- effective manner, we may not be able to generate revenue growth ~~.~~ **;** • If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced ~~.~~ **;** • Our commercial success and revenue growth are highly dependent on the demand for, and increased adoption of, our diagnostic tests, ~~including our COVID- 19 testing program,~~ which are subject to a number of risks and uncertainty ~~.~~ **;** • We need to ensure strong product performance and reliability to maintain and grow our business ~~.~~ **;** • We depend upon third- party suppliers, including ~~contract manufacturers and~~ single source suppliers, making us vulnerable to supply problems and price fluctuations ~~.~~ **;** • Natural or man- made disasters ~~, pandemics, outbreaks,~~ or other similar events **may** ~~, including a sustained outbreak or future waves of the novel strain of coronavirus disease, COVID- 19, could~~ significantly disrupt our business, and negatively impact our business, financial condition and results of operations ~~.~~ **;** • Our industry is ~~highly competitive and~~ subject to rapid change, which could make our **solutions and the** diagnostic tests **we develop** and services **we offer** obsolete. If we are unable to continue to innovate and **improve** ~~expand and enhance~~ our diagnostic tests and ~~service~~ **services** ~~offerings~~ **we offer** , we could lose customers or market share ~~.~~ **;** • Any failure to offer high- quality support for our diagnostic tests and services may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition and results of operations ~~.~~ **;** • We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our products or services and business disruption if there are ~~disruptions in our information technology systems, including~~ any security or data privacy breaches or other unauthorized or improper access. Our operations and financial results are subject to various risks and uncertainties that could adversely affect our business, financial condition, ~~and~~ results of operations and cash flows. All of the risks described below should be carefully considered together with the other information contained and incorporated by reference in this report. Risks Related to our Business and Industry We have **a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we achieve profitability, we may not be able to sustain it. We have** incurred losses since our inception and expect to continue to incur losses for the foreseeable future. We reported net losses of $ **52. 1 million and $** 65. 4 ~~million and $ 43. 2~~ million the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As a result of these losses, as of December 31, ~~2022~~ **2023** , we had an accumulated deficit of approximately $ ~~367~~ **419** . ~~4~~ **6** million. We expect that our sales and marketing, research and development, regulatory and other expenses will continue to increase as we expand our marketing efforts for our diagnostic tests and services, expand existing relationships with our customers, obtain regulatory clearances or approvals or certifications for future enhancements to our existing diagnostic tests and services and conduct further clinical trials. In addition, we expect our general and administrative expenses to increase due to the additional costs associated with scaling our business operations and testing capacity as well as being a public company, including due to legal, accounting, insurance, exchange listing and compliance, investor relations and other expenses. As a result, we expect to continue to incur operating losses and may never achieve profitability. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations. **We are** ~~The spread of COVID- 19, particularly during 2020 and~~ - **an** 2021, **emerging growth company** and **,** ~~the impact to our business has~~ - **as** ~~had~~ **such** , **we** ~~and may continue to~~ have ~~, a material~~ **incurred significant losses since inception** and ~~adverse effect on our~~ **have yet to generate positive cash flows from operations. Our** ability to ~~generate revenues, maintain~~ **meet our obligations as they come due may be impacted by our ability to remain** ~~compliance~~ **compliant** with ~~our~~ financial covenants **in our Perceptive Term Loan Facility** and **may** result in our inability to continue as a going concern. Any such impacts could have a material and adverse effect on the price of our common stock. Our financial statements as of and for the period ended December 31, ~~2022~~ **2023** were prepared on the assumption that we would continue as a going concern. These financial statements did not include any adjustments that might result from the outcome of this uncertainty. As of December 31, ~~2022~~ **2023** , we maintained cash and cash equivalents of $ ~~43~~ **26** . ~~1~~ **3** million and we have $ ~~30~~ **40** . 0 million in principal balance ~~remaining~~ **outstanding** on our Perceptive Term Loan (as defined below). We have incurred significant losses since inception and, as a result, we have funded our operations to date primarily through the sale of common stock in **both** ~~our follow- on~~ underwritten public ~~offering~~ **offerings** ~~in November 2022~~ **and private placements** , the issuance of notes payable, and from our two primary revenue sources: (i) diagnostic testing, which ~~include~~ **includes** lung diagnostic testing and **, prior to May 11, 2023,** COVID- 19 testing,

and (ii) providing biopharmaceutical companies with development and testing services **and licensing our technology** . Our ability to meet our obligations as they come due may be impacted by our ability to remain compliant with financial covenants in the Perceptive Term Loan Facility or to obtain waivers or amendments that impact the related covenants. **Based** ~~However, due to the continued uncertainty caused by the COVID- 19 pandemic and the associated impacts~~ on ~~the recovery of~~ **our current operating plan, unless we continue to raise additional capital (debt** ~~our~~ **or** ~~diagnostic~~ **equity), we expect that we will be unable to maintain our financial covenants under our** ~~testing~~ **existing loan agreement during** ~~and services, significant risks remain with respect to our ability to meet these~~ **the next twelve months** ~~thresholds and any material adverse effect on our revenues~~ , **which** ~~income and expenses~~ could ~~impact our~~ **result in an Event of Default (as defined in the Perceptive Term Loan** ~~ability~~ **Facility** ~~to maintain compliance with~~ **), causing an acceleration and repayment of** ~~these~~ **the** ~~covenants~~ **outstanding balances** . As a result ~~of the items mentioned above~~ , our management has determined that there is a substantial doubt about our ability to continue as a going concern over the next twelve months from the date these financial statements were issued. Although we have taken steps to improve our liquidity, including through **raising debt** ~~entering into the Perceptive Term Loan Facility~~ and **equity capital** ~~terminating the 2021 Term Loan~~ , and have ~~taken~~ **also undertaken several proactive** measures ~~to reduce~~ **including, among other things, the reduction of** planned capital expenditures and **certain** operating expenses, **we do not expect that** these actions alone **will** ~~may not~~ be sufficient to ~~mitigate~~ **maintain** our **financial covenants** ~~liquidity concerns in the wake of potential impacts to our revenues, operating results and cash flows from the continued uncertainty caused by the COVID- 19 pandemic and adjustments to the post- pandemic environment~~ . In addition, if we are not able to improve our operating results, we may need to limit our operations substantially. We will need to raise additional capital in the form of **debt or** equity ~~or debt~~ to increase our liquidity but there is no assurance that we will be able to secure any such funding in a sufficient amount or on terms that are acceptable to us. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. Furthermore, the reaction of investors to the inclusion of a going concern statement in this report, and our potential inability to continue as a going concern, could materially adversely affect the price of our common stock. The commercial success of our current and future diagnostic tests and services and our revenue growth depends upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies. Our commercial success depends, in part, on the acceptance of our diagnostic tests and services as being safe and relatively simple for medical personnel to learn and use, clinically flexible, operationally versatile and, with respect to providers and payers, cost effective. We cannot predict how quickly, if at all, payers, providers, clinics and patients will accept future diagnostic tests and services or, if accepted, how frequently they will be used. These constituents must believe that our diagnostic tests offer benefits over other available alternatives. The degree of market acceptance of our current and future diagnostic tests and services depends on a number of factors, including: • whether there is adequate utilization of our tests by clinicians, biopharmaceutical companies and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors; • the convenience and ease of use of our diagnostic tests relative to those currently on the market; • the effectiveness of our sales and marketing efforts; • our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests; • the coverage and reimbursement acceptance of our products and services; • pricing pressure, including from group purchasing organizations (GPOs), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members; • negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors; • the accuracy of our tests relative to those of our competitors; • product labeling or product insert requirements by the FDA or other regulatory authorities or conformity assessment bodies; and • limitations or warnings contained in the labeling cleared or approved by the FDA or other regulatory authorities or conformity assessment bodies. Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and / or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations. **We may encounter difficulties in managing** ~~There is no assurance that our COVID- 19 and antibody testing program will continue to be accepted by the market or~~ **our growth** ~~that other diagnostic tests will become more accepted~~ , **which** ~~produce quicker results or are more accurate. Further, the longevity and extent of the COVID- 19 pandemic is uncertain. On January 30, 2023, the White House issued a Statement of Administration Policy announcing the President' s intention to allow the Public Health Emergency declaration under Section 319 to expire on May 11, 2023. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a COVID- 19 test~~ could **disrupt** ~~decrease significantly and this could have an adverse effect on~~ our ~~results of operation~~ **operations** ~~and profitability~~ . As of December 31, ~~2022~~ **2023** , we had approximately ~~245~~ **217** full and part- time employees. Over the next several years, we expect to **continue to** significantly increase the number of our employees and the scope of our operations, particularly in the areas of sales, marketing and reimbursement, product development, regulatory affairs and other functional areas, including finance, accounting, quality and legal. Additionally, we expect to expand our testing capacity as we commercialize additional diagnostic tests. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and have a material and adverse effect on our ~~prospects~~ **business, financial condition, and results of operations** . Since our inception, we have experienced multiple cycles of growth and

anticipate further growth in our business operations. This future growth could ~~create~~ **put** strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue to increase headcount and to hire more specialized personnel in the future as we grow our business. 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 properly 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. We may not be able to maintain the quality or expected turnaround times of our diagnostic tests and services, 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 materially adversely affect our operations. Additionally, if we are required to reduce expenses substantially to sustain our operations, we may not have the human resources to maintain growth in our business operations. ~~We have limited experience~~ **If we fail to retain sales and** marketing **personnel** and ~~selling~~ **, as we grow, fail to increase our sales and marketing capabilities or develop broad awareness of** our diagnostic tests **in a cost- effective manner, we may not be able to generate revenue growth** . We currently rely on our direct sales force to sell our diagnostic tests in the United States, and any failure to maintain and grow our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of our diagnostic tests. The members of our United States sales force are at- will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations. In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure. Identifying and recruiting qualified sales and marketing personnel and training them on how to promote our diagnostic tests, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or diagnostic tests that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our diagnostic tests. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time, or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our diagnostic tests will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our diagnostic tests in a cost- effective manner is critical to achieving broad acceptance of our diagnostic tests. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad use of our diagnostic tests, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced. We collaborate with biopharmaceutical companies to analyze patient samples for multiple applications primarily to support clinical trials, including patient identification, companion or complementary diagnostics and retrospective testing. The revenue attributable to our biopharmaceutical customers may also fluctuate in the future, which could have a material adverse effect on our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue. Our future success depends in part on our ability to maintain these relationships and to establish new relationships. Many factors have the potential to impact such collaborations, including the type of biomarker support required and our ability to deliver it and our biopharmaceutical customers' satisfaction with our tests or services and other factors that may be beyond our control. Furthermore, our biopharmaceutical customers may decide to decrease or discontinue their use of our tests due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to research and clinical trials that facilitate the collection and incorporation of new information into our biobank ~~and proprietary AI platform~~ . We engage in conversations with biopharmaceutical companies regarding potential commercial opportunities on an ongoing basis. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical or research studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential relationships with biopharmaceutical companies can also be a catalyst for adverse speculation about us, our tests and our technology, which can adversely affect our reputation and our business. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual revenue and operating

