Risk Factors Comparison 2024-03-18 to 2023-03-20 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information included in this Annual Report on Form 10- K, including our financial statements and related notes and" Management' s Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision to purchase or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. The risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business and future prospects. Summary Risk Factors The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in this Item 1A: • We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability; • If third- party payors do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products, or if we or our partners are unable to successfully negotiate payor contracts, our commercial success could be **materially** compromised; • In the near- term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business; • We may be unable to manage our growth effectively, which could make it difficult to execute our business strategy; • Our commercial success depends on attaining and maintaining significant market acceptance of our testing products among rheumatologists, patients, third- party payors and others in the medical community; • We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to fund replacements or transition to alternative suppliers; • If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer; • If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability; • Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing; • If our sole clinical laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed; • We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations; • We ~~have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of December 31, 2022, in connection with the restatement of our financial statements as of and for the three and six months ended June 30, 2022. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations; • We~~ conduct business in a heavily regulated industry. Complying with the numerous statutes and regulations pertaining to our business is expensive and time- consuming, and any failure by us, our consultants or commercial partners to comply could result in substantial penalties; • We **have previously and** may **again in the future** be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations; • The FDA may disagree with our assessment that our AVISE ® test products and any other tests we may develop are LDTs and determine that such test products are medical devices subject to the FDCA and FDA regulations; • If we are unable to maintain intellectual property protection, our competitive position could be harmed; and • If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. Risks Related to Our Business and Strategy We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability. We have incurred net losses since our inception. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we incurred net losses of $ **23. 7 million and $** 47. 4 ~~million and $ 26. 9~~ million, respectively, and we expect to incur additional losses in ~~2023~~ **2024** and in future years. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of $ ~~255~~ **279**. ~~5~~ **2** million. Over the next several years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for, our testing products and to develop future testing products. We ~~experienced and may continue to experience decreases in test volumes due to the impact of the COVID- 19 pandemic. We~~ may not be able to generate sufficient revenue to achieve and maintain profitability. Our failure to achieve and maintain profitability in the future could cause the market price of our common stock to decline **and materially and adversely affect our prospects and business**. If third- party payors do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products, or if we or our partners are unable to successfully negotiate payor contracts, our commercial success could be compromised. Successful commercialization of our testing products depends, in large part, on the availability of coverage and adequate reimbursement from third- party payors, including government payors, such as Medicare and Medicaid and commercial payors. For the testing products that we develop and commercialize, each third- party payor

decides whether to cover the product, the amount it will reimburse for a covered product and the specific conditions for reimbursement. Reimbursement by third- party payors may depend on a number of factors, including the payor' s determination that tests using our technologies are: • not experimental or investigational; • medically necessary; • demonstrated to lead to improved patient outcomes; • appropriate for the specific patient; • cost- saving or cost- effective; • supported by peer- reviewed medical journals; and • included in clinical guidelines. If we are unable to provide third- party payors with sufficient evidence of the clinical utility and validity of our test, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenue and our ability to succeed. In addition, clinicians may be less likely to order a test unless third- party payors pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to commercial success, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected. Third- party payors and other entities also conduct technology assessments of new medical tests and devices and provide and / or sell the results of their assessments to other parties. These assessments may be **and have been** used by third- party payors and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure **, including our tests** . In addition, third- party payors have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostics industry. Effective April 25, 2012, Palmetto GBA, the Medicare MolDx Program, assigned the AVISE ® MTX assay a unique identifier and determined that the test meets the applicable Medicare coverage criteria to support dose optimization and therapeutic decision making for patients diagnosed with RA on methotrexate. Our current Medicare Administrative Contractor, Noridian, has adopted this coverage policy. In addition **,** and effective April 1, 2022, CMS agreed to recognize a new PLA code for our protein- based test, AVISE ® Lupus. Noridian priced this PLA code at $ 1, 085 per test. To determine pricing beyond 2022, CMS recommended crosswalking AVISE ® Lupus (0312U) to Vectra (81490) at a rate of $ 840. 65 per test. This pricing was finalized on the 2023 CLFS and is effective from January 1, 2023 through December 31, 2025. A pricing determination is not synonymous with a coverage determination. Having a price associated with the PLA code for any particular test does not secure coverage or reimbursement for that PLA code from Medicare or any other third- party payor. So, in an effort to improve transparency regarding Medicare support of AVISE ® Lupus, we submitted a formal request to Noridian for coverage of our AVISE ® Lupus test under the new PLA Code. On September 27, 2022, we received notice that Noridian has deemed our application for an LCD to be valid. Ultimately receiving a favorable LCD is uncertain and may be time- consuming, resource intensive and require multiple quarterly or annual periods to complete. We have faced and may again face or continue to face challenges relating to commercial payor claim processing and revenue with our tests. Other third- party payors make their own decisions as to whether to establish a policy to reimburse our testing products. Because approvals must be sought on a payor **-** by **-** payor basis, establishing broad coverage is a time- consuming and costly process. There are many third- party payors who have not yet established a coverage policy applicable to our testing products. In addition, several commercial payors issued non- coverage policies with respect to AVISE ® Lupus, determining that AVISE ® Lupus does not meet the medical criteria for coverage and is considered investigational and / or experimental. While our testing products are reimbursed by a number of third- party payors, we do not currently have contracts with significant private payors. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third- party payors due to changes in their internal processes, documentation requirements and other issues, which could cause our revenue to fluctuate from period to period. If we are not successful in reversing existing non- coverage policies, or if other third- party payors issue negative coverage policies, these policies could have a material adverse effect on our business and operations. Even if many third- party payors currently reimburse for our testing products, such payors **have in the past and** may **again** withdraw coverage at any time, review and adjust the rate of reimbursement, require co- payments from patients or stop paying for our testing products altogether, any of which ~~would~~ **could materially** reduce our revenue. In the near- term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business. A significant majority of our historical revenue has been derived from the sale of our AVISE ® CTD testing product, which we commercially launched in 2012. In the near term, we expect to continue to derive a majority of our revenue from sales of AVISE ® CTD. We are in various stages of research and development with respect to other testing products that we may offer, but there can be no assurance that we will be able to commercialize these testing products. The demand for our testing products may decrease or may not continue to increase at historical rates for a number of reasons. In addition, at any point in time we may decide to no longer commercialize any of our testing products for any number of reasons. While we have experienced revenue growth from the sale of our testing products, we may not be able to sustain this growth or maintain existing revenue levels. Further, we cannot ensure the continued availability of our testing products in commercial quantities at acceptable costs. If we are unable to increase sales of our testing products, expand reimbursement for our testing products, or successfully develop and commercialize additional testing products, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline. **Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, political instability, acts of war, including the current conflict in Ukraine and the Middle East, and other natural or manmade disasters (which may be exacerbated due to climate change) or business interruptions, for which we are predominantly self- insured. We rely on third- party manufacturers to produce our testing products. Our ability to obtain clinical supplies of our testing products could be disrupted if the operations of these suppliers were affected by a man- made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Vista, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The**

occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. Pursuant to Section 404 of Sarbanes- Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an " emerging growth company " and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and / or hire additional accounting and finance staff as we grow. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. On November 13, 2022, management and the Audit Committee determined that we made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design, implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the quarter and year to date periods ended June 30, 2022. We concluded that these were material errors in the financial statements requiring a restatement of the Form 10- Q for the three and six months ended June 30, 2022. Accordingly, management determined that this control deficiency constituted a material weakness as of December 31, 2022. In response to the material weaknesses, and as previously disclosed in Item 9A of our annual report on Form 10- K for the year ended December 31, 2022, we implemented a remediation plan which included, but was not limited to, evaluating the staffing level, skills and qualification of accounting department personnel, enhancement of our existing control structure and processes for revenue recognition and improving the detailed review process of our revenue recognition models. The enhancements made to our control environment were in place as of December 31, 2023, and based on the evaluation of relevant internal controls, management has concluded that the material weaknesses previously identified have been remediated as of December 31, 2023. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We may be unable to manage our growth effectively, which could make it difficult to execute our business strategy. In addition to the need to scale our testing capacity, our future growth plans may also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees and the need to manage additional relationships with various partners, suppliers and other third parties. In addition, if we were to experience rapid and significant growth, our administrative and operational infrastructure may be strained, requiring us to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Our ability to manage our business and growth, as well as function as a public company, will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our ongoing and future growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed. Our commercial success depends upon attaining and maintaining significant market acceptance of our testing products among rheumatologists, patients, third- party payors and others in the medical community. Our success depends on our ability to continue to develop and market testing products that are recognized and accepted as safe, effective, reliable and cost effective, and any testing product that we offer may not gain or maintain market acceptance among rheumatologists, third- party payors, patients or the medical community. Market acceptance of our testing products depends on a number of factors, including: • the perceived accuracy of our test results by rheumatologists and patients; • the potential and perceived advantages of our testing products over alternative products; • the demonstration of the performance and clinical validity of our testing products in clinical studies, the results of which, may not replicate the positive results from earlier studies; • the introduction of new tests that compete with our testing products; • the product cost in relation to alternative products; • publicity concerning our testing products or competing products and treatments; • the availability of coverage and adequate reimbursement by third- party payors, including government authorities; • relative convenience and ease of administration; and • the effectiveness of our sales and marketing efforts. In addition, if we or our future partners have to withdraw a product from the market, it could harm our business and / or impact market acceptance of our other testing products. Further, our AVISE ® testing products consist of various biomarkers, any of which could independently encounter issues with manufacturing, supply or overall quality. If any of the biomarkers in our AVISE ® CTD test were to encounter any issues, we may experience an impact in the overall success of AVISE ® CTD as a whole, including a reduction in **ASP** ~~average selling price~~ or overall revenue, until such time as it can be remedied. Moreover, if our testing