results may fluctuate significantly, which makes it difficult for us to predict our future operating results. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including, but not limited to: • the level of demand for our diagnostic tests, which may vary significantly; • the timing and cost of manufacturing our diagnostic tests, which may vary depending on the quantity of production and the terms of our agreements with third- party suppliers and manufacturers; • expenditures that we may incur to acquire, develop, or commercialize additional tests and technologies; • unanticipated pricing pressures; • the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein; • the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners; • coverage and reimbursement policies with respect to lung cancer treatment equipment, and potential future diagnostic tests that compete with our diagnostic tests; • the timing and success or failure of clinical trials for our diagnostic tests or any enhancements to such tests we develop or competing diagnostic tests; • positive or negative coverage, or public perception, of our diagnostic tests or those of our competitors or broader industry trends; • the ~~impact, if any, of the spread of COVID- 19 and any newly discovered variants, and the resulting effects on the number of patients treated or the demand for our non- COVID- 19 tests; • the~~ timing and cost of, and level of investment in, research, development, licenses, regulatory approval, conformity certification, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our diagnostic tests, which may change from time to time; • the timing and cost of obtaining regulatory approvals, conformity certifications or clearances for planned or future improvements or enhancements to our diagnostic tests; • changes in regulatory requirements or in the status of regulatory approvals or applications or conformity certifications; • pricing, discounts, and incentives for our diagnostic tests; • future accounting pronouncements or changes in our accounting policies; and • general market conditions ~~. In addition, we can provide no assurances that the demand for our COVID- 19 and antibody testing program will be sustained, and even if it is, the period of time for which it would be sustained. As vaccines for COVID- 19 become more available and widespread in the future, we have seen the demand for our COVID- 19 diagnostic and antibody tests decrease. As a result, the increase in revenue, if any, due to any increase in demand for our COVID- 19 and antibody testing program is not indicative of results expected for any future period~~ . The cumulative effects of these factors has resulted in large fluctuations and unpredictability in our quarterly and annual financial results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance. This variability and unpredictability 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 publicly stated guidance we may provide, and could in turn negatively impact our business, financial condition and results of operations. We need to **ensure strong product performance and reliability to maintain and grow our business. We need to** maintain and continuously improve the performance and reliability of our diagnostic tests, including ~~our Biodesix WorkSafe testing program,~~ the Nodify XL2 and Nodify CDT tests, and the GeneStrat and VeriStrat tests ~~,~~ to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. Our diagnostic tests may contain errors or defects, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. Performance issues with our diagnostic tests will increase our costs in the near- term and accordingly adversely affect our business, financial condition and results of operations **. We depend upon third- party suppliers, including single source suppliers, making us vulnerable to supply problems and price fluctuations** . We rely on third- party suppliers ~~, including in some instances single source suppliers,~~ to provide ~~us with~~ certain components of our diagnostic tests **, including** ~~. The number of suppliers feeding into the production of our diagnostic tests is in excess of 65 worldwide. We consider~~ a select few **(** ~~of these suppliers,~~ located in the United States, Europe and China **)** , as critical single source providers of components. Bio- Rad ~~Laboratories~~ , as described below, is the sole source supplier for our GeneStrat ~~tests~~ **test** ~~and COVID- 19 diagnostic and antibody testing program~~ . Oncimmune is also the sole source supplier for our Nodify CDT tests **but there are known secondary suppliers for these materials** . While we have initiated the second source qualification process for the majority of these critical components, we may not be successful in securing second sourcing for all of them at all or on a timely basis. ~~In addition, we may purchase supplies through purchase orders and may not have long- term supply agreements with, or guaranteed commitments from, many~~ **Many** of our suppliers ~~, including single source suppliers. Additionally, at present, we have a limited contract with a contract manufacturer for the production of certain of our diagnostic testing kits; however, during 2022 we transitioned the majority of kitting performed outside of the Company to our internal operations team for cost savings and risk management. Many of our suppliers and contract manufacturers~~ are not obligated to perform services or supply diagnostic testing materials for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers and ~~contract manufacturers~~ to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers ~~and contract manufacturers~~ may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. These suppliers ~~and contract manufacturers~~ may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers ~~and contract manufacturers~~ . If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our

relationships ~~with our suppliers and contract manufacturers~~, we may be required to change suppliers ~~or contract manufacturers~~. While we believe replacement suppliers exist for all materials, components and services necessary to manufacture our diagnostic tests, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time- consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance of our diagnostic tests or could require that we modify their processes. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which we may not obtain on a timely basis or at all. If our third- party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our diagnostic tests, the supply of our diagnostic tests to customers and the development of any future diagnostic tests will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations. We entered into a nonexclusive license and supply agreement with Bio- Rad in August 2019. We rely on Bio- Rad to supply equipment and reagents used to perform ddPCR testing, a service offered by us under a variety of fee for service agreements and the core technology powering the GeneStrat test. Under the terms of this arrangement, we were granted non- exclusive rights to utilize the intellectual property, machinery, materials, reagents, supplies and know- how necessary for the performance of ddPCR in cancer detection testing for third parties in the United States. We agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio- Rad ~~. As further consideration for the non- exclusive license, we agreed to pay a royalty of two and one half percent (2. 5 %) on net service fees (such fees are defined in the Non- Exclusive License Agreement with Bio- Rad) collected from contracted third parties who receive ddPCR services from us. In addition, we have separately been granted permission by Bio- Rad to use the Bio- Rad SARS- CoV- 2 ddPCR test and Platelia SARS- CoV- 2 Total Ab test for commercial diagnostic services. On May 24, 2021, we entered into the First Amendment to the Non- Exclusive License Agreement between Bio- Rad Laboratories, Inc., and Biodesix, Inc. which amended the original agreement such that, effective May 1, 2021, we are not required to pay a royalty of two and one half percent (2. 5 %) on net service fees~~. For more information regarding this license and supply agreement and the permission granted to us by Bio- Rad with respect to such tests, please see " Business — Material Agreements — Agreements with Bio- Rad " previously filed with our Form S- 1 on October 23, 2020 and " First Amendment to the Non- Exclusive License Agreement between Bio- Rad Laboratories, Inc., and Biodesix, Inc., dated May 24, 2021 " previously filed with our Form 10- Q on August 10, 2021. This relationship may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. We cannot be certain that, following the realization of this relationship, we will achieve the revenue or specific net income that justifies our entry into it. Any termination of this relationship, or delays in entering into new strategic partnership agreements with Bio- Rad, could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations. We may not be able to sufficiently reduce costs in the performance, manufacturing and production of our diagnostic tests to achieve sustainable gross margins. We partner with **suppliers** ~~contract manufacturers~~ in the development and production of supplies for our diagnostic tests. While we are undertaking a number of initiatives designed to reduce the cost of performing our diagnostic tests, including reducing the costs of supplies, there is no guarantee that we will be able to achieve planned cost reductions from our various cost savings initiatives. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our diagnostic tests, changes to labor costs or less favorable terms with third- party suppliers ~~or contract manufacturing partners~~. If we are unable to reduce our costs, or if cost reductions are less significant or less timely than projected, we will not be able to achieve sustainable gross margins, which would adversely affect our ability to invest in and grow our business and adversely impact our business, financial condition and results of operations. A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including ~~the~~ **a future** outbreak of the novel strain of coronavirus disease, COVID- 19, and its variants could adversely affect our business. If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. For much of 2020 and 2021, COVID- 19 spread throughout the United States and to most countries globally, creating significant uncertainty and economic disruption. Numerous U. S. state and local jurisdictions chose to impose " shelter- in- place " orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID- 19. In March 2020, the Governor of Colorado, where our headquarters are located, issued " stay at home " orders limiting non- essential activities, travel and business operations. Disruptions or potential disruptions due to the orders and restrictions have included, and in the future may continue to include, the inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to assemble diagnostic tests; inventory shortages or obsolescence; delays in actions of regulatory bodies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business; delays in growing or reductions in our sales organization, including through delays in hiring, lay- offs, furloughs or other losses of sales representatives; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our diagnostic tests. The COVID- 19 pandemic also ~~has~~ negatively affected our non- COVID- 19 testing- related revenue and our clinical studies. For example, cancer patients ~~have~~ had more limited access to hospitals, healthcare providers and medical resources as they took steps to control the spread of COVID- 19. Our biopharmaceutical customers have faced ~~, and are continuing to face,~~ challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. Further, our clinical studies, such as our ongoing INSIGHT study and our recently launched ALTITUDE

study, as well as our arrangements with our biopharmaceutical customers, are expected to take longer to complete than what we expected before the outbreak of the COVID- 19 pandemic. The **extent to which the a future pandemic or epidemic, including a future outbreak of the** COVID- 19 **virus** ~~pandemic created an opportunity for our diagnostic tests and we have commercialized three diagnostic tests to test for the presence of COVID- 19 and antibodies. However~~ , ~~there is no assurance that our COVID- 19 diagnostic and antibody testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or be accurate. Further, the longevity and extent of the COVID- 19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a COVID- 19 test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue, if any, due to any increase in demand for these diagnostic tests may not be indicative of our future revenue. The extent to which the COVID- 19 pandemic~~ impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the resurgence of COVID- 19 **or any other virus** and the actions to contain ~~COVID- 19~~ or treat its impact, among others ~~. Furthermore, there is no assurance that our diagnostic tests will continue to be effective against the virus in the future~~ . While the potential economic impact brought by, and the duration of, any pandemic, epidemic or outbreak of an infectious disease, including COVID- 19, may be difficult to assess or predict, the widespread COVID- 19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets and a reduction in our ability to access capital, which could adversely affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID- 19, could materially affect our business. Such economic recession could have a material adverse effect on our long- term business. To the extent **a** ~~the COVID- 19~~ pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this " Risk Factors " section. Natural or man- made disasters and other similar events may significantly disrupt our business, and negatively impact our business, financial condition and results of operations. A significant portion of our employee base, operating facilities and infrastructure are centralized in ~~Boulder~~ **Louisville** , Colorado and we operate a laboratory facility in De Soto, Kansas. Any of our facilities may be harmed or rendered inoperable by natural or man- made disasters, including earthquakes, wildfires, floods, nuclear disasters, riots, acts of terrorism or other criminal activities, infectious disease outbreaks or pandemic events power outages and other infrastructure failures, which may render it difficult or impossible for us to operate our business for some period of time. Our facilities would likely be costly to repair or replace, and any such efforts would likely require substantial time. Any disruptions in our operations could adversely affect our business, financial condition and results of operations and harm our reputation. Moreover, although we have disaster recovery plans, they may prove inadequate. We may not carry sufficient business insurance to compensate for losses that may occur. Any such losses or damages could have a material adverse effect on our business, financial condition and results of operations. In addition, the facilities of our suppliers and manufacturers may be harmed or rendered inoperable by such natural or man- made disasters, which may cause disruptions, difficulties or otherwise materially and adversely affect our business **. Any failure to offer high- quality support for our diagnostic tests and services may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition and results of operations** . In implementing and using our diagnostic tests and services, providers depend on our support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short- term increases in demand for customer support. Increased customer demand for support could increase costs and adversely affect our business, financial condition and results of operations. Our sales are highly dependent on our reputation and on positive recommendations from our existing patients, care partners, providers and clinics. Any failure to maintain high- quality customer support, or a market perception that we do not maintain high- quality customer support, could adversely affect our reputation, our ability to sell our diagnostic tests and services, and in turn our business, financial condition and results of operations. The sizes of the markets for our diagnostic tests and services and any future diagnostic tests and services may be smaller than we estimate and may decline. Our estimates of the annual total addressable market for our diagnostic tests and services are based on a number of internal and third- party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our diagnostic tests and services in the market. 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 total addressable market for our diagnostic tests and services in different market segments may prove to be incorrect. If the actual number of patients who would benefit from our diagnostic tests, the price at which we can sell them or the annual total addressable market for them is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations. Our industry is subject to rapid change, which could make our solutions and the diagnostic tests we develop and services we offer, obsolete. If we are unable to continue to innovate and improve our diagnostic tests and services we offer, we could lose customers or market share. 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 diagnostic tests and others we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers 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 offerings and develop new and improved diagnostic tests to keep pace with evolving standards of care. If we do not leverage or scale our sample and data biobank to discover new diagnostic tests or applications or update our diagnostic tests to reflect new scientific knowledge, including about lung cancer biology, information about new cancer therapies or relevant clinical trials, our diagnostic tests could become

obsolete and sales of our current diagnostic tests and any new tests we develop could decline or fail to grow as expected. This failure to make continuous improvements to our diagnostic tests to keep ahead of those of our competitors could result in the loss of customers or market share that would adversely affect our business, financial condition and results of operations ~~. We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our products or services and business disruption if there are any security or data privacy breaches or other unauthorized or improper access~~ . In connection with various facets of our business, we collect and use a variety of personal data, such as names, mailing addresses, email addresses, mobile phone numbers, location information, prescription information and other medical information. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant liability under state, (e. g., state breach notification and privacy laws such as the CCPA) federal (e. g., HIPAA), and the HITECH Act and laws in other jurisdictions (e. g., the GDPR). Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users of our diagnostic tests and services and potentially disrupt our business. Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. We have in the past experienced, and may in the future, experience security incidents. While no security incidents in the past have had a material adverse effect on our business, financial condition and results of operations, we cannot predict the impact of any such future events. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third- party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break- ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investments to protect against security breaches or to mitigate the impact of any such breaches. In addition, to the extent that our cloud and other service providers, experience security breaches that result in the unauthorized or improper use of confidential data, employee data or personal data, we may not be indemnified for any losses resulting from such breaches. There can be no assurance that we or our third- party providers will be successful in preventing cyber- attacks or successfully mitigating their effects. Recent cyber- attacks purportedly originated by Russian controlled entities have exacerbated in the wake of Russia' s invasion of Ukraine and our systems may be infiltrated by foreign actors. If we are unable to prevent or mitigate the impact of such security breaches, our ability to attract and retain new customers, patients and other partners could be harmed as they may be reluctant to entrust their data to us, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences. We have significant payer concentration, with a limited number of customers accounting for a substantial portion of our revenues. For **the** year ended December 31, ~~2022~~ **2023** , Medicare reimbursed ~~37~~ **43** % of our diagnostic test revenue to us and one customer accounted for 10 % of our total revenue. For the year ended December 31, ~~2021~~ **2022** , Medicare reimbursed ~~18~~ **37** % of our diagnostic test revenue to us and one customer accounted for ~~40~~ **10** % of our total revenue. There are risks whenever a large percentage of total revenues are concentrated with a limited number of payers and customers. It is not possible for us to predict the level of demand for our diagnostic tests and services that will be generated by any of these customers in the future. In addition, revenues from these larger customers may fluctuate from time to time based on these customers' business needs, the timing of which may be affected by market conditions or other factors outside of our control. These payers and customers could also potentially pressure us to reduce the prices we charge for our diagnostic tests and services, which could have an adverse effect on our margins and financial position and could negatively affect our revenues and results of operations. If any of our largest payers terminates its relationship with us or our tests are no longer reimbursable by such payer, such termination could negatively affect our revenues and results of operations. Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, our diagnostic tests and manage our inventory. To ensure adequate inventory supply, we must forecast inventory needs and manufacture our diagnostic tests based on our estimates of future demand for our diagnostic tests. Our ability to accurately forecast demand for them could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our diagnostic tests or for those of our competitors, our failure to accurately forecast customer acceptance of new diagnostic tests, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory

levels in excess of customer demand may result in inventory write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our diagnostic tests, our supply chain ~~, manufacturing~~ partners and / or internal manufacturing team may not be able to deliver components and diagnostic tests to meet our requirements, and this could result in damage to our reputation, sales growth and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations. If we experience significant disruptions in our information technology systems, our business may be adversely affected. We depend on our information technology systems for the efficient functioning of our business, including the performance, distribution and maintenance of our diagnostic tests and services, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology in all aspects of our systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions would disrupt our operations, including our ability to timely ship and track diagnostic test orders and results, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use our diagnostic tests. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could have a material adverse effect on our business, financial condition and results of operations. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our diagnostic tests and services. The expense and potential unavailability of insurance coverage for liabilities resulting from issues with our diagnostic tests and services could harm us and negatively impact sales. We face an inherent risk of product liability as a result of the marketing and sale of our diagnostic tests and services. For example, we may be sued if our diagnostic tests or services cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre- existing health of the patient. For example, medical personnel, care partners and patients collect samples for our diagnostic tests. If these medical personnel, care partners or patients are not properly trained, are negligent or use our diagnostic tests incorrectly, the capabilities of such tests may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub- assemblies for our diagnostic tests. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of our diagnostic tests and services. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our diagnostic tests and services; • harm to our reputation; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals, or labeling, marketing, or promotional restrictions; • loss of revenue; • adverse impact on the market price of our common stock; and • exhaustion of any available insurance and our capital resources. We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive **and costs may continue to rise** . We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of our diagnostic tests and services. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales. We face competition from many sources, including larger companies, and we may be unable to compete successfully. There are a number of lung cancer diagnostic solutions companies in the United States, Europe and Asia. Notable competitors in the United States include Veracyte, Inc., Guardant Health, Inc. ~~,~~ and Foundation Medicine, Inc. These competitors all provide cancer- focused diagnostic tests to hospitals, researchers, clinicians, laboratories and other medical facilities. Many of these organizations are significantly

larger with greater financial and personnel resources than us, and enjoy significantly greater market share and have greater resources than we do. As a consequence, they may be able to spend more on product development, marketing, sales and other product initiatives than we can. Some of our competitors have: • substantially greater name recognition; • broader, deeper, or longer- term relations with healthcare professionals, customers, and third- party payers; • more established distribution networks; • additional lines of diagnostic tests and the ability to offer rebates or bundle them to offer greater discounts or other incentives to gain a competitive advantage; • greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval or certification for diagnostic tests; and • greater financial and human resources for product development, sales and marketing and patent litigation. Our continued success depends on our ability to: • further penetrate the lung disease diagnostic solutions market and increase utilization of our diagnostic tests; • maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis; and • cost- effectively manufacture our diagnostic tests and their component parts as well as drive down the cost of service. In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or diagnostic tests that could effectively compete with our existing diagnostic tests, which may cause our revenue to decline and would harm our business. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, development of our diagnostic tests. Because of the complex and technical nature of diagnostic testing and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our diagnostic tests, which would have a material adverse effect on our business, financial condition and results of operations. As we attain greater commercial success, our competitors are likely to develop diagnostic tests that offer features and functionality similar to our diagnostic tests that are currently on the market. Improvements in existing competitive diagnostic tests or the introduction of new competitive diagnostic tests may make it more difficult for us to compete for sales, particularly if those competitive diagnostic tests demonstrate better reliability, convenience or effectiveness or are offered at lower prices. Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point- to- point transport of our diagnostic tests to our customers and for tracking of these shipments, and from time to time require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our diagnostic tests on a timely basis. We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost- efficient manner and if these delivery services are disrupted, our business will be harmed. Our business depends on our ability to quickly and reliably deliver test results to our customers. Blood samples are typically received within days from the United States and outside the United States for analysis at our ~~Boulder~~ **Louisville** , Colorado and De Soto, Kansas facilities. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, civil unrest or disturbances, terrorist acts or threats or for other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected. Cost- containment efforts of our customers, purchasing groups and governmental purchasing organizations could have a material adverse effect on our sales and profitability. In an effort to reduce costs, many hospitals in the United States have become members of GPOs and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors on behalf of their members, which may include hospitals and other providers. GPOs and IDNs typically award contracts on a category- by- category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our diagnostic tests, thereby reducing our revenue and margins. While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative diagnostic tests due to the price or quality offered by other companies, which could result in a decline in our revenue. Pricing and reimbursement of medical devices is not harmonized at **the** European level, but is the exclusive competence of the EU Member States. In Europe, pricing and reimbursement decisions are generally made by regional or centralized bodies based on an assessment of the efficacy and clinical effectiveness of the devices or broad device types or procedures. There is a general trend for EU Member States to adopt cost containment measures to control public spend on medical devices. Due to the competitive nature of product offers and prices, we may not be able to obtain new, or maintain existing, contract positions with the EU Member States. Litigation and other legal proceedings may adversely affect our business. From time to time, we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims,

employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and / or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long- term demand for our diagnostic tests and services, even if the regulatory or legal action is unfounded or not material to our operations. We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. General economic and financial market conditions may exacerbate our business risks. Global macroeconomic conditions and the world' s financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. As a result of uncertainties with respect to financial institutions and the global credit markets and other macroeconomic challenges such as inflationary pressures currently or potentially affecting the economy of the United States and other parts of the world, customers and distributors may experience serious cash flow problems and other financial difficulties, decreasing demand for our products. Our customers and distributors may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. In addition, events in the United States or foreign markets, such as the United Kingdom' s exit from the European Union, the worldwide effects from the spread of COVID- 19, Russia' s invasion of Ukraine and political and social unrest in various countries around the world, can impact the global economy and capital markets. Additionally, if our customers and distributors are not successful in generating sufficient revenue or are precluded from securing financing, their businesses will suffer, which may materially and adversely affect our business, financial condition and results of operations. We may not realize the benefits or costs of our Co- Development and Collaboration Agreement with AVEO Oncology. In 2014, we entered into a Co- Development and Collaboration Agreement with AVEO Oncology (formerly known as AVEO Pharmaceuticals, Inc.) (AVEO) whereby the two parties agreed to various terms and conditions necessary for the co- development of AVEO' s compound ficlatuzumab (the Collaboration Agreement). We were granted a limited legal interest in ficlatuzumab and may not have the right to control the development and exploitation of ficlatuzumab. As consideration for the grant, we agreed to cover the first $ 15. 0 million of ficlatuzumab' s clinical development costs, with both parties then sharing all costs equally after the cap was reached. In October of 2016, the Collaboration Agreement was amended to eliminate the requirement that we cover all of the initial costs. Under the amended terms, we agreed to allow AVEO to recapture its cost that it otherwise would not have been responsible for said recapture to occur out of any royalties or revenues eventually derived from the Collaboration Agreement. As part of the Collaboration Agreement, unless we or AVEO ~~exercise~~ **exercised** our right to opt- out of co- development, we **would** equally share in any income received from licensing rights to ficlatuzumab to any third parties. In September 2020, we exercised our opt- out right for the payment of half of the development and regulatory costs for ficlatuzumab. This opt- out was effective as of December 2, 2020 with remaining obligations estimated to be $ 0. 1 million. Following the effective date, we will be entitled to a 10 % royalty of net sales of ficlatuzumab and 25 % of license income generated from the licensing of ficlatuzumab. Ficlatuzumab is currently being evaluated in squamous cell carcinoma of the head and neck (SCCHN), metastatic pancreatic ductal cancer (PDAC), and acute myeloid leukemia (AML). Our relationship with AVEO may require us to incur non- recurring and other charges, increase our near and long- term expenditures, or disrupt our management and business. We cannot be certain that, following the realization of this relationship, we will achieve the revenue or specific net income that justifies our entry into it. Any termination of this relationship, or delays in entering into new strategic partnership agreements with AVEO, could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations. We are exposed to significant future payments and other obligations associated with our acquisitions of Integrated Diagnostics and Oncimmune, U. S. A., and may not realize the advantages we expect from these acquisitions. In 2018, we purchased select assets and liabilities from Integrated Diagnostics, Inc. and IND Funding, LLC (collectively, the Seller or Indi) which included the CLIA lab in Seattle, Washington, and all rights to the Nodify XL2 test and intellectual property rights related to that test. The purchase was made for total consideration of $ 27. 6 million, consisting of $ 8. 0 million (10, 649, 604 shares) of our Series G Preferred Stock and contingent consideration with an initial fair market value of $ 19. 6 million. The acquisition of Indi included a contingent consideration arrangement that requires additional consideration to be paid by us to the Seller based on the milestone of the attainment of a three consecutive month gross margin target of $ 2 million within a seven- year period. Under the terms of the original agreement, when the gross margin target was achieved, the Company was required to issue 2, 520, 108 shares of common stock. For the six months following the achievement of the milestone, Indi had the option to require the Company to redeem the common shares for $ 37. 0 million in cash over eight equal installments. If Indi elected not to exercise this option, we had 12 months to repurchase the common stock in two equal quarterly cash installments totaling $ 37 million. In August 2021, the Company entered into an amendment to the original agreement in which all parties agreed to forgo the issuance of common stock and agreed that the Company would instead make six quarterly installments of approximately $ 4. 6 million each, which began in January 2022, and final payment of approximately $ 9. 3 million in July 2023 for a total of $ 37. 0 million (together, the Milestone Payments). The aggregate amount of payments owed by the Company under this amendment is the same as if Indi had exercised the put right or the Company had exercised the call right provided for in the original agreement. On April 7, 2022, the Company entered into Amendment No. 3 to the Indi APA **,** in which the parties agreed to

restructure the Milestone Payments ~~whereby the~~ **. The** Company ~~will make~~ **made** five quarterly installments of $ 2. 0 million each beginning in April 2022, three quarterly installments of $ 3. 0 million ~~beginning~~ **which began** in July 2023, **will make** one installment of $ 5. 0 million in April 2024, and **will make** one installment of approximately $ 8. 4 million in July 2024. In addition, the Company agreed to an exit fee of approximately $ 6. 1 million in October 2024. Interest shall accrue on the difference between the payment schedule as agreed in the August 2021 amendment and the April 2022 amended payment schedule, at an aggregate per annum rate equal to 10 %, with such interest to be payable quarterly on the following installment payment date. Our ability to make these payments is subject to ongoing compliance under the Perceptive Term Loan **,** and **,** commencing January 1, 2024, consent from Perceptive. In addition, on October 31, 2019 we completed an acquisition of **Freenome'** ~~United Kingdom- based Oncimmune, Ltd.'~~ s ~~(Oncimmune)~~ United States operations **(formerly" Oncimmune USA" or" Oncimmune")** including its CLIA lab in De Soto, Kansas and its incidental pulmonary nodule (IPN) malignancy test, then marketed in the United States as the EarlyCDT **Lung** ® **test** ~~- Lung~~ . We renamed ~~the test~~ and relaunched the test on February 28, 2020 as the Nodify CDT test and the De Soto, Kansas lab is the sole United States provider of the Nodify CDT test. As part of the acquisition, we and Oncimmune entered into several agreements to govern the relationship between the parties and to allow us to provide the Nodify CDT test. The overarching umbrella Purchase and Commercialization Agreement (PCA) defines the general relationship between the parties. Included under the PCA was (a) an APA whereby we acquired all of the United States assets associated with the De Soto, Kansas clinical laboratory, as well as the trademarks and patent application associated with the test; (b) an intellectual property license granting us the rights necessary under Oncimmune' s background intellectual property rights to perform the Nodify CDT test; (c) a supply agreement for supplying us with the necessary materials and reagents needed to run the Nodify CDT test; and (d) a development agreement where Oncimmune agrees to assist us in further developing the Nodify CDT test. We agreed to a revenue share payment of 8 % of recognized revenue for non-screening tests up to an annual minimum volume and 5 % thereafter, with an escalating minimum through the first four years of sales. Royalty expenses were $ **1.** 0 ~~. 9~~ million and $ 0. ~~7~~ **9** million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. Our acquisitions may require us to incur non- recurring and other charges, increase our near and long- term expenditures, or disrupt our management and business. We cannot be certain that, following the realization of these acquisitions, we will achieve the revenue or specific net income that justifies our entry into them. This could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations. We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success. We are highly dependent on our senior management and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition and results of operations. 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 headquarters in ~~Boulder~~ **Louisville** , Colorado and our laboratory facility in De Soto, Kansas. 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. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovation, creativity and teamwork fostered by our culture and our business may be harmed. We believe that our culture has been and will continue to be a critical contributor to our success. We expect to continue to hire aggressively as we expand, and we believe our corporate culture has been crucial in our success and our ability to attract highly skilled personnel. If we do not continue to develop our corporate culture or maintain and preserve our core values as we grow and evolve, we may be unable to foster the innovation, curiosity, creativity, focus on execution, teamwork and the facilitation of critical knowledge transfer and knowledge sharing we believe we need to support our growth. Moreover, liquidity available to our employee securityholders could lead to disparities of wealth among our employees, which could adversely impact relations among employees and our culture in general. Our anticipated headcount growth may result in a change to our corporate culture, which could harm our business. Our ability to utilize our net operating loss carryforwards and research and development credit may be limited. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) a corporation that undergoes an ownership change, generally defined as a greater than 50 % change by value in its equity ownership by certain shareholders over a three- year period, is subject to limitations on its ability to utilize its pre- change net operating losses (NOLs) and its research and development credit carryforwards to offset future taxable income. The applicable rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5 % or more of the stock of a company, as well as changes in ownership arising from new issuances of stock by the company. We believe that our NOLs are currently not subject to limitation