products do not achieve an adequate level of acceptance by rheumatologists, hospitals, third- party payors or patients, we may not generate sufficient revenue from that testing product and may not become or remain profitable. Our efforts to educate the medical community and third- party payors regarding the benefits of our testing products may require significant resources and may never be successful. We may experience limits on our revenue if rheumatologists decide not to order our testing products or if we are otherwise unable to create or maintain demand for our testing products. If we are unable to create or maintain demand for our testing products in sufficient volume, we may not generate sufficient revenue to become profitable. To generate increased demand, we will need to continue to educate rheumatologists about the benefits of our testing products through publications in peer- reviewed medical journals, presentations at medical conferences and other similar means. For example, in the fourth quarter of ~~2022~~ **2023**, we were featured in ~~nine~~ **five** scientific presentations at the ~~2022~~ **2023** ACR Annual Conference, ACR Convergence ~~2022~~ **2023**. We will also need to generate demand for our testing products through one- on- one education by our sales force. We also plan to focus on educating patients about the benefits of these testing products, which we believe will be necessary to generate further demand. In addition, our inability to obtain and maintain coverage and adequate reimbursement from third- party payors may limit adoption by rheumatologists, as well as third- party payors exerting pressure on rheumatologists and healthcare providers to order in- network testing products which could adversely affect our revenue. Rheumatologists may rely on guidelines issued by industry groups regarding the diagnosis, prognosis, treatment and monitoring of autoimmune and autoimmune- related diseases, and the monitoring of the effectiveness of therapeutic drugs used to treat such diseases before utilizing any diagnostic test or monitoring solution. The sizes of the markets for our testing products have not been established with precision ~~,~~ and may be smaller than we estimate. Our estimates of the annual total addressable markets for our current and potential future testing products are based on a number of internal and third- party estimates. These include, without limitation, the number of patients with autoimmune and autoimmune- related diseases and the assumed prices at which we can sell testing products and our partners can sell therapeutics in markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current and potential future testing products may prove to be incorrect. If the actual number of patients who would benefit from our testing products, the price at which we and our partners can sell future testing products, or the annual total addressable market for our testing products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. We may expend our limited resources to pursue a particular testing product and fail to capitalize on other testing products that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on specific testing products. As a result, we may forego or delay pursuit of opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. In addition, our spending on current and future research and development programs for testing products may not yield any commercially viable testing products. If we do not accurately evaluate the commercial potential or target market for a potential testing product, we may forego other similar arrangements which would have been more advantageous for us to pursue. 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 operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: • our ability to successfully market and sell our AVISE ® testing products; • the extent to which our current testing and future testing products, if any, are eligible for coverage and reimbursement from third- party payors; • ~~public health crises such as the COVID- 19 pandemic; •~~ the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our testing products, which may change from time to time, and our ability to successfully commercialize new testing products; • the cost of supplies, equipment and materials used for our testing products and laboratory operations, 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 testing products and technologies; • the level of demand for our testing products, which may vary significantly; • the receipt, timing and mix of revenue for our testing products; • future accounting pronouncements or changes in our accounting policies; • **our ability to collect timely reimbursement for our tests; •** the rate and extent to which payors make an overpayment determination and require us to return all or some portion of payments which we received in a prior period; and • the timing and success or failure of competing products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. **For instance during 2023, our operating results varied due, in part, to our efforts regarding revenue cycle management.** As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our 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 forecasts we may provide to the market, it could have a material adverse effect on our business, financial condition and results ~~or~~ **of** operations. We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and **a sole third- party fulfillment center used to supply healthcare providers with our testing products, and** we may not be able to find replacements or transition to alternative suppliers **or fulfillment centers**. We rely on sole suppliers for critical supply of reagents, equipment and other materials that we use to perform the tests that comprise our testing products. We also purchase components used in our specimen collection and transportation kits from sole- source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies

for many of these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. We are not a major customer of some of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours. If our suppliers can no longer provide us with the materials we need to perform the tests that comprise our testing products **,** if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing could occur and, in certain circumstances, we may be required to amend or cancel test results we have issued. **Additionally** ~~For example, in November 2019, we identified a potential quality issue with reagents for Anti- CarP, a biomarker that can be ordered with our AVISE ® CTD test that was resolved in September 2020. However~~ , if we are unable to remedy future potential quality issues with unique reagent suppliers, or otherwise find a supplier for future biomarkers with issues, we may experience difficulties obtaining market acceptance for our products. Moreover, any issues with quality may result in a change from time to time of the composition of our tests, including our AVISE ® CTD test, which could impact the average selling price and revenues received from sales of such test. In addition, if we should encounter delays or difficulties in securing the quality and quantity of equipment we require for our testing products, we may need to reconfigure our test processes, which could result in an interruption in sales. Any such interruption may significantly affect our future revenue and harm our customer relations and reputation. In addition, in order to mitigate these risks, we may need to maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available **. We rely on a third party as our sole fulfillment center in Florida to supply healthcare providers with our testing products. Our sole fulfillment center could be harmed or rendered inoperable by natural or man- made disasters, including fire, earthquake, hurricane, flooding, pandemics or other disease outbreaks and power outages, which may render it difficult or impossible for us to supply healthcare providers with our testing products for some period of time. The inability to supply healthcare providers with our testing products or the backlog of tests that could develop if our sole fulfillment center is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or business relationships, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our sole fulfillment center could be costly and time- consuming to repair or replace. If our sole fulfillment center is destroyed or otherwise rendered inoperable, we may have difficulty replacing this fulfillment center and there can be no assurance we could do so in a timely manner, on terms favorable to us or at all** . If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer. If demand for our testing products or any of our future testing products or solutions grows, we will need to continue to scale our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We may also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our testing products. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our software and computing capacity to meet increased demand. Failure to implement necessary procedures, transition to new processes, hire the necessary personnel, obtain any necessary additional equipment and increase software and computing capacity could result in higher costs of processing tests or inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations, expand our personnel, equipment, software and computing capacities, or implement process enhancements will be successfully implemented and will not negatively affect the quality of test results. In addition, there can be no assurance that we will have adequate space in our laboratory facility to accommodate such required expansion. We are also currently collaborating with third parties in an effort to implement multiplex technology in our laboratory. We may experience difficulties securing a partner for this technology and integrating such technology into our existing laboratory operations, which could affect our ability to meet demand for our testing products. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer. Billing for our testing products is complex, and we must dedicate substantial time and resources to the billing process to be paid for our testing products. Billing for our testing products is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, we bill various third- party payors, including Medicare and Medicaid, and commercial payors, as well as patients, all of which have different billing requirements. We generally bill third- party payors for our testing products and pursue reimbursement on a case- by- case basis where pricing contracts are not in place. We may also face increased risk in our collection efforts, including long collection cycles and potential delays in claims processing, which could adversely affect our business, results of operations and financial condition. Several factors contribute to the complexity of the billing process, including: • differences between the list price for our testing products and the reimbursement rates of third- party payors; • compliance with complex federal and state regulations related to billing Medicare and Medicaid; • disputes among third- party payors as to which party is responsible for payment; • differences in coverage among third- party payors; • the effect of patient deductibles, co- payments or co-insurance; • differences in information and billing requirements among third- party payors; • changes to billing codes used for our testing products; • risk of government audits related to billing; • incorrect or missing billing information; and • the resources required to manage the billing and claims appeals process. We use standard industry billing codes, known as CPT codes, to bill for our testing products. If these codes were to change, there is risk that errors could be made in the claim adjudication process. Such errors can occur with claims submission, third- party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. As we introduce new testing products, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting. Our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and

regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received. Additionally, providers and suppliers must report and return overpayments received from the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under the federal False Claims Act. Additionally, from time to time, third- party payors change processes that may affect timely payment. These changes **have in the past and** may **again** result in uneven cash flow or impact the timing of revenue recognized with these payors. With respect to payments received from government healthcare programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal healthcare programs. In addition, third- party payors may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. These billing complexities, and the related uncertainty in obtaining payment for our testing products could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations. In ~~2022~~ **2023** , Noridian posted the calendar year ~~2023~~ **2024** Medicare Physician Fee Schedule (MPFS), and CLFS, which establishes the reimbursement rates to be paid by Medicare for our jurisdiction for services performed on or after January 1, ~~2023~~ **2024** . ~~We do~~ **PAMA and changes to the PFS did** not ~~expect that PAMA or changes to the PFS will~~ have a significant impact to Medicare reimbursement for AVISE ® CTD in ~~2023~~ **2024** compared to levels experienced in ~~2022~~ **2023** . Revenue from Medicare comprised **34 % and** 39 ~~% and 19~~ % of our revenue for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. Revenue from the sale of our AVISE ® CTD testing products comprised **88 % and** 84 ~~% and 81~~ % of our revenue for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. We also rely on a third- party provider to provide revenue cycle management software systems for certain processing and collection functions. In the past, we have experienced delays in claims processing as a result of our third- party provider making changes to its invoicing system, as well as not submitting claims to payors within the timeframe required. If claims for our testing products are not submitted to payors on a timely basis, or if we are required to switch to a different systems provider, it could have an adverse effect on our revenue and our business. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. At times, we share our proprietary technology and confidential information, including trade secrets, with third parties that conduct studies and other services on our behalf. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets and despite our efforts to protect our trade secrets, a competitor' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to maintain or expand our sales and marketing force, as needed, to adequately address our customers' and future partners' needs, our business may be adversely affected. We sell our testing products through our own specialized sales force. Our testing products compete in a concentrated specialty market of autoimmune and autoimmune- related diseases, and utilizing a specialized sales force is integral to our strategy. As such, we believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds and industry expertise and expect to continue to evaluate the reach and frequency with rheumatologists, including as we launch our pipeline products. We may be required to expand our specialized sales force as our company grows. Training of additional sales representatives can be costly and time consuming, particularly given the level of experience and sophistication we seek in our sales force. If we are unable to effectively retain, train and integrate additional sales representatives, as needed, it may adversely affect our ability to effectively market and sell our testing products. In addition, competition for highly specialized sales personnel is intense, and we may not be able to attract and retain personnel or be able to maintain an efficient and effective sales and marketing force. Our future sales will depend in large part on our ability to maintain an effective sales force. If we are unsuccessful in this regard, it could negatively impact our revenue growth and potential profitability. If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability. Our principal competition for our testing products is traditional methods used by healthcare providers to test patients with CTD- like symptoms. Such traditional methods include testing for a broad range of diagnostic, immunology and chemistry biomarkers, such as ANA and anti- dsDNA and serum complement biomarkers, such as C3 and C4. We also face competition from commercial laboratories, such as **ARUP Laboratories, Inc.;** Laboratory Corporation of America Holdings ~~,~~ **; the Mayo Clinic; and** Quest Diagnostics Incorporated ~~, ARUP Laboratories, Inc. and the Mayo Clinic~~ , all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university- based clinics may provide in- house clinical laboratories offering autoimmune and autoimmune- related disease testing services. Additionally, we compete against regional clinical laboratories providing testing in the autoimmune and autoimmune- related disease field, including Rheumatology Diagnostics Laboratories, Inc. (acquired by Laboratory Corporation of America in June 2020). Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as **AMPEL BioSolutions, LLC; DxTerity Diagnostics Inc.; Genalyte Inc.; Immunovia AB; Oncimmune plc;** Progentec Diagnostics Inc. ~~,~~ **; and** Scipher Medicine Corporation ~~, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc., AMPEL BioSolutions, and Immunovia AB~~ . In the future, we may also face competition from companies developing new products or technologies. We believe the principal competitive factors in our target market include: quality and strength of clinical and analytical validation