under these rules. However, if we undergo an ownership change now or in the future, our ability to utilize NOLs and research and development credit carryforwards could be limited by Sections 382 and 383 of the Code. Future changes in stock ownership may be beyond our control. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability. The terms of the Perceptive Term Loan Facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. On November 16, 2022 (Closing Date), we entered into a credit agreement and guaranty (the Credit Agreement) with Perceptive Credit Holdings IV, LP as the lender and administrative agent (the Lender) that provides for a senior secured delayed draw term loan facility with Perceptive Advisors LLC (Perceptive), in an aggregate principal amount of up to $ 50. 0 million (the Perceptive Term Loan Facility) to refinance long- term debt. The ~~initial funding of the~~ Perceptive Term Loan Facility ~~was subject to a capital raise of at least $ 30. 0 million in gross proceeds from an equity offering of our common stock, and~~ provides for an " interest- only " period during the term of the loan with principal due at the maturity date, which will be November 21, 2027. The Perceptive Term Loan Facility may be prepaid at any time, subject to a prepayment premium equal to 2 % to 10 % of the aggregate outstanding principal amount being prepaid, depending on the date of prepayment. The Perceptive Term Loan Facility contains customary affirmative and negative covenants for a loan, requires us to comply with a minimum cash requirement covenant, and has a trailing twelve month net revenue requirement. Failure to comply with the covenants and loan requirements may result in an event of default. **On May 10, 2023, the Company entered into the First Amendment with the Lender, whereby, subject to the terms and conditions of the First Amendment, the Minimum Net Revenue Covenant (as defined in the Credit Agreement) was amended to reduce the relevant threshold of each fiscal quarter commencing on the fiscal quarter ending June 30, 2023 through and including the fiscal quarter ending March 31, 2024. As consideration for the First Amendment, the Company agreed to issue to Perceptive a warrant to purchase up to 500, 000 shares of the Company' s common stock which are equity classified at a per share exercise price equal to $ 1. 6254. On August 4, 2023, the Company entered into the Second Amendment to the Credit Agreement and Guaranty (the Second Amendment) with Perceptive as lender and administrative agent and the Company, as borrower, whereby, subject to the terms and conditions of the Second Amendment, the Minimum Net Revenue Covenant (as defined in the Credit Agreement) was amended to reduce the relevant threshold as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2024 through and including the fiscal quarter ending December 31, 2025.** The Perceptive Term Loan Facility contains certain covenants limiting our ability to, among other things, engage in certain corporate changes, make certain restricted payments, repay other certain indebtedness or enter into, amend or terminate any other agreements that have the impact of restricting ~~the~~ our ability to make loan repayments. The Credit Agreement also contains certain customary events of default, the occurrence of which could result in the declaration that all outstanding principal and interest under the Perceptive Term Loan Facility is immediately due and payable in whole or in part, which could have a material adverse effect on our business, financial condition, and results of operations. We will need to raise additional capital to fund our existing operations, develop our platform, commercialize new diagnostic tests or expand our operations. We will need to raise 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 to drive market adoption of and address competitive developments; • fund development and marketing efforts of our diagnostic tests or any other future diagnostic tests; • expand our technologies into other types of cancer management and lung disease detection diagnostic tests; • 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 payer coverage and reimbursement arrangements with domestic and international commercial third- party payers and government payers; • the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts; • our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for our diagnostic tests; • our rate of progress in, and cost of research and development activities associated with, diagnostic tests in research and early development; • the effect of competing technological and market developments; • costs related to international expansion; and • the potential cost of and delays in product development as a result of any regulatory oversight applicable to our diagnostic tests. The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders could experience dilution. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or diagnostic tests, pay a portion of our royalties, or grant licenses on terms that are not favorable to us. Risks Related to our Governmental Regulation The insurance coverage and reimbursement status of newly approved diagnostic tests, particularly in a new category of diagnostics and therapeutics, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for current or future diagnostic tests could limit our ability, and that of our collaborators, to fully commercialize our diagnostic tests and decrease our ability to generate revenue. The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford the clinical diagnostic tests and cellular therapeutics that we and our collaborators currently or in the future plan to develop and sell. In addition, because our clinical diagnostics and diagnostic tests represent new approaches

to the research, diagnosis, detection and treatment of diseases, we cannot accurately estimate how our diagnostic tests, and those jointly created with our collaborators, would be priced, whether reimbursement could be obtained or any potential revenue generated. Sales of our diagnostic tests will depend substantially, both domestically and internationally, on the extent to which the costs of our diagnostic tests are paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payers. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize some of our diagnostic tests or services. Even if coverage is provided, the available reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment in any of our diagnostic tests or services. Changes in the reimbursement landscape may occur, which are outside of our control, and may impact the commercial viability of our diagnostic tests. There is significant uncertainty related to the insurance coverage and reimbursement of newly launched, cleared, authorized or approved diagnostic tests. In the United States, many significant decisions about reimbursement for new diagnostics and medicines are typically made by the CMS, an agency within ~~the~~ HHS. CMS decides whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare, although it frequently delegates this authority to local Medicare Administrative Contractors (MACs). Private payers tend to follow Medicare to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel diagnostic tests such as ours. Additionally, reimbursement authorities or bodies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement, or have been approved under restricted conditions, in certain European countries. Outside the United States, the reimbursement process and timelines vary significantly. In Europe, pricing and reimbursement of medical devices is the exclusive competence of the European Union (EU) Member States. However, the European Commission is facilitating a voluntary corporation between the EU Member States on health technology assessments (HTA) which consists of a network of the EU Member States' national authorities and bodies responsible for HTA and a joint action to support cooperation at scientific and technical level between the HTA bodies. We cannot be sure that such prices and reimbursement decisions will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to control the healthcare budget by focusing cost- cutting efforts on medicinal products, and to a lesser extent, medical devices, provided under their state- run healthcare systems. These price control efforts have impacted all regions of the world, but have been most prominent in the EU. Additionally, some countries require approval of the sale price of a product before it can be marketed or mandatory discounts or profit caps may be applied. Further, after the sale price is approved, it remains subject to review during the product lifecycle. In many countries, the pricing review period begins after marketing or product licensing approval is granted or the CE mark is obtained. As a result, we or our collaborators might obtain marketing approval for a product or service in a particular country, but then may experience delays in the reimbursement approval or be subject to price regulations that would delay the commercial launch of our product or service, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of that product or service in that particular country. Moreover, increasing efforts by governmental and third- party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly cleared, authorized, certified or approved devices and medicines and, as a result, they may not cover or provide adequate payment for our clinical diagnostics to be sold by us or our collaborators. For example, in May 2018 the United States government released a " blueprint, " or plan, to reduce the cost of drugs. This blueprint contains certain measures that HHS has been working to implement, although it is possible that HHS' s regulatory priorities may change under the Biden administration. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, which are, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect to experience pricing pressures on our clinical diagnostics sold by us and our collaborators due to the trend toward value- based pricing and coverage, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new diagnostic tests. Measures to reduce healthcare costs may hurt our business. The majority of our customers are healthcare providers who depend upon reimbursement by government and commercial insurance payers for lung cancer diagnostic solutions services. With a majority of United States patients with lung cancer covered by Medicare, the Medicare reimbursement rate is an important factor in a customer' s decision to use our diagnostic tests and limits the prices we may charge for them. Commercial insurance payers may also exert downward pressure on payment rates for lung cancer treatment services. A reduction in reimbursement rates for lung cancer treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may include reducing the scope of their programs, thereby potentially reducing demand for our diagnostic tests. Healthcare reform measures could hinder or prevent the commercial success of our diagnostic tests. In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may harm our future revenues and profitability and the demand for our diagnostic tests. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our diagnostic tests. The effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our diagnostic tests. For example, the ACA, contains a

number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. There have been judicial challenges to certain aspects of the ACA, as well as efforts by the Trump administration and Congress to repeal, replace or alter the implementation of certain aspects of the ACA. For example, as part of the TCJA, Congress eliminated the tax penalty, starting January 1, 2019, for not complying with the ACA' s individual mandate to carry health insurance. The Further Consolidated Appropriations Act of 2020, Pub. L. No. 116- 94, signed into law December 20, 2019, fully repealed the ACA' s " Cadillac Tax " on certain high- cost employer- sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share (repeal effective in 2021), and the medical device excise tax on non- exempt medical devices. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2 % cut in Medicare payments from May 1, 2020 through March 31, 2022, and a reduction of the cut to 1 % from April 1, 2022 through June 30, 2022. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years. The Biden administration and Congress may continue to pursue significant changes to the current healthcare laws, and the Biden administration has indicated its intent to strengthen the ACA and focus on reducing the cost of healthcare. We face uncertainties that might result from modifications or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the ACA are likely to have an impact on our results of operations, and may negatively affect our business, financial condition and results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm: • our ability to set a price that we believe is fair for our diagnostic tests; • our ability to generate revenue and achieve or maintain profitability; and • the availability of capital. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. Future changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Future changes in healthcare policy could also decrease our revenue and impact sales of and reimbursement for our current and future diagnostic tests. We must comply with anti- corruption, anti- bribery, anti- money laundering and similar laws. We are subject to the FCPA, which generally prohibits companies in the United States from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls. We are also subject to requirements under the United States Treasury Department' s Office of Foreign Assets Control, United States domestic bribery laws and other anti- corruption, anti- bribery and anti- money laundering laws. While we have policies and procedures in place designed to promote compliance with such laws, our employees or other agents may nonetheless engage in prohibited conduct under these laws for which we or our executives might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have an adverse effect on our business, financial condition and results of operations. Furthermore, international customers may currently order our diagnostic tests, either directly from us or through a potential joint venture, and we are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non- United States government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our reliance on independent distributors to sell our diagnostic tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other United States companies in the medical device and biopharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti- bribery laws in the jurisdictions in which we operate, including laws promulgated by OECD countries in which we operate, such as Israel. These laws are complex and far- reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees and could result in a material adverse effect on our business, prospects, financial condition and results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures. We must comply with healthcare fraud and abuse laws. Various federal and state laws, as well as the laws of foreign countries, prohibit payments to induce the referral, purchase, order or use of healthcare products or services and require medical device companies to limit prevent, and / or monitor, and report certain payments to third- party payers, health care professionals, and other individuals. These healthcare fraud and abuse, anti- kickback, public reporting and aggregate spend laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with lung cancer treatment providers, hospitals, physicians or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. These laws prohibit certain marketing initiatives that are commonplace in other industries. If we were to offer or pay inappropriate inducements for the purchase, order or use of our diagnostic tests or our

services, or our arrangements are perceived as inappropriate inducements, we could be subject to claims under various healthcare fraud and abuse laws. Restrictions under applicable United States federal and state healthcare laws and regulations include the following: • the federal Anti- Kickback Statute, a criminal law, prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease, order of any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid; • the Eliminating Kickbacks in Recovery Act, which prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program; • the Beneficiary Inducement Statute, which prohibits any person, organization, or entity from giving anything of value to a federal health care program beneficiary that is likely to induce or influence the beneficiary' s choice of provider, practitioner, or supplier for covered services; • the federal civil False Claims Act, which may be enforced through civil whistleblower or qui tam actions and is often used to enforce the federal Anti- Kickback Statute and other healthcare laws and regulations, imposes civil penalties and potential exclusion from federal healthcare programs, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government; • federal criminal statutes created by HIPAA impose criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private insurance plans, or, in any matter involving a healthcare benefit program, for knowingly and willfully making materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for health care benefits; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payers, including private insurers. Other federal and state laws, as well as the laws of foreign countries, generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to government or commercial payers that are false or fraudulent, or for items or services that were not provided as claimed. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates and medical devices from government- funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time- consuming response. If any physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Manufacturers can also be held liable under these laws if they are deemed to " cause " the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities. We attempt to ensure that any billing and coding information we provide for our diagnostic tests emphasizes the need for physicians and other providers to make independent judgments, use accurate and appropriate billing and coding that complies with all applicable payer policies, and document the medical need for their patients as appropriate. Nevertheless, the government may not regard any billing errors that may be made by our customers as inadvertent and may examine our role in providing information to our customers, physicians and patients concerning the benefits and potential coverage of more frequent therapy. FDA regulation of our industry generally or our tests specifically could be disruptive to our business. Our operations are subject to extensive federal, state, local and foreign laws and regulations, including FDA laws and regulations, all of which are subject to change. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. We believe that we are in material compliance with all statutory and regulatory requirements applicable to us, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third- party payers. The FDA has recently increased its attention to marketing of pharmacogenetic tests. For example, in late 2018, the FDA issued a safety communication regarding genetic laboratory tests with claims to predict a patient' s response to specific medications that have not been reviewed by the FDA and may not be supported by clinical evidence. Among other tests, the FDA notice cited genetic tests that claim results can be used to help physicians identify which antidepressant medication would have increased effectiveness or side effects compared to other antidepressant medications. As explained by the FDA in its update to this safety communication, the FDA sent notices to several firms marketing such pharmacogenetic tests where the FDA believes the relationship between genetic variations and the medication' s effects has not been established, including a warning letter sent to a laboratory, in part, for failing to obtain premarket review of its test. If the FDA were to determine that our tests are not within the **current** enforcement discretion policy for LDTs for any reason, or if FDA **finalizes its proposed rule to end enforcement discretion or** issues new rules, policies, or guidance, due to new legislation or on its own accord, our tests may become subject to FDA requirements, including pre- market review. If this were to happen, it may impact our marketing practices relating to the relevant tests, which in turn may have an adverse impact on our business, financial condition and results of operations. ~~The SARS- CoV- 2 tests we perform are currently the subject of EUAs, which permit the use of~~

unapproved medical products or unapproved uses of medical products to be used in an emergency to diagnose, treat, or prevent serious or life- threatening diseases or conditions when there are no adequate, approved, and available alternatives, as provided under section 564 of the FDCA. EUAs are temporary authorizations that are revoked at the end of the public health emergency, when there is an adequate, approved, or available alternative, or when there are performance or safety concerns. These EUAs also set out conditions for laboratories who are authorized to perform the particular test. Because the EUA declaration under Section 564 of the FDCA is distinct from the declaration under Section 319 of the PHS Act, an EUA may remain in effect beyond the duration of the Section 319 declaration. The EUA for Bio- Rad' s SARS- CoV- 2 ddPCR test provides several conditions for authorized laboratories, including that the test result reports will include Fact Sheets that are authorized as part of the EUA, deviations from the authorized procedures, including specimen types, are not permitted, notification of public health authorities of intent to run the test prior to initiating testing, collection and reporting of performance data to the FDA, including false positives, false negatives, and significant deviations from the established performance characteristics, and appropriate training and protective equipment for laboratory staff. This EUA also states that authorized laboratories must maintain records associated with the EUA and be made available to the FDA for inspection upon request. Printed materials, advertising, and promotion related to use of the test must be consistent with the authorized labeling and Fact Sheets, as well as other terms set forth in the EUA and any applicable requirements under the FDCA and its implementing regulations, and conspicuously bear the following statements: • This test has not been FDA cleared or approved; • This test has been authorized by the FDA under an EUA for use by authorized laboratories; • This test has been authorized only for the detection of nucleic acid from SARS- CoV- 2, not for any other viruses or pathogens; and • This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and / or diagnosis of COVID- 19 under Section 564 (b) (1) of the Act, 21 U. S. C. § 360bbb- 3 (b) (1), unless the authorization is terminated or revoked sooner. Other statements that appear in advertising and promotional materials must not represent or suggest that this test is safe or effective for the detection of SARS- CoV- 2. The EUA for Bio- Rad' s serological test for the antibodies associated with SARS- CoV- 2, also sets out several conditions for authorized laboratories that mirror the conditions for the PCR test described above, except that the printed materials, advertising, and promotion of the test must conspicuously bear the following statements: • This test has been authorized only for the detection of total antibodies, including IgM / IgG / IgA, against SARS- CoV- 2, not for any other viruses or pathogens; and Failure to comply with federal, state and foreign laboratory licensing requirements 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 diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts , including the application of the FDA' s EUA authority. As noted above, the EUAs for the COVID- 19 tests that are part of our Biodesix WorkSafe testing program set out certain conditions for authorized laboratories using the tests, which have not received premarket clearance, approval, or a De Novo authorization from the FDA. If we fail to meet these conditions, the FDA may take enforcement action, such as issuing a warning letter, seeking an injunction, seizure, fines, or criminal penalties. Moreover, if we or others fail to meet applicable conditions, the FDA may revoke the EUAs for the COVID- 19 tests that are part of our Biodesix WorkSafe testing program. Laboratory tests that have already received an EUA to detect the COVID- 19 virus were " unaffected " by the announcement . Tests without FDA clearance, approval, or authorization would not be considered covered countermeasures under the Public Readiness and Emergency Preparedness Act (PREP Act), which authorizes HHS to provide limited liability immunity protection to certain individuals and entities against a claim of loss under federal and state law " caused by, arising out of, relating to, or resulting from " the manufacture, distribution, administration, or use of a covered medical countermeasure, except for claims involving willful misconduct. Consequently, any violations of applicable laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees and could result in a material adverse effect on our business, prospects, financial condition and results of operations. We are also 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 requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many private third- party payers, for laboratory testing services. As a condition of CLIA certification, each of our laboratories is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA certificate of accreditation, a CMS- approved accreditation organization. Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory' s CLIA certificate, which is necessary to conduct our business, as well as the imposition of significant fines or criminal penalties. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. If the CLIA certificate of any one of our laboratories is revoked, CMS could seek revocation of the CLIA certificates of our other laboratories based on their common ownership or operation, even though they are separately certified. In addition, we are subject to state laws and regulations governing laboratory licensure. Some states have enacted state licensure laws that are more stringent than CLIA. 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. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other

limitations that may limit our ability to make our tests 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. Changes in state or foreign licensure laws that affect our ability to offer and provide diagnostic services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries. 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 certificate 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 certificate, a state or foreign license or accreditation, 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. Our ~~Boulder~~ **Louisville** , Colorado and De Soto, Kansas laboratories are both CAP- accredited clinical laboratories regulated by CMS pursuant to CLIA. We also have a current CLIA certificate for each facility. To maintain these certificates, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time. Furthermore, our diagnostic tests are categorized as LDTs and are not currently subject to FDA regulation, although certain components provided by third parties and used to create and / or administer the test may be. LDTs are a subset of IVDs that are intended for clinical use and developed, validated, and offered within a single laboratory for use only in that laboratory. Failure to adhere to any new FDA regulation would result in fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal penalties. Our current line of diagnostic tests is covered under CLIA and CMS, ~~however,~~ **but the FDA may end its general policy of enforcement discretion and regulate laboratory developed tests as medical devices.** ~~changes~~ **Changes** in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future. ~~In addition, our COVID testing program and select partnerships we may enter may cause us to be subject to additional FDA requirements.~~ The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the FDCA, the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, potentially our clinical laboratory tests. 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. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as our and many other laboratories' tests, as medical devices, it has generally exercised enforcement discretion and is currently not otherwise regulating most tests developed and performed within a single high complexity CLIA- certified laboratory. Pursuant to this enforcement discretion policy, FDA does not require laboratories that furnish LDTs to comply with the agency' s requirements for medical devices (e. g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post- market controls). **We believe that our tests, as utilized in our clinical laboratory, are and would be considered LDTs and that as a result, the FDA does not require that we obtain regulatory clearances or approvals for our LDTs or their components pursuant to the FDA' s current policies and guidance. Although we believe that our tests and test components are either exempt from FDA medical device regulations or are subject to an enforcement discretion policy, it is possible that the FDA would not agree with our determinations or that the FDA will change its regulations and policies such that our products become regulated as medical devices.** In recent years, ~~however,~~ the FDA **has** publicly announced its intention to regulate certain LDTs and has set forth various proposals for a phased- in risk- based regulatory framework that would apply varying levels of FDA oversight to LDTs. **Until recently, the** FDA ~~' s~~ **has articulated such** policies ~~to date have been articulated~~ through guidance documents, compliance manuals, website statements, and other informal issuances ~~. The FDA could~~ , **but not through** ~~at any time, engage in~~ notice- and- comment rulemaking **. On September 29** , **2023, the FDA announced a proposed rule to amend its regulations to explicitly regulate LDTs as IVD tests in accordance with the agency' s regulatory authority over medical devices. If this rule is finalized,** ~~or~~ **our tests that are currently offered as LDTs would become subject to statutory and regulatory provisions that are applicable to medical devices, including but not limited to, medical device reporting and correction and removal reporting requirements, quality systems regulations, registration and listing requirements, and premarket review requirements. Even if the proposed rule is not finalized,** Congress could take action to amend the law to change the current regulatory framework for in vitro diagnostics and LDTs to require premarket review of LDTs **and other regulatory requirements. New requirements** , ~~which~~ **whether imposed through legislation or administratively,** could result in delay or additional expense in offering our tests and tests that we may develop in the future. ~~We believe that~~ **Moreover, failure to comply with applicable requirements under the relevant timeframes could cause us to lose the ability to perform** our tests, **experience disruptions to** ~~as utilized in our clinical laboratory, are and would be considered LDTs and that as a result, the FDA does not require that we obtain regulatory clearances or~~ **our** ~~approvals~~ **business,** ~~for~~ **or become** ~~our LDTs or their components pursuant to the FDA' s current policies and guidance. Although we believe that our tests and test components are either exempt from FDA medical device regulations or are~~ subject to **administrative or judicial enforcement actions, which in turn may have** an **adverse impact on** ~~enforcement discretion policy, it is possible that the FDA would not agree with our determinations or~~ **our business** ~~that the FDA will change its regulations and policies such that our products become regulated as medical devices. In contrast with our LDTs~~ , **financial condition, and results** ~~the FDA has regulatory jurisdiction over the three FDA EUA- authorized COVID- 19 tests which we offer as part~~ of **operations** ~~our~~

~~Biodesix WorkSafe testing program~~ . Our operations, therefore, are or may become subject to extensive regulation by the FDA in the United States. Government regulations specific to medical devices are wide ranging and govern, among other things: • test design, development, manufacture, and release; • laboratory and clinical testing, labeling, packaging, storage, and distribution; • product safety and efficacy; • premarketing clearance or approval; • service operations; • record keeping; • product marketing, promotion and advertising, sales, and distribution; • post- marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals; • post- market approval studies; and • product import and export. The premarket submission process for medical devices can be expensive, lengthy and unpredictable. The FDA can delay, limit, or deny clearance or approval of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or conformity assessment body that the diagnostic tests are safe or effective for their proposed intended uses; • the disagreement of the FDA with the design or implementation of our clinical trials or the interpretation of data from clinical trials; • serious and unexpected adverse device effects experienced by participants in our clinical trials; • the data from our clinical trials may be insufficient to support clearance or approval, where required; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • the manufacturing process or facilities we use may not meet applicable requirements; and • the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions: • adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recall or seizure of our diagnostic tests; • operating restrictions, partial suspension, or total shutdown of production; • denial of our requests for regulatory clearance or premarket approval of new diagnostic tests or services, new intended uses, or modifications to existing diagnostic tests or services; • withdrawal of regulatory clearance or premarket approvals that have already been granted; or • criminal prosecution. As discussed above, we believe that our current line of diagnostic tests and their components are LDTs, which are subject to state licensing requirements and federal regulation by CMS under CLIA, although our COVID- 19 testing program and select partnerships we may enter may cause us to be subject to additional FDA regulations discussed above. While we believe that we are currently in material compliance with applicable laws and regulations, it is possible that the FDA, or other regulatory agencies, would not agree with our determinations. If our products became become subject to premarket submission and other FDA requirements, we would need to comply with the applicable regulations or face significant civil and criminal penalties. In addition, IVDs and CDx tests are widely considered to be Class III devices, and it is possible that in the future, we may develop tests that fall into this category. CDx tests in particular may require further administrative procedures in the PMA process. Exposure to these additional regulatory requirements would also affect our business, financial condition and results of operations. Our future success depends on our ability to develop, receive regulatory clearance or approval or certification for, and introduce new diagnostic tests or enhancements to existing diagnostic tests that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510 (k) clearance, De Novo authorization, or PMA approval of our future diagnostic tests and failure to obtain necessary clearances or approvals for our future diagnostic tests would adversely affect our ability to grow our business. It is important to our business that we build a pipeline of diagnostic test offerings that address limitations of current lung disease diagnostic tests. As such, our success will depend in part on our ability to develop and introduce new diagnostic tests. However, we may not be able to successfully develop and obtain regulatory clearance or approval or certification for enhancements to our existing diagnostic tests, or new diagnostic tests for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these diagnostic tests may not be accepted by physicians or users. The success of any new diagnostic test or enhancement to an existing diagnostic test will depend on a number of factors, including our ability to, among others: • identify and anticipate physician and patient needs properly; • develop and introduce new diagnostic tests or enhancements to our existing diagnostic tests in a timely manner; • avoid infringing upon, misappropriating, or violating the intellectual property rights of third parties; • demonstrate, if required, the safety and efficacy of new diagnostic tests with data from clinical studies; • obtain the necessary regulatory clearances or approvals or certifications for new diagnostic tests or enhancements to existing diagnostic tests; • comply fully with FDA and foreign regulations on marketing of new diagnostic tests or modified diagnostic tests; and • provide adequate training to potential users of our diagnostic tests. If we do not develop new diagnostic tests or enhancements to our existing diagnostic tests in time to meet market demand or if there is insufficient demand for these diagnostic tests or enhancements, or if our competitors introduce new diagnostic tests with functionalities that are superior to ours, our results of operations will suffer. Some of our future diagnostic tests may require FDA clearance of a 510 (k) submission. Other diagnostic tests may require the approval of a PMA. In addition, some of our future diagnostic tests may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these diagnostic tests for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510 (k) clearance, De Novo authorization, or premarket approval of new diagnostic tests. Failure to receive clearance or approval for our new diagnostic tests would have an adverse effect on our ability to expand our business. Modifications to our marketed tests may require new 510 (k) clearances, De Novo authorizations, or PMA approvals, or may require us to cease marketing or recall the modified tests until clearances or approvals are obtained. Modifications to our diagnostic tests may require new regulatory approvals or clearances, including 510 (k) clearances, De Novo authorizations, or premarket approvals, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new submission is necessary. However, the FDA can review a