data; confidence in diagnostic results; sales and marketing capabilities; the extent of reimbursement; inclusion in clinical guidelines; cost- effectiveness; and ease of use **. We rely upon independent sources for phlebotomy to obtain patient samples; interruptions to this capability could dramatically impact patient access to our tests** . Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by rheumatologists and payors as functionally equivalent to our solution or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our products and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline. To compete successfully we must be able to demonstrate, among other things, that our testing products are accurate and cost effective. Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing. We may not be able to develop testing products with the clinical utility necessary to be useful and commercially successful. There are certain products for which a commercial launch would trigger additional payment obligations to licensors of the technology. In these cases, if the economic projections of the product do not outweigh the additional obligations, we may not launch these products. In order to develop and commercialize testing products, we need to: • expend significant funds to conduct substantial research and development; • conduct successful verification, validation and utility studies; • develop and scale our laboratory processes to accommodate different tests; • achieve and maintain required regulatory certifications, including the hiring of appropriately licensed laboratory personnel; • develop and scale our infrastructure to be able to analyze increasingly large amounts of data; and • build the commercial infrastructure to market and sell new testing products. Our testing product development process involves a high degree of risk and may take several years. Our testing product development efforts may fail for many reasons, including: • failure to identify additional biomarkers to incorporate into our testing products; • failure or sub- optimal performance of the testing product at the research or development stage; • obtaining patient consent inclusive of genetic analysis; • difficulty in accessing archival patient specimens, especially specimens with known clinical results; or • failure of clinical validation, utility and outcome studies to support the effectiveness of the test. Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a testing product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new testing product and our ability to invest in other products in our pipeline. In ~~2022, we completed the conversion of approximately 8, 000 square feet of warehouse space into additional clinical laboratory space and approximately 6, 000 square feet of warehouse space into additional research and development facility space. In light of our renewed focus on our flagship product, AVISE CTD, and selective approach to research and development projects, we expect to sublet the converted research and development space to a third party and to continue to use the remainder of our existing laboratory space. In~~ addition, as we develop testing products, we may have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the testing product or product feature that was the subject of the clinical study, which could harm our business. Additionally, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost. Developing new testing products and enhancements to our existing technologies is expensive and time consuming, and there is no assurance that such activities will result in significant new marketable testing products, enhancements to our current technologies, design improvements, cost savings, revenue or other expected benefits. If we spend significant resources on research and development and are unable to generate an adequate return on our investment or divert resources away from other, more attractive growth opportunities, our business and results of operations may be materially and adversely affected. If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed. In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer- reviewed medical journals is a crucial step in commercializing and obtaining reimbursement for testing products such as ours, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from any solution. We may acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense. As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements and other strategic transactions or collaborations with third parties. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, make investments in other companies or acquire ownership rights to therapeutics that are synergistic with our testing products. To date, other than our acquisition of the medical diagnostics division of Cypress **Bioscience, Inc.** in 2010, we have not acquired other companies or therapeutics and we have limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write- offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an

acquired company, business or assets also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment. To finance any acquisitions or investments, we may choose to issue shares of our stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions. Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. In addition, our loan agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. The diagnostic industry is subject to rapidly changing technology, which could make our current and future testing products obsolete. Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. These advances require us to continuously develop our technology and work to develop new solutions to keep pace with evolving standards of care. Our testing products could become obsolete unless we continually innovate and expand our testing product offerings to include new clinical applications. If we are unable to develop new testing products or to demonstrate the applicability of our testing products for other diseases, our sales could decline and our competitive position could be harmed. Our failure to maintain relationships or build new relationships with key opinion leaders could materially adversely impact our business and prospects. Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into clinical guidelines. We rely on key opinion leaders early in the development process to help ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our testing products to healthcare providers and payors. Our failure to maintain or build new relationships with such key opinion leaders could affect rheumatologist and patient perception of our testing products and result in a loss of existing and future customers and therefore materially adversely impact our business and prospects. If we are sued for errors and omissions or professional liability, we could face substantial liabilities that exceed our resources. The marketing, sale and use of our testing products could lead to liability claims if someone were to allege that any such testing product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to rheumatologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. We may also be subject to similar types of claims related to testing products we may develop in the future. Any errors or omissions or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain professional liability insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any errors or omissions 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. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our testing products. Similarly, any product liability lawsuit affecting our partners could also cause injury to our reputation. We may also initiate a correction or removal for one of our testing products, issue a safety alert or undertake a field action or recall to reduce a risk to health posed by potential failure of our products to perform as designed, which could lead to increased costs and lead to increased scrutiny by regulatory authorities and our customers regarding the quality and safety of our testing products and to negative publicity, including safety alerts, press releases or administrative or judicial actions. The occurrence of any of these events could have an adverse effect on our business and results of operations. The loss of members of our senior management team or our inability to attract and retain highly skilled scientists, technicians and salespeople could adversely affect our business. Our success depends largely on the skills, experience and performance of key members of our executive management team, including John Aballi, our President and Chief Executive Officer, and others in key management positions. The efforts of each of these persons will be critical to us as we continue to develop our technologies and test processes and focus on our growth. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists and biostatisticians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in Southern California. Because it is expected that there will be a shortage of clinical laboratory scientists in coming years, it may become more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, our success depends on our ability to attract and retain qualified and highly- specialized salespeople. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our testing products. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development, clinical laboratory and sales efforts. All of our employees are at- will, which means that either we or the employee may terminate their employment at any time. If our sole clinical laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed. We currently derive all of our revenue from tests conducted at a single laboratory

facility located in Vista, California. Vista is situated on or near earthquake fault lines. Our facility and equipment could be harmed or rendered inoperable by natural or man- made disasters which may be exacerbated due to climate change, including earthquake, fire, flood, power loss, communications failure or terrorism, or public health crises ~~such as the COVID- 19 pandemic~~ . In particular, we store all of our flow cytometers, the instrument we use to detect CB- CAPs on cells, at our Vista facility. If all of our flow cytometers were rendered inoperable simultaneously pursuant to a natural or man- made disaster, we would be unable to perform these key tests as we do in the ordinary course of our business. The inability to perform the tests contained in our testing products or to reduce the backlog of analyses that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Additionally, we store our bio- repository of specimens, which were collected in collaboration with leading academic institutions and help us to further validate our testing products, at our Vista facility. If these specimens were destroyed pursuant to a natural or man- made disaster or otherwise become unavailable, our ability to develop new testing products may be delayed. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time- consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements for a commercial laboratory like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct the tests contained in our testing products, we may be unable to negotiate commercially reasonable terms. In order to rely on a third party to perform the tests contained in our testing products (even assuming we are able to do so in compliance with applicable regulations), we would need to engage another facility with established state licensure and CLIA certification under the scope of which tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA- certified facility willing to comply with the required procedures, that any such facility would be willing to perform the tests contained in our testing products for us on commercially reasonable terms, or that it would be able to meet our quality standards. In order to establish additional clinical reference laboratory facilities, we have to spend considerable time and money securing adequate space, which may include constructing additional facilities, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in any new or converted facility. Additionally, any new clinical reference laboratory facility opened by us would be subject to certification under CLIA and licensing by several states, including, as applicable, California and New York, which could take a significant amount of time and result in delays in our ability to begin operations. We believe we have the capacity to meet our projected needs for at least the next 12 months, although we may grow at a rate that is faster than we expect. We may need to further expand our laboratory space in the future. Any future expansion could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the expanded facilities. Adverse consequences resulting from a delay in the laboratory expansion could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue. We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all ~~of~~ the risks associated with damage or disruption to our business, provide coverage in amounts sufficient to cover our potential losses or continue to be available to us on acceptable terms, if at all. Our testing process involves the use of sophisticated state- of- the- art equipment that requires precise calibration, and issues affecting such equipment may delay delivery or impact the quality of the test results to rheumatologists or otherwise adversely affect our operations. As part of our process of determining CB- CAPs, the key biomarker detection and measurement technology incorporated into our AVISE ® Lupus and AVISE ® CTD products, we utilize a number of flow cytometers that require calibration and performance validation according to the requirements of the CAP at specified time intervals. While we believe we have implemented appropriate controls and metrics in our laboratory to meet such requirements, we cannot provide any assurance that our instruments will not fall out of specification, in which case we would be required to re- calibrate them. Failure to timely re- calibrate our instruments could negatively impact the test results, which could result in liability and harm our reputation. Patient specimens degrade and become unusable generally within 48 hours of collection. Therefore, if we do not have other sufficient properly functioning flow cytometers due to failure to meet specifications or they otherwise become inoperable, our ability to process patient specimens in the required timeframe would be compromised and our business could be harmed. Failure in our information technology, telephone or other systems could significantly disrupt our operations and adversely affect our business and financial condition. Information technology and telephone systems are used extensively in virtually all aspects of our business, including laboratory testing, sales, billing, customer service, logistics and management of medical data. The success of our business depends on the ability to obtain, process, analyze, maintain and manage this data. Our management relies on our information systems because: • patient specimens must be received, tracked and processed on a timely basis; • test results must be reported on a timely basis; • billings and collections for all customers must be managed efficiently and accurately; • third- party ancillary billing services require proper tracking and reporting; • pricing and other information related to our services is needed by our sales force and other personnel in a timely manner to conduct business; • patient- identifiable health information must be securely held and kept confidential; • regulatory compliance requires proper tracking and reporting; and • proper recordkeeping is required for operating our business, managing employee compensation and other personnel matters. Our business, results of operations and financial condition may be adversely affected if, among other things: • our information technology, telephone or other systems fail or are interrupted for any extended length of time; • services relating to our information technology, telephone or other systems are not kept current; • our information technology, telephone or other systems do not have the capacity to support expanded operations and increased levels of business; • data is lost or unable to be restored or processed; or • data is corrupted due to a breach of security. Despite the precautionary measures we have taken to prevent breakdowns in our information

technology, telephone and other systems, sustained or repeated system failures that interrupt our ability to process test orders, deliver test results or perform testing in a timely manner or that cause us to inadvertently disclose or lose patient information could adversely affect our business, results of operations and financial condition. Security breaches, loss of data and other disruptions to us, our third- party service providers or our partners could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. In the ordinary course of our business, we and our partners, and our respective third- party service providers collect and store sensitive data, such as PHI (including test results), personally identifiable information and credit card information. We also store business and financial information, intellectual property, research and development information, trade secrets, and other proprietary and business critical information, including that of our customers, payors and third- party partners. We manage and maintain our applications and data utilizing a combination of on- site and vendor- owned systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, unauthorized disclosure and unauthorized access, as well as risks associated with our ability to identify and audit such events and risks associated with the need to reconstruct any lost or stolen data. In addition, we have limited control over the storage of sensitive data by our third- party partners as well as risks related to the transfer and sale of de- identified data files to such partners. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third- party billing and collections provider, may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Additionally, most of our employees have the ability to work remotely, which may increase the risk of security breaches, loss of data and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. While we do not believe that we have experienced any such attack or breach, if such an event were to occur, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. A security breach or privacy violation that leads to unauthorized access, disclosure or modification of, or prevents access to, patient information, including PHI, could implicate state and federal breach notification laws. Any such access, disclosure or other loss of information could also result in legal claims or proceedings, and liability under laws that protect the privacy of personal information, such as HIPAA, as amended by the HITECH Act, and their implementing regulations **and similar state data privacy and security laws and regulations** including civil and criminal penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our products and other patient and rheumatologist education and outreach efforts through our website and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business. Any breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position. In addition, the interpretation and application of federal and state consumer, health- related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government- imposed fines or orders requiring that we change our practices, as well as private litigation, which could adversely affect our business. Moreover, these laws and their interpretations are constantly evolving and may become more stringent or inclusive over time. For example, increasing concerns about health information privacy have recently prompted the federal government to issue guidance taking a newly expansive view of the scope of the laws and regulations that they enforce. Complying with these various laws 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. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures in connection with security incidents, we may suffer loss of reputation, financial loss, and civil or criminal fines or other penalties. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Our financial condition, commercialization efforts and results of operations ~~could~~ **has been and may again in the future** be adversely affected by outbreaks of contagious diseases ~~, including the COVID- 19 pandemic~~ . Any outbreak of a contagious disease ~~, such as the COVID- 19 pandemic~~ , or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers, including our sole laboratory. ~~The~~ **While the impact of the COVID- 19 pandemic on our business, financial condition, results of operations and cash flows has subsided, the** extent to which COVID- 19 **will** ~~affects~~ **affect** our operations **in the future** will depend on future developments, which are highly uncertain and cannot be predicted with confidence ~~, additional information that may emerge concerning the severity of COVID- 19 and ongoing actions to contain COVID- 19 or mitigate its impact, among others, which could have a further adverse effect on our business, financial condition, results of operations, and cash flows~~ . Performance issues, service interruptions or price increases by our shipping carrier could adversely affect our business, results of operations and financial condition, and harm our reputation and ability to provide testing services on a timely basis. Expedited, reliable shipping is essential to our operations. We have been utilizing both United Parcel

Service and Federal Express Corporation **(Federal Express)** for reliable and secure point- to- point transport of patient specimens to our laboratory and enhanced tracking of these patient specimens. Should Federal Express, United Parcel Service, or any other carrier we may use in the future, encounter delivery performance issues such as loss, damage or destruction of a specimen, it may be difficult to replace our patient specimens in a timely manner and such occurrences may damage our reputation and lead to decreased utilization from rheumatologists for our testing services and increased cost and expense to our business. In addition, any significant increase in shipping time or disruption to delivery service, whether due to bad weather, natural disaster (which may be exacerbated due to climate change), public health epidemics or pandemics ~~(including, for example, the COVID- 19 pandemic)~~ , terrorist attacks or threats **, labor strikes, work stoppages or boycotts** , or for other reasons, could adversely affect our ability to receive and process patient specimens on a timely basis. If we, Federal Express, or United Parcel Service were to terminate our relationship, we would be required to find another party to provide expedited, reliable point- to- point transport of our patient specimens. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time- consuming and costly and result in delays in our ability to provide our testing services. Even if we were to enter into an arrangement with any such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by Federal Express and United Parcel Service. If any new provider does not provide, or if Federal Express or United Parcel Service does not continue to provide, the required quality and reliability of transport services at the same or similar costs, it could **materially and** adversely affect our business, reputation, results of operations and financial condition. Inflation could adversely affect our business and financial results. Inflation increased significantly during ~~2021~~ **2022** and continued to increase through ~~2022~~ **2023** . The current inflationary environment has resulted in higher prices, which have impacted our costs incurred to generate revenue from our laboratory testing services, costs to attract and retain personnel, and other operating costs. The severity and duration of the current inflationary environment remains uncertain and may continue to impact our financial condition and results of operations. Inflation may continue to adversely affect us by increasing the costs of products, materials (including reagents and laboratory supplies), and labor needed to operate our business in future periods. Actions by the government to stimulate the economy may increase the risk of significant inflation, which may have an adverse impact on our business or financial results. Moreover, we may not be able to pass those costs along in the products we sell. As such, inflationary pressures could have a material adverse effect on our performance and financial statements. The failure of financial institutions or transactional counterparties could adversely affect our current and projected business operations and our financial condition and results of operations. On March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the **Federal Deposit Insurance Corporation (** FDIC **)** as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. A statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts. Although we do not have any funds deposited with SVB and Signature Bank, we regularly maintain cash balances with other financial institutions in excess of the FDIC insurance limit. A failure of a depository institution to return deposits could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an " ownership change " (generally defined as a greater than 50 percentage- point change (by value) in its equity ownership by " 5- percent shareholders, " as defined in the Code, over a rolling three- year period), the corporation' s ability to use its pre- change net operating loss (NOL), carryforwards and other pre- change tax attributes to offset its post-change federal taxable income and taxes, as applicable, may be limited. We previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from our formation through December 31, 2019. Based upon this study, we determined that ownership changes had occurred in 2003, 2008, 2012, 2017 and 2019, and that our ability to use a significant portion of our NOL carryforwards is subject to limitation under Section 382 of the Code as a result of a prior ownership change. If we undergo an ownership change as a result of subsequent shifts in our stock ownership, our ability to utilize our NOL carryforwards and other pre- change tax attributes could be further limited by Sections 382 and 383 of the Code. Similar provisions of state tax law may also apply. In addition, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, in taxable years beginning after December 31, 2020, may only be used to offset 80 % of our taxable income. As a result of the foregoing, if we earn net taxable income, our ability to use NOL carryforwards and other tax attributes to offset taxable income and taxes, as applicable, may be limited. Our term loan contains restrictions that limit our flexibility in operating our business, and if we fail to comply with the covenants and other obligations under our loan agreement, the lenders may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations. In September 2017, we entered into the loan and security agreement **(the 2017 Term Loan)** with Innovatus Life Sciences Lending Fund I, LP (Innovatus), which we subsequently amended in November 2019 ~~and~~ **,** November 2021 **and April 2023** (the Amended Loan Agreement). The Amended Loan Agreement is collateralized by substantially all of our personal property, including our intellectual property. The Amended Loan Agreement also subjects us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain a minimum liquidity of at least $ 2. 0 million, achieve certain minimum amounts of annual revenue, as measured on a rolling twelve- month basis, periodically deliver financial statements to Innovatus with an unqualified opinion (including no " going concern ") from our independent certified public accounting firm, and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants, we have certain limitations on the manner in which we can conduct our business, and we may be

restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of Innovatus, which we may not be able to obtain. As of December 31, ~~2022~~ **2023** , there was $ ~~25~~ **15** . 0 million in principal outstanding under the term loan and an additional $ **3.** 2 ~~. 8~~ million outstanding representing interest ~~at 2. 0 % per annum~~ payable in- kind by adding the **paid in- kind interest** amount to the outstanding principal balance of the term loans. Under the Amended Loan Agreement, we are required to repay any outstanding principal and capitalized interest in monthly installments over a ~~two~~ **ten** - ~~year~~ **month** period commencing on ~~December~~ **April** 1, ~~2024~~ **2026** . At December 31, ~~2022~~ **2023** , we were in compliance with all covenants of the Amended Loan Agreement. We cannot be certain that we will be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and accrued interest on our debt. In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes, but is not limited to, our failure to pay any amount due and payable under the Amended Loan Agreement, the occurrence of a material adverse change in our business as defined in the Amended Loan Agreement, our breach of any representation or warranty in the Amended Loan Agreement, our breach of any covenant in the Amended Loan Agreement (subject to a cure period in some cases), a change in control as defined in the Amended Loan Agreement, our default on any debt payments to a third party in an amount exceeding $ 0. 5 million or any voluntary or involuntary insolvency proceeding. If an event of default occurs and we are unable to repay amounts due under the Amended Loan Agreement, Innovatus could foreclose on substantially all of our personal property, including our intellectual property. We cannot be certain that future working capital, borrowings or equity financings will be available to repay or refinance our debt to Innovatus or any other debt we may incur in the future. We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations. We believe, based on our current plan, that our current cash and cash equivalents and anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. If our available cash balances and anticipated future revenue are insufficient to satisfy our liquidity requirements, including because of lower demand for our testing products or lower- than- expected rates of reimbursement from commercial payors and government payors, or other risks described in this " Risk Factors " section, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. On November ~~10~~ **17** , ~~2020~~ **2023** , we filed a shelf registration statement on Form S- 3 **, as amended by Amendment No. 1 to Form S- 3 filed on November 27, 2023, that provides for aggregate offerings of up to $ 150. 0 million of our securities subject to various limitations** . We filed a prospectus on ~~September 15~~ **November 29** , ~~2022~~ **2023** pursuant to this registration statement, registering sales of our common stock in an amount not to exceed $ 50. 0 million, pursuant to a **sales agreement by and between us and Cowen and Company, LLC (TD Cowen), as amended by Amendment No. 1 to** Sales Agreement **dated November 17** ~~by and between us and Cowen and Company~~ , ~~LLC~~ **2023** (the **Amended** Sales Agreement). Using a shelf registration statement to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a registration statement on Form S- 1 and companies may be able to receive more favorable terms by raising capital pursuant to a shelf registration statement on Form S- 3. Our ability to raise capital under our current shelf registration statement (and any future registration statement on Form S- 3) is, and may again in the future be, limited by, among other things, current and future SEC rules and regulations impacting the eligibility of smaller companies to use Form S- 3 without restrictions. As of the date of this Annual Report, we are subject to the" baby shelf rule" because the market value of our outstanding shares of common stock held by non- affiliates, or public float, was less than $ 75. 0 million as of the date of this Annual Report. As a result, for sales following the date of this Annual Report and until we again have a public float with a value in excess of $ 75. 0 million, if ever, we will be unable to use our shelf registration statement on Form S- 3 or the **Amended** Sales Agreement to raise additional funds to the extent the aggregate market value of securities sold by us or on our behalf pursuant to Instruction I. B. 6. of Form S- 3 during the 12 calendar months immediately prior to, and including, any intended sale does not exceed one- third of the aggregate market value of our public float, calculated in accordance with the instructions to Form S- 3. In the case of the incurrence of further indebtedness, the Amended Loan Agreement, subject to certain customary exceptions, restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus. Under the Amended Loan Agreement, we are required to make monthly interest payments at a rate equal to **the sum (the Basic Rate) of (a) the greater of** 8 **. 0 % or The Wall Street Journal prime rate (the Prime Rate), plus (b) 2** . 0 % (provided that ~~2~~ **1** . ~~0~~ **5** % of the **Basic Rate** ~~8. 0 %~~ is payable in- kind by adding the amount to the outstanding principal balance of the term loans). We may also consider raising additional capital in the future to expand our business, pursue strategic investments, take advantage of financing opportunities, or for other reasons. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The timing and amounts of our future capital requirements are difficult to forecast and will depend on numerous factors, including: our ability to maintain and grow sales of our testing products, as well as the costs associated with conducting clinical studies to demonstrate the utility of our testing products and support reimbursement efforts; fluctuations in working capital; the costs to expand our sales and marketing capabilities; the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation studies; the additional costs we may incur as a result of operating as a public company and the extent to which we in- license, acquire or invest in complementary businesses or products. Additional funding may not be available to us on acceptable

terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result, and the market price of our common stock could decline. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants **(similar to our current obligations pursuant to the Amended Loan Agreement)** , such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, our Amended Loan Agreement restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus, subject to certain exceptions. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves ~~,~~ or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our testing products or market development programs, which could lower the economic value of those products or programs to our company. We ~~have identified~~ **are an emerging growth company and** a ~~material weakness~~ **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 Jumpstart Our** Business Startups Act of 2012 (the JOBS Act) and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our ~~initial public offering (~~ IPO ~~)~~ ,or December 31,2024.However,if certain events occur prior to the end of such five- year period,including if we become a " large accelerated filer," our annual gross revenue exceeds $ 1.235 billion or we issue more than $ 1.0 billion of non- convertible debt in any three- year period,we will cease to be an emerging growth company prior to the end of such five- year period.For so long as we remain an emerging growth company,we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies.These exemptions include:• being permitted to provide only two years of audited financial statements,in addition to any required unaudited interim condensed financial statements,with correspondingly reduced " Management' s discussion and analysis of financial condition and results of operations " disclosure;• not being required to comply with the auditor attestation requirements in the **assessment of** our internal control over financial reporting ~~and determined~~ **; • not being required to comply with any requirement** that **may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation** ~~our~~ **or a supplement to** ~~disclosure controls and procedures were ineffective as of December 31, 2022, in connection with~~ the ~~restatement of our~~ **auditor' s report providing additional information about the audit and the** financial statements **; • reduced disclosure obligations regarding executive compensation; and • exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive** as ~~of and~~ **a result, there may be a less active trading market** for ~~the three~~ **our common stock** and ~~six months ended June 30, 2022~~ **our stock price may be reduced or more volatile** . In ~~the future, we may identify additional~~ -- **addition** ~~material weaknesses~~ **, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period** ~~or~~ **for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would** otherwise ~~fail~~ **apply** to ~~maintain~~ **private companies. We have elected to avail ourselves of this exemption** ~~an~~ **and** ~~effective system~~ **, therefore, we may 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** ~~internal control over financial~~ **financials to those of other public companies more difficult. We are also a " smaller** reporting **company " as** ~~or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed~~ - **defined** ~~to ensure that information required to be disclosed~~ in ~~our reports that we file or submit under~~ the Exchange Act ~~,~~ **. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non- voting common stock held by non- affiliates** is **less** ~~recorded, processed, summarized and reported within the time period specified in the SEC' s rules and forms, and that~~ **than $ 250. 0 million measured on** the ~~information required to be disclosed~~ **last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held** by **non- affiliates** ~~us in such reports~~ is **less than $ 700. 0 million measured on the last business day of** ~~accumulated and communicated to our management, including our principal executive officer and principal financial officer or~~ **our second fiscal** ~~persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily is required to apply its judgment in evaluating the cost- benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all~~

~~potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. On November 13, 2022, management and the audit committee of our board of directors determined that we made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design and implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the~~ quarter ~~and year to date periods ended June 30, 2022. We then determined that there were material errors in the financial statements requiring a restatement of the Form 10- Q for the three and six months ended June 30, 2022. Accordingly, management has determined that this control deficiency constituted a material weakness and, as a result, management has concluded that, as of December 31, 2022, our internal control over financial reporting was not effective based on the criteria in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management is actively engaged in the implementation of remediation efforts to address the material weakness. The remediation plan includes: (i) evaluating the staffing level, skills and qualification of accounting department personnel, (ii) enhancement of our existing control structure and processes for revenue recognition and (iii) improving the detailed review process of our revenue recognition models. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects. If we are not able to comply with the applicable requirements of the Sarbanes- Oxley Act of 2002 or if we are unable to maintain effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by us in the reports that we file with the SEC, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Any failure of our internal control over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, expose us to sanctions or investigations by the SEC or other regulatory authorities, or impact our results of operations~~ . Risks Related to Regulatory and Compliance Matters Healthcare policy changes, including recently enacted and proposed new legislation reforming the U. S. healthcare system, could cause significant harm to our business, operations and financial condition. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and commercial payors. The ACA also introduced mechanisms to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. Any such reductions could affect reimbursement payments for our tests. In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under the CLFS. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for their tests, and laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Medicare reimbursement for CDLTs is based on the weighted- median of the payments made by private payors for these tests, rendering private payor payment levels even more significant than in the past. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of diagnostic tests generally and any given test individually. The impact of this payment system on rates for our tests, including any current or future tests we may develop, is uncertain. We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the ACA and the changes to reimbursement amounts paid by Medicare for tests such as ours based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare ~~policy changes~~ **laws, regulations and policies** could be amended or additional healthcare initiatives could be implemented in the future. Further, the impact on our business of the expansion of the federal and state governments' role in the U. S. healthcare industry generally, including the social, governmental and other pressures to reduce healthcare costs while expanding individual benefits, is uncertain. Any future changes or initiatives could have a materially adverse effect on our business, financial condition, results of operations and cash flows. Complying with numerous regulations pertaining to our business is an expensive and time- consuming process, and any failure to comply could result in substantial penalties. We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA because we are accredited to perform testing by CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, inspectors from CMS or CAP may make random inspections of our clinical reference laboratory. Although we are required to hold a certificate of accreditation or compliance under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program. If our accreditation under CAP were to terminate, either voluntarily or involuntarily, we would need to convert our certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization) in order to maintain our ability to perform clinical testing and to continue commercial operations. Whether we would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these were addressed to the satisfaction of the surveyors for the CLIA program (or another accrediting organization). The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of accreditation, as well as a directed plan of correction, state on- site monitoring, civil money penalties, civil injunctive suit and / or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for tests provided to Medicare beneficiaries. If we

were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so. We are also required to maintain a license to conduct testing in California. California laws establish standards for day- to- day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, our clinical reference laboratory is licensed on a product- specific basis by New York as an out of state laboratory and our testing products, as LDTs, must be approved by the NYSDOH on a product- by- product basis before they are offered in New York. We are also subject to periodic inspection by the NYSDOH and required to demonstrate ongoing compliance with NYSDOH regulations and standards. To the extent NYSDOH identified any non- compliance and we are unable to implement satisfactory corrective actions to remedy such non- compliance, the State of New York could withdraw approval for our testing products. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out- of- state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future. If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our testing products, which would limit our revenue and harm our business. If we were to lose our license or fail to obtain or maintain NYSDOH approval for our laboratory developed tests in New York or if we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states, which would limit our revenue. We conduct business in a heavily regulated industry. Complying with the numerous statutes and regulations pertaining to our business is expensive and time- consuming, and any failure by us, our consultants or commercial partners to comply could result in substantial penalties. Our industry and our operations are heavily regulated by various federal, state, local and foreign laws and regulations, and the regulatory environment in which we operate could change significantly and adversely in the future. These laws and regulations currently include, among others: • CLIA' s and CAP' s regulation of our laboratory activities; • FDA laws and regulations, including but not limited to requirements for offering LDTs; • federal and state laws and standards affecting reimbursement by government payors, including certain coding requirements to obtain reimbursement and certain payment mechanisms for clinical laboratory services resulting from PAMA; • HIPAA and HITECH, which establish comprehensive federal standards with respect to the privacy and security of PHI, and requirements for the use of certain standardized electronic transactions with respect to transmission of such information, as well as similar laws protecting other types of personal information; • state laws governing the maintenance of personally identifiable information of state residents, including medical information, and which impose varying breach notification requirements, some of which allow private rights of action by individuals for violations and also impose penalties for such violations; • the federal Anti- Kickback Statute, which generally prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce a person to refer to an individual any good, facility, item or service that is reimbursable under a federal healthcare program; • the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by Medicare or Medicaid, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services; • the federal False Claims Act, which imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Civil Monetary Penalties Law, which generally prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary' s selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or Medicaid; • EKRA, which imposes criminal penalties for knowing and willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) covered by healthcare benefit programs (including commercial insurers) unless a specific exception applies; • the ACA, which, among other things, establishes a requirement for providers and suppliers to report and return any overpayments received from the Medicare and Medicaid programs; • other federal and state fraud and abuse laws, such as anti- kickback laws, prohibitions on self- referral, fee- splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption and false claims acts, some of which may extend to services reimbursable by any third- party payor, including private payors; • the prohibition on reassignment of Medicare claims and other Medicare and Medicaid billing and coverage requirements; • state laws that prohibit other specified healthcare practices, such as billing physicians for tests that they order, waiving coinsurance, copayments, deductibles and other amounts owed by patients, business corporations practicing medicine or employing or engaging physicians to practice medicine and billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; • the FCPA, and applicable foreign anti- bribery laws; • federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste and workplace safety for healthcare employees; • laws and regulations relating to health and safety, labor and employment, public reporting, taxation and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017; and • similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future. Any future growth of our business, including, in particular, continued reliance on consultants, commercial partners and other third parties, may increase the potential for violating these laws. In some cases, our risk of violating these or other laws and regulations is further increased because of the lack of their