manufacturer' s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our diagnostic tests in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our diagnostic tests as modified, which could require us to redesign our diagnostic tests and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. Where we determine that modifications to our diagnostic tests require a new premarket submission, we may not be able to obtain the additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time- consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced diagnostic tests in a timely manner, which in turn would harm our future growth. If we or our suppliers fail to comply with ongoing FDA or other domestic and foreign regulatory authority or conformity assessment body requirements, or if we experience unanticipated problems with our diagnostic tests, they could be subject to restrictions or withdrawal from the market. Any medical device that we manufacture, including those for which we obtain regulatory clearance or approval or certification, and the manufacturing processes, reporting requirements, post- approval clinical data and promotional activities for such diagnostic test, will be subject to continued regulatory review, oversight, and periodic inspections by the FDA and other domestic and foreign regulatory bodies or conformity assessment bodies. In particular, we and our suppliers may be required to comply with FDA' s QSR (QSR codified at 21 C. F. R. § 820) for medical devices and ISO regulations for the manufacture of our diagnostic tests and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any diagnostic test for which we obtain clearance or approval. Regulatory bodies, such as the FDA, and conformity assessment bodies enforce the QSR and other regulations through periodic inspections and audits. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies or conformity assessment bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, one or more of the following enforcement actions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • unanticipated expenditures to address or defend such actions; • customer notifications for repair, replacement, or refunds; • recall, detention, or seizure of our diagnostic tests; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying our requests for 510 (k) clearance, De Novo authorization, or premarket approval of new diagnostic tests or modified versions of current diagnostic tests; • operating restrictions; • withdrawing 510 (k) clearances, De Novo authorization, or PMA approvals that have already been granted; • revocation of EUAs that have been authorized previously; • refusal to grant export approval for our diagnostic tests; and If any of these actions were to occur it would harm our reputation and cause our diagnostic test sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our diagnostic tests on a timely basis and in the required quantities, if at all. In addition, we are required to conduct surveillance to monitor the safety or effectiveness of our diagnostic tests, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our diagnostic tests. Later discovery of previously unknown problems with our diagnostic tests, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such diagnostic tests or manufacturing processes, withdrawal of the diagnostic tests from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. Our diagnostic tests and services may in the future be subject to product recalls that could harm our reputation, business and financial results. Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government- mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our diagnostic tests and services in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations. Other jurisdictions have similar recall requirements. Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval or certification of any future diagnostic tests and to manufacture, market and distribute our diagnostic tests after clearance or approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, the Verifying Accurate, Leading- edge IVCT Development (VALID) Act recently introduced in Congress would codify into law the term " in vitro clinical test " in order to create a new medical product category separate from medical devices that would include products currently regulated as in vitro diagnostics as well as LDTs. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our diagnostic tests. **For example, FDA announced a proposed rule in September 2023 to phase out its enforcement discretion over LDTs and regulate such diagnostic tests as medical devices.** Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future diagnostic tests. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations

changed, and what the impact of such changes, if any, may be. Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future diagnostic tests could make it more difficult and costly to obtain clearance or approval for new diagnostic tests or to produce, market and distribute existing diagnostic tests. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new diagnostic tests would have an adverse effect on our ability to expand our business. Clinical trials may be necessary to support future product submissions to FDA. These clinical trials are expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new diagnostic tests and will adversely affect our business, operating results and prospects. Initiating and completing clinical trials necessary to support any future PMA applications, De Novo requests, and additional safety and efficacy data beyond that typically required for a 510 (k) clearance, for our possible future product candidates, will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of our diagnostic tests or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and / or for a longer follow- up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our diagnostic tests or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects. If the third parties on which we rely to conduct our clinical trials and to assist us with pre- clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval or certification for or commercialize our diagnostic tests and services. We may not have the ability to independently conduct our pre- clinical and clinical trials for our future diagnostic tests and services and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre- clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our diagnostic tests and services on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third- party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. Our use, disclosure, and other processing of personally identifiable information, including health information, is subject to HIPAA and other federal, state, and foreign privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our business, operating results and prospects. We maintain and process, and our third- party vendors, collaborators, contractors and consultants maintain and process on our behalf, a large quantity of sensitive information, including confidential business, personal and patient health information in connection with our clinical studies and our employees, and are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure by us or our third- party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in notification obligations or enforcement actions against us, which could result in fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. These laws, rules and regulations evolve frequently and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health- related and data protection laws, especially with respect to genetic samples and data, in the United States, the EU and elsewhere, are often uncertain, contradictory and in flux. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. Domestic laws in this area are complex and developing rapidly. Many state legislatures have adopted legislation relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data

breach is costly. States are also frequently amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California recently enacted the CCPA, which became effective on January 1, 2020. The CCPA, among other things, requires new disclosures to California consumers and affords such consumers new abilities to access and delete their personal information, opt- out of certain sales of personal information and receive detailed information about how their personal information is used. The CCPA provides for fines of up to $ 7, 500 per violation, as well as a private right of action for data breaches that is expected to increase the frequency of data breach litigation. While the CCPA has already been amended multiple times, it is unclear how this legislation will be further modified or how it will be interpreted. Interpretations of the CCPA may continue to evolve with regulatory guidance and the CCPA continue to be amended, including through a ballot initiative, adopted by voters in November 2020, known as the California Privacy Rights Act, or CPRA. The CPRA imposes additional data protection obligations on companies doing business in California, including additional consumer rights, including regarding certain uses of sensitive data. It also creates a new California data protection agency- the California Privacy Protection Agency- specifically tasked to enforce the law, which may likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The effects of this legislation potentially are far- reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance- related costs and expenses. The CCPA and other changes in state and federal laws or regulations relating to privacy, data protection and information security, particularly any new or modified laws or regulations that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer or disclosure, could increase the cost of providing our offerings, require significant changes to our operations or even prevent us from providing certain offerings in jurisdictions in which we currently operate and in which we may operate in the future. Because of the breadth of these data protection laws and the narrowness of their exceptions and safe harbors, it is possible that our business or data protection policies could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of heightened regulatory focus on data privacy and security issues. Although we endeavor to comply with our published policies and documentation and ensure their compliance with current laws, rules and regulations, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policy and other documentation that provide promises and assurances about privacy and security can subject us to potential state and federal action in the United States if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Any failure by us or other parties with whom we do business to comply with this documentation or with federal, state, local or international regulations could result in proceedings against us by governmental entities, private parties or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. If our operations are found to be in violation of any of the data protection laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, class action litigation and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corrective action plan or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations. In addition, numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of PHI and PII. These laws and regulations include HIPAA. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA, PHI) by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities (CE), and the business associates (BA) with whom such covered entities contract for services. We are a CE under HIPAA when we are conducting our clinical trials. We are a CE with regard to our observational studies and clinical trials, and also a BA under HIPAA for certain other business activities, and we execute BA agreements with our clients. HIPAA requires CEs and BAs, such as us, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach. HIPAA imposes mandatory penalties for certain violations. Penalties for violations of HIPAA and its implementing regulations start at $ 119 per violation and are subject to a cap of $ 1, 785, 651 for violations of the same standard in a single calendar year. However, a single breach incident can result in violations of multiple standards. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA CEs and BAs. With regard to BAs, those audits assess the business associate' s compliance with the HIPAA Privacy and Security Standards. Such audits are conducted randomly and after an entity experiences a breach affecting more than 500 individuals' data. Undergoing an audit can be costly, can result in fines or onerous obligations, and can damage a BAs reputation. In addition to HIPAA, numerous other federal, state, and foreign laws and regulations protect the confidentiality, privacy, availability, integrity and security of PHI and other types of PII. Some of these laws and regulations may be preempted by HIPAA with respect to PHI, or may exclude PHI from their scope but impose obligations with regard to PII that is not PHI, and in some cases, can impose additional obligations with regard to PHI. These laws and regulations are often uncertain, contradictory, and subject to changing or differing interpretations, and we expect new laws, rules and regulations regarding privacy, data protection, and information security to be proposed and enacted in the future. HHS is also proposing amendments to the HIPAA Privacy Rule to modernize certain data sharing provisions and enhance patient access to their information. This complex, dynamic legal landscape regarding privacy, data protection, and information security creates significant compliance issues for us and our clients and potentially exposes us to additional expense, adverse

publicity and liability. While we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information is transmitted to us by third parties, who may not implement adequate security and privacy measures, but it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government- imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business. We may eventually operate in a number of countries outside of the United States whose laws, including data privacy laws, may in some cases be more stringent than the requirements in the United States. For example, EU and UK data privacy laws have specific requirements relating to cross- border transfers of personal data to certain jurisdictions, including to the United States, have strict requirements relating to personal data collection, use or sharing, and have more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, we may also be subject to evolving international privacy and data security regulations which could result in greater compliance costs and in turn lead to penalties, where such compliance programs are not implemented correctly. Certain of our processing activities are subject to the EU General Data Protection Regulation and the UK General Data Protection Regulation (collectively, the " GDPR ") – including, those involving pseudonymised / key- coded data- as the GDPR applies extra- territorially. The GDPR imposes strict requirements on controllers and processors processing personal data, including, for example, requirements to: (i) identify a legal basis for the processing of personal data, (ii) provide robust disclosures to individuals, (iii) respond to requests from individuals to exercise their data subject rights, (iv) provide personal data breach notifications within 72 hours after discovering the breach, (v) limit the collection and retention of personal data, (vi) impose specific contractual obligations on processors engaged to process personal data on the instructions of the controller, and (vii) apply enhanced protections to health data and other special categories of personal data. The EU GDPR also provides that EU Member States may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share such personal data and cause our costs to increase and harm our financial condition. Failure to comply with the requirements of the GDPR may result in fines of up to € 20 million (£ 17. 5 million in the case of the UK GDPR) or up to 4 % of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. GDPR compliance may require us to put in place additional mechanisms, which may result in compliance costs and other substantial expenditures. This may be onerous and adversely affect our business, financial condition, results of operations and the profitability of our platform of diagnostic tests. Failure to comply with the GDPR and other countries' privacy or data security- related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with contracts entered into with our collaborators and other third- party payers, and have an adverse effect on our business and financial condition. Currently, the GDPR is only applicable to us as a processor, but as we continue to expand into the European market, the GDPR will have direct applicability to us as a controller. The GDPR also prohibits the transfer of personal data from the EEA / UK to a country outside of the EEA / UK (e. g., the United States) unless made to a country deemed to have adequate data privacy laws by the European Commission (or UK Government in case of the UK GDPR) or a data transfer mechanism has been put in place. Until recently, one such data transfer mechanism was the EU- US Privacy Shield. However, in July 2020 the Court of Justice of the European Union (CJEU) declared the Privacy Shield to be invalid. Following an executive order on trans- Atlantic data flows issued by President Biden in October 2022, the European Commission in December 2022 announced that it had initiated the process of drafting a new adequacy decision based on a modified data transfer framework that would replace the Privacy Shield **, which it completed in July 2023** . Though adoption of a new adequacy decision may have the effect of making data transfers to the United States easier, it is widely expected that the updated transfer framework and the adequacy decision will also be reviewed by the CJEU. The CJEU also upheld the validity of standard contractual clauses (SCCs) as a legal mechanism to transfer personal data but companies relying on SCCs will need to carry out a transfer privacy impact assessment, which among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. In turn, the findings of the CJEU will have significant implications for cross- border data flows and may lead to increased transaction, compliance, and technological costs to support international data transfers. Organizations operating in Canada and covered by the Personal Information Protection and Electronic Documents Act (PIPEDA), or equivalent Canadian provincial laws, must obtain an individual' s consent when they collect, use or disclose that individual' s personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual' s consent. We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third- party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our vendors that support our IT or have access to our data, including any third- party vendors that collect, process and store personal data on our behalf, fail to comply with laws requiring the protection of personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information

security was unreasonable or otherwise violated applicable laws or contractual obligations. Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and / or negligent conduct or unauthorized activity that violates: • FDA regulations, including those laws requiring the reporting of true, complete, and accurate information to the FDA authorities; • federal and state healthcare fraud and abuse laws and regulations; or • laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or exclusion by the HHS Office of Inspector General (OIG) could result in penalties, a loss of business from third parties, and severe reputational harm. We have adopted a Code of Business Conduct and Ethics and compliance policies to govern and deter such behaviors, but it is not always possible to identify and deter misconduct by our employees and other agents, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws 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 civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations. Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Our ongoing research and development and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting pre- and post- market clinical studies of some of our tests. In the future we may conduct clinical trials to support approval of new diagnostic tests and services, or new indications. Clinical studies may need to be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support marketing authorization for these diagnostic tests and services. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities and conformity assessment bodies will agree with our conclusions regarding them. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre- clinical studies. The clinical trial process may fail to demonstrate that our tests are safe and effective for the proposed indicated uses, which could cause us to abandon development of our tests and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, may impact our ability to commercialize our tests and generate revenues. 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 or certification. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions, and contract research organizations to perform the trials, and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties would not relieve us of our regulatory responsibilities. We and our third- party contractors are required to comply with good clinical practices (GCPs) which are regulations and guidelines enforced by the FDA, and comparable regulations enforced by foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third- party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities or conformity assessment bodies may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval or certification process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors could be beyond our control. We may not be able to undertake additional trials, repeat trials or enter into new arrangements with third parties without undue delays or considerable expenditures. If there are delays in testing or clearances or approvals as a result of the failure to perform by third parties, our research and development costs would increase and we may not be able to obtain regulatory clearance or approval or certification for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability. The results of our clinical

trials may not support our product candidate claims or may result in the discovery of adverse side effects. We cannot be certain that the results of our future clinical trials will support our future product claims or that the FDA or comparable foreign regulatory authorities or conformity assessment bodies will agree with our conclusions regarding them. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre- clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the future product' s profile. Our billing, collections and claims processing activities are complex and time- consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements, could have an adverse effect on our future revenue. Billing for our tests is complex, time- consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, such as government payers, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts, including long collection cycles and the risk that we may never collect at all, either of which could adversely affect our business, financial condition and results of operations. Several factors make the billing process complex, including: • differences between the list price for our tests and the reimbursement rates of payers; • compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid, to the extent our tests are covered by such programs; • differences in coverage among payers and the effect of patient co- payments or co- insurance; • differences in information and billing requirements among payers; • changes to codes and coding instructions governing our tests; • incorrect or missing billing information; and • the resources required to manage the billing and claims appeals process. These billing complexities and the related uncertainty in obtaining payment for our tests 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, if claims for our tests are not submitted to payers on a timely basis, or if we fail to comply with applicable billing requirements, it could have an adverse effect on our revenue and our business. Third-party payers require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology (CPT) code. The CPT code set is maintained by the American Medical Association (AMA). In cases where there is not a specific CPT code to describe a test, such as with **the** GeneStrat NGS **test** , the test may be billed under an unlisted molecular pathology procedure code or through the use of a combination of single gene CPT codes, depending on the payer. The Protecting Access to Medicare Act of 2014 (PAMA) authorized the adoption of new, temporary billing codes and unique test identifiers for FDA- cleared or approved tests as well as advanced diagnostic laboratory tests. The AMA has created a new section of CPT codes, Proprietary Laboratory Analyses codes to facilitate implementation of this section of PAMA. In addition, CMS may assign unique level II Healthcare Common Procedure Coding System codes to tests that are not already described by a unique CPT code. **The** VeriStrat, Nodify XL2, and Nodify CDT **tests** have test specific CPT codes, but the GeneStrat NGS test does not at this time. In the instance where a code used does not describe a specific test, the insurance claim must be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. As a result, obtaining approvals from third-party payers to cover our tests and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming and costly process and we may never be successful. We and our third- party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business. Our research and development activities and our third- party manufacturers' and suppliers' activities involve the generation, use, storage and disposal of hazardous materials. We work with materials, including chemicals, biological agents and compounds and samples that could be hazardous to human health and safety or the environment. Our operations also produce hazardous and biological waste products. Accordingly, we and our third- party manufacturers and suppliers are subject to federal, state, local and foreign environmental, health and safety laws and regulations, and permitting and licensing requirements, including those governing the generation, use, manufacture, storage, handling, transportation, release and disposal of, and exposure to, these materials, and worker health and safety. We cannot eliminate the risk of contamination or injury resulting from such hazardous materials. We also cannot guarantee that the procedures utilized by our third- party manufacturers for handling and disposing of hazardous materials and wastes comply with all applicable environmental, health and safety laws and regulations. As a result, we may be held liable for any resulting damages, costs or liabilities, including cleanup costs and liabilities, which could be significant, or our commercialization, research and development efforts and business operations may be restricted or interrupted. Environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. Compliance with such laws and regulations is expensive, and current or future environmental, health and safety laws and regulations may restrict our operations. If we do not comply with applicable environmental health and safety laws and regulations, and permitting and licensing requirements, we may be subject to fines, penalties, a suspension of our business or other sanctions. Risks Related to our Intellectual Property Our success may be impaired if we are unable to obtain, maintain and protect our intellectual property rights. Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our diagnostic tests, products and services and technology. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, to protect our proprietary technology and prevent others from duplicating our suite of diagnostic tests and products. However, these means may afford only limited protection and may not: • prevent our competitors from duplicating our diagnostic tests and products, including our ~~COVID- 19 testing program and~~ Nodify XL2, Nodify CDT, GeneStrat and VeriStrat tests; • prevent our competitors from gaining access to our proprietary information and technology,

including the Diagnostic Cortex platform, tech platforms such as the DeepMALDI analysis and intellectual property covering technologies that allow us to develop " test algorithms "; or • allow us to gain or maintain a competitive advantage. Any of our patents, including those we may license, may be challenged, invalidated, rendered unenforceable or circumvented. Consequently, we do not know whether any of our diagnostic tests, products and services will be protectable or remain protected by valid and enforceable patents. We may not prevail if our patents are challenged by competitors or other third parties. The United States federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents, find them unenforceable, or narrow their scope. Furthermore, competitors may be able to design around our patents by developing similar or alternative technologies or products in a non- infringing manner, or obtain patent protection for more effective technologies, designs or methods, including for treating lung cancer. If these developments were to occur, our diagnostic tests and products may become less competitive and sales may decline. We have filed numerous patent applications seeking protection of diagnostic tests and other inventions originating from our research and development. Our patent applications may not result in issued patents, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted and significantly reduced after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with the protection or competitive advantages we are seeking. Moreover, some of our owned and in- licensed patents and patent applications are, and may in the future be, co- owned with third parties. If we are unable to obtain or maintain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects. The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. Various courts, including the United States Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to biotechnology. 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 or abstract idea is uncertain, and it is possible that certain aspects of our technology could be considered unpatentable under applicable law. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Depending on decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce our existing owned or in- licensed patents and patents that we might obtain or in- license in the future. Additionally, our pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. The scope of patent protection outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property rights or narrow the scope of our owned and licensed patents. If we are unable to obtain and maintain patent protection for our technology, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize diagnostic tests, products and services similar or superior to ours, and our competitive position may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. In addition, the patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Additionally, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, primarily rely on protecting our software as a trade secret. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our copyrights may be limited. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to seeking patent protection for the patents underlying our diagnostic tests, products and services, we also rely upon unpatented trade secrets, know- how and continuing technological innovation to develop and maintain a competitive position. Trade secrets and know- how can be difficult to protect. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses

containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties. We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know- how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions. Consequently, we may be unable to prevent our proprietary technology from being exploited in the United States and abroad, which could affect our ability to expand in domestic and international markets or require costly efforts to protect our technology. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property rights owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions, which could have a material adverse effect on our business, financial condition and results of operations. We may be subject to claims that we or our employees have misappropriated the intellectual property rights of a third party, including trade secrets or know- how, or are in breach of non- competition or non- solicitation agreements with our competitors, and third parties may claim an ownership interest in intellectual property we regard as our own. Many of our employees and consultants were previously employed at or engaged by universities or other medical device, diagnostic, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property rights, proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Any litigation or the threat of litigation may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize potential diagnostic tests, products and services, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property rights we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our diagnostic tests or products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our diagnostic tests or products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our rights to ~~our COVID- 19 testing program,~~ either of the Nodify XL2 and Nodify CDT tests, or the VeriStrat and GeneStrat tests. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property rights. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future diagnostic tests, products and services. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy- Smith America Invents Act (Leahy- Smith Act) was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first- to- invent system to a first- inventor- to- file system, allow third- party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings, including post- grant review, inter partes review and derivation proceedings.

Under a first- inventor- to- file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor was the first to invent the claimed invention. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. If our trademarks and ~~tradenames~~ **trade names** are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or 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 trademarks or trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively 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 registered several connected to our diagnostic tests, products and services in the United States. If we apply to register these and trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. 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 trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our efforts to enforce or protect our rights related to trademarks, trade secrets, domain names or other intellectual property rights may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition and results of operations. We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors or other third parties may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or other intellectual property rights, or we may be required to defend against claims of infringement, misappropriation or other violations. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their patents or other intellectual property. In any such proceeding, a court or other administrative body may decide that a patent or other intellectual property right owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non- enablement or failure to claim patent- eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post- grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, including opposition proceedings. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our diagnostic tests, products and services or prevent third parties from competing with our diagnostic tests, products and services. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our diagnostic tests, products and services. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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 litigation. Moreover, some of our owned and in- licensed

patents and patent applications are, and may in the future be, co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing diagnostic tests, products, services or technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. The intellectual property landscape in the field of precision oncology is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in- licensed, and other third party, intellectual property and proprietary rights in the future. As we move into new markets and applications for our diagnostic tests, products or services, incumbent participants in such markets may assert their patents and other intellectual property rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success depends in part on our non- infringement of the patents or other intellectual property rights of third parties. However, we may in the future be subject to claims that we, or other parties we have agreed to indemnify, infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because patent applications are published sometime after filing, and because applications can take several years to issue, there may be additional currently pending third- party patent applications that are unknown to us, which may later result in issued patents. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There is a substantial amount of litigation and other patent challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are developing diagnostic tests and in which we may develop future diagnostic tests, products and services. As the precision oncology industry expands and more patents are issued, the risk increases that our diagnostic tests may be subject to claims of infringement of the patent rights of third parties. Numerous significant intellectual property issues have been litigated, are being litigated and will likely continue to be litigated, between existing and new participants in our existing and targeted markets, and competitors have and may assert that our diagnostic tests or services infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third- party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third- party patents. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell diagnostic tests, products or services, and could result in the award of substantial damages against us, including treble damages, attorney' s fees, costs, and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, which could be significant, and obtain one or more licenses from third parties, or be prohibited from selling certain diagnostic tests, products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non- exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in diagnostic test introductions while we attempt to develop alternative diagnostic tests, products or services to avoid infringing third- party

patents or intellectual property rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing diagnostic tests, products or services, and the prohibition of sale of any of our diagnostic tests, products or services could materially affect our business and our ability to gain market acceptance for our diagnostic tests, products and services. 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. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition. We may be subject to claims challenging the priority or inventorship of our patents and other intellectual property rights. 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 rights 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 product candidates. 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 rights. 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, or right to use, intellectual property rights that are important to our product candidates. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of our diagnostic tests, products or services. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. 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. 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 will be due to 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- United States patent agencies. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property rights. The USPTO and various non- US 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 some 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. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business. Issued patents covering our diagnostic tests and any other or future diagnostic tests, products or services could be found invalid or unenforceable if challenged. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and some of our patents or patent applications, including licensed patents, may be challenged, in courts or patent offices in the United States and abroad, in opposition, derivation, reexamination, inter partes review, post- grant review or interference. Additionally, if we and our licensing partners initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our diagnostic tests, products, services or technologies, the defendant could counterclaim that the patent covering our diagnostic tests, products or services is invalid or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. In addition, the United States now awards patent priority to the first party to file a patent application, and others may submit patent claims covering our inventions prior to us. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our diagnostic tests or any diagnostic tests, products and services that we may develop. A successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our