complete interpretation by applicable regulatory authorities or courts, and their provisions are thus open to a variety of interpretations. We have adopted policies and procedures designed to comply with these laws and regulations and, in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to review by applicable government agencies. However, these laws and regulations are subject to change and additional interpretation and guidance from regulatory authorities. For instance, in April 2022, the HHS OIG issued a new advisory opinion indicating that a particular clinical laboratory' s practice of contracting with hospitals for the collection of samples for testing could, based on the facts provided and assuming the requisite intent, be a violation of the federal Anti- Kickback Statute. If this Advisory Opinion ultimately limits our ability to collect samples in a hospital setting, we may be required to contract for sample collection with other collection sites or sources, such as mobile phlebotomists, that could be more expensive and less convenient for patients, which could adversely affect both demand for our tests and the margins and profitability of our tests. Given the complexity of these existing and changing rules and regulations, it is not always possible to identify and deter misconduct by employees, distributors, consultants and commercial partners 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 government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. **For additional information see the risk factor below entitled " We have previously and may again in the future be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations. "** Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management' s attention from the operation of our business and harm our reputation. If our operations, including the conduct of our employees, consultants and commercial partners, are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us and curtailment or cessation of our operations. Any of these consequences could seriously harm our business and our financial results. It is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws may prove costly. If we or our operations, or any of the rheumatologists or entities with whom we do business are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and / or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in U. S. federal or state healthcare programs, such as Medicare and Medicaid, and similar programs outside the United States, a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. To the extent that any of our testing products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post- marketing requirements, including safety surveillance, anti- fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. **If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.** We **are subject** ~~may be required~~ to ~~modify~~ **federal, state and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination** ~~our~~ **or** ~~business~~ **injury to employees or third** ~~practices~~ **parties from the use** , ~~pay~~ **storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or** fines, ~~incur~~ **and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become** significant ~~expenses~~ **, and** ~~or~~ **our failure** ~~experience losses due~~ to ~~litigation~~ **comply may result in substantial fines or other consequences, either of which could negatively affect** ~~or~~ **our** ~~governmental investigations~~ **operating results** . From time to time and in the ordinary course of our business, we have been and may be subject to litigation or governmental investigation on a variety of matters in the United States or foreign jurisdictions, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, false claims, whistleblower, ~~Qui Tam~~ **qui tam** , privacy, anti- kickback, anti- bribery, environmental, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business. Our activities relating to our products and services are subject to extensive regulation in the United States and foreign jurisdictions. Like many companies in our industry, we have in the ordinary course of business received inquiries, subpoenas, civil investigative demands, and other types of information requests from government authorities. ~~For example, in February 2022, we received a subpoena issued by the U. S. Department of Justice requesting documents related to its investigation of potential federal regulatory healthcare offenses. We are fully cooperating with the U. S. Department of Justice to promptly respond to the requests for information in this subpoena, but we cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on our business which may ultimately be greater than we expect.~~ In addition, ~~responding to this subpoena, and~~ any litigation or government investigation generally, diverts the attention of our management team and ~~diverts~~ resources from our core business **and limits** ~~. As such,~~ the time and attention of our management team **otherwise** ~~in responding to these matters may limit their time~~ available to devote to our business ~~,~~ **. Government investigation** and ~~we~~ **litigation in general** may ~~also~~ **cause us to** incur significant expenses ~~or~~ **, to**

experience **significant** losses ~~in relation to these~~ **, and, as a result of such** matters ~~. As a result of these matters~~, we may also be required to **materially** alter the conduct of our operations or pay **significant** penalties **. For example, pursuant to a settlement agreement, we made a single lump- sum remittance to the government in the amount of $ 0. 7 million plus interest in October 2023, the U. S. Attorney' s Office dismissed this " covered conduct " in the qui tam with prejudice, while non- covered conduct was dismissed without prejudice. In November 2023, the complaint was unsealed and served on Exagen. Exagen filed a motion to dismiss the complaint. In February 2024, the relator filed a motion for leave to amend the complaint. Exagen opposed this motion, and all motions are still pending. The Company intends to vigorously defend against the claims being asserted in the complaint** . Any of these circumstances may adversely affect our business, prospects, reputation and results of operations ~~expenses~~ .We are subject to U.S.and certain foreign export and import controls,sanctions,embargoes,anti- corruption laws and anti- money laundering laws and regulations.Compliance with these legal standards could impair our ability to compete in domestic and international markets.We can face criminal liability and other serious consequences for violations,which can harm our business.We are subject to export control and import laws and regulations,including the U.S.Export Administration Regulations,U.S.Customs regulations,various economic and trade sanctions regulations administered by the U.S.Treasury Department' s Office of Foreign Assets Controls,the FCPA,the U.S.domestic bribery statute contained in 18 U.S.C.§ 201,the U.S.Travel Act,the USA PATRIOT Act,and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities.Anti- corruption laws are interpreted broadly and prohibit companies and their employees,agents,contractors and other collaborators from authorizing,promising,offering,or providing,directly or indirectly,improper payments or anything else of value to recipients in the public or private sector.We may engage third parties to sell our testing products outside the United States,to conduct clinical trials,and / or to obtain necessary permits,licenses,patent registrations and other regulatory approvals.We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals,universities and other organizations.We can be held liable for the corrupt or other illegal activities of our employees,agents,contractors,and other collaborators,even if we do not explicitly authorize or have actual knowledge of such activities.Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties,imprisonment,the loss of export or import privileges,debarment,tax reassessments,breach of contract and fraud litigation,reputational harm and other **consequences** . The FDA may disagree with our assessment that our AVISE ® test products and any other tests we may develop are LDTs and determine that such test products are medical devices subject to the FDCA and FDA regulations. The FDA regulates any diagnostic test that meets the definition of a medical device, except under specific, narrow circumstances. The FDCA defines a medical device as " an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. " By this definition, in vitro reagents and diagnostic tests are considered medical devices. Specifically, the FDA defines an IVD as " reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. " Therefore, the FDA generally considers diagnostic testing products to be IVDs subject to the agency' s regulatory requirements for IVDs. However, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs, which are IVDs that are designed, manufactured, and used within a single high- complexity CLIA- certified laboratory ~~for use only in that laboratory~~ . We believe that all of our AVISE ® test products are LDTs, as are our near- term pipeline candidate tests. If the FDA were to disagree with our conclusion that our AVISE ® test products fall within the scope of the agency' s LDT definition and determines that the AVISE ® tests are thus subject to FDA' s medical device authorities and implementing regulations, we would become subject to extensive regulatory requirements and may be required to stop selling our existing tests or refrain from launching any other tests we may develop. In particular, the FDA may require us to obtain PMAs or another type of device marketing authorization in order for us to commercialize our AVISE ® tests. The premarket review process for diagnostic testing products can be lengthy, expensive, time- consuming, and unpredictable. As part of the process to prepare regulatory submissions for FDA review, we may be required to conduct formal clinical trials before applying for commercial marketing authorization. Performing additional, new nonclinical studies or clinical trials in order to obtain product approval from the FDA, if any were to become necessary, would take a significant amount of time and would substantially delay our ability to commercialize our AVISE ® tests, all of which would adversely impact our business. While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA with respect to LDTs, we cannot assure you that the FDA will agree with our determination. Any finding by the FDA or another regulatory authority that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations ~~and~~ **or** financial condition. The FDA may ~~undertake~~ **finalize its** rulemaking to regulate LDTs or Congress may **take action to** reform the current legal requirements applicable to LDTs, **and** in ~~which~~ **either** case **,** we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business. We currently market our AVISE ® tests as LDTs and may **,** in the future **,** market other tests as LDTs. ~~The~~ **Although historically the** FDA has ~~adopted~~ **applied** a policy of enforcement discretion with respect to LDTs whereby the FDA does not generally actively enforce its regulatory requirements for such tests ~~. However~~ , in ~~the past~~ **October 2023,** the FDA **issued a proposed rule to regulate LDTs under the current medical device framework. The agency' s proposal also includes a plan to** ~~has~~ **phase** ~~stated~~ **out** its **current** ~~intention to modify its~~ enforcement discretion policy ~~with respect~~ **over several years. This FDA rulemaking was initiated after years of failed congressional attempts to harmonize the**