inability to manufacture or commercialize products without infringing third- party patent rights, which could have a material adverse impact on our business. Furthermore, 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, products or services. We may not be aware of all third- party intellectual property rights potentially relating to our current or future diagnostic tests, products or services. 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, not until such patent applications issue as patents. We, or our current or future license partners or collaborators, 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 may have to participate in interference proceedings, derivation proceedings or other post- grant proceedings declared by the USPTO. The outcome of such proceedings is uncertain, and other patent applications may have priority over our patent applications. Such proceedings could also result in substantial costs to us and divert our management' s attention and resources. We rely on licenses from third parties in relation to certain diagnostic tests, products and services and if we lose these licenses then we may be subjected to future litigation. We are a party to license agreements that grant us rights to use certain intellectual property rights, including patents and patent applications, typically in certain specified fields of use, in connection with our diagnostic tests, products and services. Some of those licensed rights could provide us with freedom to operate for aspects of our diagnostic tests, products and services. We may need to obtain additional licenses from others to advance our research, development and commercialization activities. 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 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 product candidates 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 be unable to in- license or acquire the third- party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with these obligations or other obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product or use any technology that is covered by these agreements. If our license agreements terminate, or we experience a reduction or elimination of licensed rights under these agreements, we may have to negotiate new or reinstated licenses with less favorable terms or we may not have sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business. Our success may depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property rights. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property rights we license, other companies might be able to offer substantially identical diagnostic tests for sale, which could adversely affect our competitive business position and harm our business prospects. 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 also arise between us and our current or future licensors regarding intellectual property rights subject to a license agreement, including those relating to: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether, and the extent to which, our diagnostic tests, products, services, technology, and processes infringe on intellectual property rights of the licensor that is not subject to the licensing agreement; • whether our licensor or its licensor had the right to grant the license agreement; • whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization; • our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy; • the amounts of royalties, milestones, or other payments due under the license agreement; • our right to sublicense patent and other rights to third parties under 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 rights by our licensors and us and our collaborators; and • the priority of invention of patented technology. If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements. In addition, the agreements under which we currently license intellectual property rights 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 rights 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 rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property rights, we may be unable to successfully develop and commercialize any affected diagnostic tests, products or services, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. 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 to us and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses and royalties or be enjoined from selling our diagnostic tests, products or services, which could adversely affect our ability to offer diagnostic tests, products or services, our ability to continue operations and our financial condition. Some intellectual property that we in- license may have been developed through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for companies based in the United States. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with manufacturers that are not based in the United States. Certain of the intellectual property that we license may have been developed through the use of United States government funding and therefore may be subject to certain federal regulations. As a result, the United States government may have certain rights to intellectual property embodied in our diagnostic tests, products and services pursuant to the Bayh- Dole Act of 1980 (Bayh- Dole Act). These United States government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). To date, none of our commercialized products are subject to march- in rights. The United States government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail 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 or the applicable licensor to expend substantial resources. In addition, the United States government requires that any products of the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner 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 United States manufacturers may limit our ability to contract with product manufacturers outside of the United States for products covered by such intellectual property. To the extent any of our current or future owned or licensed intellectual property is generated through the use of United States government funding, the provisions of the Bayh- Dole Act may similarly apply. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of United States government funding could have a material adverse effect on our business, financial condition, results of operations, and prospects. Patent terms may be inadequate to protect our competitive position on our diagnostic tests, products and services for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our diagnostic tests, products and services are obtained, once the patent life has expired, we may be open to competition from competitive diagnostic tests, products and services. Given the amount of time required for the development, testing and regulatory review of potential new diagnostic tests, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests, products or services similar or identical to ours. We may not be able to protect our intellectual property rights throughout the world. Third parties may attempt to commercialize competitive diagnostic tests, products or services in foreign countries where we do not have any patents or patent applications and / or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations. Filing, prosecuting and defending patents on our diagnostic tests, products and services in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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 diagnostic tests or products made using our inventions in and into the United States or other jurisdictions. Competitors may use our diagnostic tests, products, services and technologies in jurisdictions where we have not obtained patent protection to develop their own diagnostic tests and, further, may export otherwise infringing diagnostic tests or products to territories where we have patent protection but enforcement is not as strong as that in the United States. These diagnostic tests and products may compete with our diagnostic tests, products or services and 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 certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing diagnostic tests, products and services in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put 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. Many countries, including India, China, and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third

parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our current or future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be adversely affected. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make diagnostic tests or products that are similar to our Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests or ~~the COVID- 19 tests that we use in our COVID- 19 testing program or~~ utilize similar technology that is not covered by the claims of our patents or that incorporates certain technology in our Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests ~~or such COVID- 19 tests that is in the public domain~~ ; • we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own or license now or may own or license in the future; • we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their 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 current or future pending patent applications will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties 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 diagnostic tests, products and services for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. General Risk Factors We expect that the price of our common stock will fluctuate substantially and you may not be able to sell your shares at or above the price you paid for them. The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including: • volume and customer mix for our ~~COVID- 19,~~ Nodify XL2, Nodify CDT, GeneStrat ddPCR, GeneStrat NGS, and VeriStrat testing; • the introduction of new diagnostic tests or enhancements to such tests by us or others in our industry; • disputes or other developments with respect to our or others' intellectual property rights; • our ability to develop, obtain regulatory clearance or approval or certification for, and market new and enhanced diagnostic tests on a timely basis; • product liability claims or other litigation; • quarterly variations in our results of operations or those of others in our industry; • media exposure of our diagnostic tests or of those of others in our industry; • changes in governmental regulations or in the status of our regulatory approvals or applications; • changes in earnings estimates or recommendations by securities analysts; and • general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance, and you may not realize any return on your investment in us and may lose some or all of your investment. In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management' s attention and resources from our business. Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline. **The** ~~If a~~ trading market for our common stock develops **is** ~~, the trading market will be~~ influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. As a small reporting company and emerging growth company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with us, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline. We are an " emerging growth company " and a " smaller reporting company, " and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act. We may take advantage of certain exemptions and relief from various public reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes- Oxley Act. We will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor' s report on financial statements; we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. Section 7 (a) (2) (B) of the Securities Act, for complying with new or revised accounting standards. In other words, an " emerging growth company " can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available

to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. Additionally, because we have taken advantage of certain reduced reporting requirements, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We will remain an " emerging growth company " until the earliest to occur of (i) the last day of the fiscal year in which we have more than $ 1. 24 billion in annual revenue; (ii) the date we qualify as a " large accelerated filer, " with at least $ 700 million of equity securities held by non- affiliates; (iii) the date on which we have issued, in any three- year period, more than $ 1. 0 billion in non- convertible debt securities; and (iv) **until December 31, 2025 (** the ~~last day of the fiscal~~ year ~~ending after~~ **ended December 31st following** the fifth anniversary of ~~the completion of~~ our IPO **)** . We are also a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common shares held by non- affiliates exceeds $ 250 million as of the end of that year' s second fiscal quarter, or (2) our annual revenues exceeded $ 100 million during such completed fiscal year and the market value of our common shares held by nonaffiliates exceeds $ 700 million as of the end of that year' s second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile. If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock. The preparation of financial statements in conformity with generally accepted accounting ~~principals~~ **principles** (GAAP) requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. It is possible that interpretation, industry practice and guidance may evolve over time. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock. Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders. Our officers, directors and principal stockholders each holding more than 5 % of our common stock collectively control approximately ~~61~~ **67** . 0 % of our outstanding common stock as of December 31, ~~2022~~ **2023** . As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders. Operating as a public company requires us to incur substantial costs and requires substantial management attention. As a public company, we have incurred and will continue to incur costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, and the Securities Exchange Act of 1934, as amended (the Exchange Act), as well as the rules of NASDAQ. Compliance with these rules and regulations have significantly increased our accounting, legal and financial compliance costs and make some activities more time- consuming. These rules and regulations could make it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors or as executive officers. Accordingly, increases in costs incurred as a result of ~~becoming~~ --- **being** a publicly traded company may adversely affect our business, financial condition and results of operations. If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. As a result of ~~becoming~~ --- **being** a public company, we are required, under Section 404 of the Sarbanes- Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company' s annual and interim financial statements will not be detected or prevented on a timely basis. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including: • faulty human judgment and simple errors, omissions, or mistakes; • fraudulent action of an individual or collusion of two or more people; • inappropriate management override of procedures; and • the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control. When we cease to be an " emerging growth company " under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock 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 have designed our disclosure controls and procedures to provide reasonable assurance 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, 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. 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. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all 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 specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. Notwithstanding the foregoing, the exclusive forum provision will not apply to any claim to enforce any liability or duty created by the Exchange Act or the Securities Act and for which the federal courts have exclusive jurisdiction. We believe this exclusive forum provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. 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, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our amended and restated articles of incorporation provide that we will indemnify our directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporate Law. In addition, as permitted by the Delaware General Corporate Law, our amended and restated articles of incorporation and our indemnification agreements that we have entered into with our directors and officers provide that: • we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by applicable law. Such law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful; • we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law; • we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; • the rights conferred in our amended and restated articles of incorporation are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and • we may not retroactively amend our amended and restated articles of incorporation provisions to reduce our indemnification obligations to directors, officers, employees and agents. 1B. Unresolved Staff Comments. None. **1C. Cybersecurity. Risk Management and Strategy Our business relies on secure and continuous processing of information and the availability of our IT networks and IT resources, as well as critical IT vendors that support our technology, research and other data processing operations. We have integrated cybersecurity risk management into our broader risk management framework. This integration ensures that cybersecurity considerations are an integral part of our decision- making processes at every level. Our IT department continuously evaluates and addresses cybersecurity risks in alignment with our business objectives and operational needs. The Company maintains comprehensive security policies and procedures. These policies and procedures include but are not limited to security and data privacy training for staff, physical security, and electronic data security. Our electronic data security policies and procedures follow HIPAA, GDPR, SEC guidelines, and examples encompass data access controls, data privacy controls, password controls, data encryption, and incident response including an in- depth process for determining materiality. On top of the policies, our network is protected via firewall implementation and cyber- threat monitoring which includes 24 / 7 vulnerability**

scanning and 24 / 7 monitoring using extended detection and response for advanced intrusion detection. The Company also engages with a range of external experts in evaluating and testing our risk management systems. These partnerships allow us to leverage specialized knowledge and insights, ensuring our cybersecurity strategies and processes remain at the forefront of industry best practices. Our collaboration with these third- parties includes audits, threat assessments, and consultation on security enhancements. The Company is also aware of the risks associated with third- party service providers. To oversee these risks, we conduct thorough security assessments of all third- party providers before engagement and maintain ongoing monitoring to ensure compliance with our cybersecurity standards. Current Cybersecurity Risks As of the date of this Annual Report on Form 10- K, the Company has not experienced any cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company. In the event of a cybersecurity incident, the Company is equipped with a well- defined incident response plan. This plan includes immediate actions to mitigate the impact and long- term strategies for remediation and prevention of future incidents. See" Risk Factors — We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our products or services and business disruption if there are any security or data privacy breaches or other unauthorized or improper access." Management and Board Oversight Our management is responsible for day- to- day risk management activities. Our Board of Directors, acting directly and through its committees, is responsible for the oversight of our risk management. The Nominating and Governance Committee monitors our cybersecurity risk profile, receives periodic updates from management on all matters related to cybersecurity and reports to our full Board of Directors on an annual basis or as necessary. The Nominating and Governance Committee is composed of members with diverse expertise that allows them to oversee cybersecurity risks effectively. Management is involved in assessing and managing material cybersecurity risks and incidents through dialogue with our Information Security Officer. Our Information Security Officer brings expertise to this role through his in- depth knowledge and experience in technology management and cybersecurity. Our Information Security Officer is continually informed about the latest developments in cybersecurity. This is crucial for the effective prevention, detection, mitigation and remediation of cybersecurity incidents, and allows him to regularly inform our Chief Executive Officer and Chief Financial Officer of any and all aspects of our business related to cybersecurity and information technology. Our Chief Executive Officer, Chief Financial Officer and Information Security Officer regularly report to the Nominating and Governance Committee to ensure effective and efficient oversight of our cybersecurity threats and material risks, and to assist in proper risk management. Significant cybersecurity matters and strategic risk management decisions will be escalated from the Nominating and Governance Committee to the Board of Directors, ensuring that there is comprehensive oversight and the full Board of Directors can provide guidance on critical cybersecurity issues.