regulatory paradigms applicable to LDTs **and other in vitro diagnostic tests, as discussed further below. The likelihood of the FDA finalizing the proposed rule following a public comment period, as well as potential litigation challenging its authority to take such action, is uncertain at this time as stakeholders continue to press for a comprehensive legislative solution instead of administrative agency action** . If there are changes in FDA regulations ~~and~~ **or** legislative authorities such that the agency begins to exercise oversight over **LDTs, or if the FDA disagrees that our marketed tests are within the scope of its criteria used for defining** LDTs, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make do not include the claims necessary or desirable for successful commercialization, orders from healthcare providers or reimbursement for our tests may decline. ~~Since 2017~~ **In addition, as noted above** , Congress ~~has~~ **had** been working on legislation to create an LDT and IVD, regulatory framework that would be separate and distinct from the existing medical device regulatory framework. ~~Most recently,~~ **Reform legislation called** the VALID Act **garnered** ~~has been garnering~~ bipartisan and bicameral support **in recent years but failed to move out of committee during the last congressional session** . ~~The~~ **As drafted and re- introduced for consideration by the current Congress, the** VALID Act would codify the term IVCT to create a new medical product category separate from medical devices ~~that to includes~~ **include** products currently regulated as IVDs as well as LDTs, among other provisions. The VALID Act would also create a new system for laboratories to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it would take for the agency to approve such tests ~~,~~ and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. **The FDA' s October 2023 publication of an LDT proposed rule that would apply the existing medical device framework to laboratory- developed products has renewed stakeholder calls for a more targeted approach to modernizing the federal government' s oversight of clinical diagnostic tests. It remains possible that congressional action in this area could displace the need for the FDA to complete its recently proposed rulemaking.** If Congress were to pass the VALID Act or any other legislation applicable to the FDA' s regulation of LDTs **, or if the FDA were to successfully promulgate new regulations for such products through the recently initiated notice- and- comment rulemaking or a future rulemaking proceeding** , we will likely be subject to increased regulatory burdens such as registration and listing requirements, adverse event reporting requirements and quality control requirements. Any legislation or formal FDA regulatory framework affecting LDTs is also likely to have premarket application requirements prohibiting commercialization without FDA authorization and controls regarding modification to the tests that may require further FDA submissions. The premarket review process can be lengthy, expensive, time- consuming and unpredictable. Further, obtaining premarket clearance may involve, among other things, successfully completing clinical trials, which require significant time and cash resources and are subject to a high degree of risk, including risks of experiencing delays, failing to complete the trial or obtaining unexpected or negative results. If we are required to obtain premarket clearance or approval and / or conduct premarket clinical trials, our development costs could significantly increase, marketing of any new tests we may develop may be delayed, and sales of our existing tests could be interrupted or stopped. Any of these outcomes could reduce our revenue or increase our costs and materially adversely affect our business, prospects, results of operations or financial condition. The outcome and ultimate impact on our business of any changes to the federal government' s regulation of LDTs is difficult to predict. Failure to comply with any applicable FDA requirements could trigger a range of enforcement actions, including warning letters, fines, penalties, suspension of operations, product recalls or seizures, denial of applications for clearance or approval, injunctions and other civil or criminal sanctions, which could have a material and adverse effect upon our business, operating results and financial condition. Furthermore, should it be required in the future, we cannot be sure that our AVISE ® tests, or any new tests that we may develop, will be reviewed and authorized for marketing by the FDA in a timely or cost- effective manner, if authorized at all. Even if such tests are authorized for marketing by the FDA, the agency could limit the test' s indications for use, which may significantly limit the market for that product and may adversely affect our business and financial condition. ~~FDA regulation of our AVISE ® RADR test could be disruptive to our business. As described further above, the FDA has long claimed authority to regulate LDTs but has exercised its enforcement discretion to limit enforcement of IVD regulatory requirements on this category of products. However, the FDA has from time to time appeared to increase its attention to the marketing of pharmacogenetic tests. For example, in late 2018, the FDA issued a safety communication regarding " 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. " This safety communication explained that the FDA had reached out to several firms marketing such pharmacogenetic tests where the FDA believed the relationship between genetic variations and a medication' s effects had not been established, including a warning letter to Inova Genomics Laboratory. More recently, in April 2022, a safety communication from the FDA warned patients and providers about the risks of false results with genetic non- invasive prenatal screening tests, which it noted have not been authorized, cleared, or approved by the agency via one of the medical device premarket pathways. Our AVISE ® RADR test, one of our pipeline programs we are currently developing in collaboration with QMUL, may be considered by FDA to be a pharmacogenetic test because it involves the analysis of total RNA expression data from an individual RA patient through an algorithm to predict the patient' s biological therapeutic response. In response to various public letters from the national laboratory trade association and patient groups, on February 20, 2020, the FDA announced a new " collaboration between FDA' s Center for Devices and Radiological Health and Center for Drug Evaluation and Research intended to provide the agency' s view of the state of the current science in pharmacogenetics. " Although the announcement again asserted that some of pharmacogenetic test offerings may pose significant risks to patients, the agency also acknowledged that pharmacogenetic testing " offers promise for informing the selection or dosing of some medications for certain individuals. " In conjunction with the announcement, the FDA also released an updated " Table of Pharmacogenetic~~

~~Associations, " which lists gene- drug interactions that the agency believes are supported by FDA- approved drug labeling and / or " sufficient scientific evidence based on published literature. " The table has been updated periodically since that time. While these developments may signal a positive shift in the FDA' s approach to regulating pharmacogenetic tests, we cannot predict with certainty the outcome of this matter or its timing, or whether FDA may object to the ultimate form of our AVISE ® RADR product candidate.~~ The FTC and / or state enforcement or regulatory agencies may object to the methods and materials we use to promote our tests and initiate enforcement against us, which could adversely affect our business and financial condition. The FTC and / or state enforcement or regulatory agencies (including but not limited to the offices of state attorneys general) may object to the materials and methods we use to promote our current tests or other LDTs we may develop in the future, including with respect to the product claims in our promotional materials, and may initiate enforcement actions against us. Enforcement actions by the FTC may include, among others, injunctions, civil penalties and equitable monetary relief. Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations and financial condition. Any failure or perceived failure by us to comply with federal or state laws or regulations, our internal policies and procedures or our contracts governing our use and disclosures of personal information could result in negative publicity, government investigations and enforcement actions including significant penalties, claims by third parties, and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business. Failure to comply with HIPAA, the HITECH Act, their implementing regulations and similar comparable state laws and regulations affecting the transmission, security and privacy of health information could result in significant penalties. Numerous federal, state and foreign laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, disclosure, security, use and confidentiality of individually identifiable health information health- related and other personal information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of PHI within our company and with third ~~-~~parties. The privacy, security and breach notification rules promulgated under HIPAA, as amended by the HITECH Act, Standards for Privacy of Individually Identifiable Health Information (Privacy Standards) and the Security Standards for the Protection of Electronic Protected Health Information (Security Standards) under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by Covered Entities and ~~the~~ **their** Business Associates. HIPAA requires Covered Entities, such as us, to develop and maintain policies and procedures with respect to individually identifiable health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect the privacy and security of such information. HIPAA also requires us to provide individuals with certain rights with respect to their PHI. If we engage a Business Associate to help us carry out healthcare activities and functions, we must have a written Business Associate contract or other arrangement with the Business Associate that establishes specifically what the Business Associate has been engaged to do and requires the Business Associate to comply with the requirements of HIPAA. Further, in the event of a breach of unsecured PHI we must notify each individual whose PHI is breached as well as federal regulators and in some cases, must publicize the breach in local or national media. HIPAA also includes standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, and privacy and electronic security of individually identifiable health information. Covered Entities, such as certain healthcare providers, are required to conform to such transaction set standards, known as the Standards for Electronic Transactions, pursuant to HIPAA. Submission of electronic healthcare claims and payment transactions that do not comply with the HIPAA electronic data transmission standards could result in delayed or denied payments. In the conduct of our business, we process, maintain, and transmit sensitive data, including PHI. There can be no assurance that a breach of privacy or security will not occur. If there is a breach, we could be subject to various lawsuits, penalties and damages and may be required to incur costs to mitigate the impact of the breach on affected individuals. Penalties for failure to comply with HIPAA requirements are substantial and could include corrective action plans and / or the imposition of civil or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can 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 HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may apply more broadly or be more stringent than HIPAA. For example, the CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the CPRA went into effect in California amending the CCPA and may increase our compliance costs and potential liability, imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and adds opt outs for certain uses of sensitive data. It also created a new **regulatory authority, the** California ~~data~~ **Privacy** ~~protection~~ **Protection** ~~agency~~ **Agency (CPPA), which is** authorized to issue substantive regulations and could result in increased privacy and information security enforcement. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws (for example Virginia' s Consumer Data Protection Act and other similar laws that recently went into effect in **in other states, such as** Utah, Colorado ~~and~~ **,** Connecticut **, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, and Texas**), any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. In Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is

greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the EU. ~~Further~~ **In July 2023** , **however, the European Commission adopted an adequacy decision for a new mechanism for transferring data** from **the EU** ~~January 1, 2021, companies have~~ to ~~comply~~ **the United States – the EU- US Data Privacy Framework, which provides EU individuals** with **several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards addressing the reasons behind the Court of Justice of the EU' s invalidation of the original Privacy Shield. The European Commission will continually review developments in the United States along with its adequacy decision. However, future actions of EU data protection authorities are difficult to predict. Relatedly, following the United Kingdom' s withdrawal from the EU,** the GDPR ~~and also~~ **was implemented in the United Kingdom as** the U. K. GDPR ~~, which, together with~~ **. The U. K. GDPR sits alongside** the amended U. K. Data Protection Act 2018, ~~retains~~ **which implements certain derogations in** the **EU** GDPR ~~in~~ **into** U. K. ~~national~~ law. The U. K. GDPR mirrors the fines under the GDPR, i. e., fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover. ~~The relationship between~~ **In June of 2021, the European Commission issued a decision, which will sunset on June 27, 2025 without further action, that** the United Kingdom **ensures** ~~and~~ **an adequate level of protection for personal data transferred under** the EU **GDPR** ~~in relation to certain aspects of data protection law remains unclear, and it is unclear how U. K. data protection laws and regulations will develop in the medium to longer term, and how data transfers to and~~ from **the EU to** the United Kingdom **. The Parliament of the United Kingdom is currently considering the Data Protection and Digital Information** ~~will~~ **Bill to harmonize** ~~be regulated in~~ the ~~long term~~ **2018 Data Protection Act, U. K. GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework** . The regulatory framework governing the collection, storage, use and sharing of certain information, particularly financial and other personal information, is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. Additionally, increasing concerns about health information privacy have recently prompted the federal government to issue guidance taking a newly expansive view of the scope of the laws and regulations that they enforce. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing practices. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our privacy policies, changing expectations, evolving laws, rules and regulations, industry standards or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrence of significant fines, penalties or other liabilities. In addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition and results of operations. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize our testing products in foreign markets. We are not permitted to market or promote any of our testing products before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our testing products. To obtain separate regulatory approval in many other countries, ~~parties~~ **we and our collaborators and service providers** must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our testing products. If we obtain regulatory approval of our testing products and ultimately commercialize our testing products in foreign markets, we would be subject to additional risks and uncertainties, including **any or all of the following** : • different regulatory requirements for approval of IVDs in foreign countries; • reduced protection for intellectual property rights; • the existence of additional third- party patent rights of potential relevance to our business; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue and other obligations incident to doing business in another country **; • inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services** ; • foreign reimbursement, pricing and insurance regimes; • workforce uncertainty in countries where labor unrest is common; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism **,** such as ~~the~~ current ~~conflict~~ **conflicts** in Ukraine ~~, or~~ **and the Middle East;** natural disasters which may be exacerbated due to climate change, including earthquakes, typhoons, floods and fires **; outbreak of disease; boycotts; or other business restrictions** . Risks Related to our Intellectual Property If we are unable to maintain intellectual property protection, our competitive position could be harmed. Our ability to protect our technologies, such as ~~CB- CAPs and MTXPGs~~ **the AVISE ® Lupus test** , affects our ability to compete and to achieve sustained profitability. We rely on a combination of U. S. and foreign patents and patent applications, copyrights, trademarks

and trademark applications, and contractual restrictions to protect our intellectual property rights. We cannot be certain that the claims in our granted patents and pending patent applications covering our AVISE ® testing products will be considered patentable or enforceable by the United States Patent and Trademark Office (the USPTO) courts in the United States, or by patent offices and courts in foreign countries. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. We apply for patents covering our testing products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important testing products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions, or we may cease our prosecution and maintenance of patents in potentially relevant jurisdictions. Currently, we ~~own or~~ have an exclusive license to ~~11~~ **12** issued U. S. patents **, one Patent Cooperation Treaty application,** and certain corresponding foreign counterpart patents, relevant to our AVISE ® testing products. We own ~~one~~ **five** issued U. S. ~~patent~~ **patents** , ~~three~~ **six** pending U. S. patent applications, ~~a~~ **one** pending ~~Patent Cooperation Treaty~~ **U. S. provisional** patent application and certain corresponding foreign counterpart patents ~~and patent applications~~ relevant to our AVISE ® testing products. While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if such patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the further development of our AVISE ® testing products. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our AVISE ® testing products or prevent others from designing around our claims. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post- grant proceedings declared by the USPTO that could result in substantial cost to us. No assurance can be given that our patent applications will have priority over other patent applications. In addition, recent changes to the patent laws of the United States allow for various post- grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction. **We previously held licenses to five patent families related to CB- CAPs technology from the University of Pittsburgh (UPitt). We have terminated these license agreements (related to U. S. Patent Nos. 7, 361, 517, 7, 390, 631, 7, 585, 640, 7, 588, 905, 8, 080, 382, 8, 126, 654, and foreign equivalents thereof), effective March 22, 2024, and as a result may face increased competition with respect to the portion of our testing products previously protected by these patents.** In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our AVISE ® testing products and development processes that involve proprietary know- how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. While we use commercially reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors and other advisors may unintentionally or willfully disclose such trade secret information to third parties and competitors. We attempt to protect our proprietary technology in large part by entering into confidentiality and non- disclosure agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we will have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our testing products, technologies, services or know- how or require licensing and the payment of significant fees or royalties by us in order to produce our testing products, technologies or services. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If we are unable to prevent unauthorized material disclosure of our trade secrets and other confidential information to third parties, and in particular in jurisdictions where we have not filed for patent protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. Certain of our testing products utilize unpatented technology that is publicly available and can be used by our competitors. Certain of our AVISE ® testing products, such as AVISE ® CTD, utilize both patented technology and publicly available technology that is not protected by patents or other intellectual property rights. We believe that using certain publicly available technology allows us to offer a better and more comprehensive testing product. However, the publicly available technology which we rely upon is also used in, and may continue to be used in, products which compete with our AVISE ® testing products. Our competitors may independently develop competing diagnostic products and services that do not infringe our intellectual property. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our AVISE ® testing products. Our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the diagnostics industry involves both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. The United States has enacted and is currently implementing wide- ranging patent reform legislation. Recent ~~U. S.~~ Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing

patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. We may not develop additional proprietary products, methods and technologies that are patentable. Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. Some of the intellectual property rights we have acquired or licensed or may acquire or license in the future may have been generated through the use of U. S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work related to our CB- CAPs technology was funded by government research grants. As a result, the U. S. government may have certain rights to intellectual property embodied in our testing products pursuant to the Bayh- Dole Act of 1980 (Bayh- Dole Act). These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right, under certain limited circumstances, 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; (ii) 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 "). The U. S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our AVISE ® testing products in all countries throughout the world would be prohibitively expensive. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical and other related fields. This may limit our ability to obtain or utilize those patents internationally. In order to manage our foreign patent costs and focus on the U. S. market, we made the decision to cease the prosecution and maintenance of certain of our foreign patents and patent applications related to our CB- CAPs technology, which is used in our AVISE ® testing products. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection , but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our AVISE ® testing products 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, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent 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, 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. The patent protection and patent prosecution for some of our testing products may be dependent on third parties. We or our licensors may fail to identify patentable aspects of inventions made in the course of 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. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. As a licensee of third parties, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had

and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it may permit other parties to compete with us. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering any of our testing products, our ability to develop and commercialize those testing products may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution. Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in- licensed technology, we may be unable to successfully develop, out- license, market and sell our testing products, which could adversely affect our business. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out- license or market and sell our testing products. We are a party to a number of license agreements under which we are granted intellectual property rights that are important to our business. For example, **we license** certain patent rights ~~related to AVISE ® Lupus are licensed~~ from ~~UPitt~~ **AHN, QMUL and JHU** . Our existing license agreements ~~as related to our AVISE ® testing products~~ impose various regulatory and / or commercial diligence obligations, payment of milestones and / or royalties and other obligations. If we fail to comply with our obligations under a license agreement, the license agreement may be terminated, in which event we would not be able to further develop or market certain AVISE ® testing products. Additionally, we may not always have the first right to maintain, enforce or defend our licensed intellectual property rights and, although we would likely have the right to assume the maintenance, enforcement and defense of such intellectual property rights if our licensors do not, our ability to do so may be compromised by our licensors' acts or omissions. Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including the scope of rights granted under the license agreement and other interpretation- related issues, and whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the licensing agreement. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and / or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and / or applications. Our outside counsel has systems in place to monitor deadlines to pay these fees and to remind us of these fees, and our outside counsel employs an outside firm to pay these fees due to the USPTO and to foreign patent agencies based on our instructions. In the aggregate, these fees can be cost prohibitive for an early- stage company. Accordingly, we made a financially- driven decision to prioritize our payment of these fees and to allow certain of our applications to lapse, particularly with respect to our ex- U. S. rights licensed from UPitt related to our CB- CAPs technology. The permanent lapse of certain of these ex- U. S. rights may result in our patent position being stronger in the United States than abroad, such as in countries that are part of the European Patent Convention, and third parties may be able to compete more effectively against us in countries outside the United States, including in those countries that belong to the European Patent Convention. Additionally, while an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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 might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. Presently we have intellectual property rights, through licenses from third parties and under patents that we own, related to our AVISE ® testing products. Because our programs may involve additional products that require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in- license or use these proprietary rights. We may be unable to acquire or in- license proprietary rights that we identify as being necessary for our AVISE ® testing

products. Even if we are able to obtain a license to such proprietary rights, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. The licensing and acquisition of third- party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party proprietary rights that we may consider necessary or attractive in order to further develop our AVISE ® testing products. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights on commercially reasonable terms, our ability to further develop our AVISE ® testing products and our business, financial condition and prospects for growth could suffer. Third- party claims alleging intellectual property infringement may prevent or delay our development efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the diagnostics industry, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. The Leahy- Smith America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures ~~bring~~ **brings** the possibility of third- party challenges to our patents and the outcome of such challenges could result in a loss or narrowing of our patent rights. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our AVISE ® testing products. As the diagnostics industry expands and more patents are issued, the risk increases that our activities related to our AVISE ® testing products may give rise to claims of infringement of the patent rights of others. We cannot assure you that any of our current or future AVISE ® testing products will not infringe existing or future patents. Although we are not aware of any issued patents that will prevent us from marketing our AVISE ® testing products, there may be third- party patents of which we are currently unaware with claims to materials or methods of manufacture related to the use or manufacture of our AVISE ® testing products. If a third party that owns such a patent asserts it successfully against one of our current or future AVISE ® testing products, we may be unable to market our product, which could materially harm our business and because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third- party patent applications which may later result in issued patents that our AVISE ® testing products or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop one or more of our AVISE ® testing products. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party' s patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or development of our AVISE ® testing products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop our AVISE ® testing products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property. In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our AVISE ® testing products and technology. We may be involved in proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Third parties may infringe, misappropriate or otherwise violate our existing patents, patents that may **be** ~~issue~~ **issued** to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering one of our AVISE ® testing products, the defendant could counterclaim that the patent covering such AVISE ® testing product is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Such proceedings could result in an invalidation of our patents. 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 defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our AVISE ® testing products. Such a loss of patent protection could have a material adverse impact on our business. Litigation

proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. 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, 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. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. We are not aware of any third- party infringement of our intellectual property rights that would have a materially adverse impact on our business. In addition, there can be no assurance that our licensors will be willing to bring and enforce claims to prevent third parties from infringing intellectual property that is licensed to us, particularly if the affected intellectual property is less important to the licensor' s business than to ours. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other companies in our industry. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our AVISE ® testing products. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Risks Related to Our Common Stock Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid. The public trading price for our common stock is affected by a number of factors, including: • actual or anticipated variations in our and our competitors' financial condition and results of operations; • announcements by us or our competitors of new products, strategic partnerships or capital commitments; • changes in reimbursement by current or potential third- party payors; • issuance of new securities analysts' reports or changed recommendations for our stock; • actual or anticipated changes in regulatory oversight of our testing products; • developments or disputes concerning our intellectual property or other proprietary rights; • commencement of, or our involvement in, litigation; • announced or completed acquisitions of businesses or technologies by us or our competitors; • any major change in our management; • changes in accounting principles; • announcement or expectation of additional financing efforts; • future sales of our common stock by our executive officers, directors and other stockholders; and • general economic conditions and slow or negative growth of our markets, including as a result of the current conflict in **the** Ukraine **and the Middle East** . In addition, the stock market in general, and the market for stock of life sciences companies in particular, has 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, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our common stock, regardless of our actual operating performance. As a result of this volatility, 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, following periods of volatility in the overall market and the market price of a particular company' s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management' s attention and resources. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments. Future sales of shares by existing stockholders could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the trading price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. In addition, our directors and executive officers have and may continue to establish programmed selling plans under Rule 10b5- 1 of the Exchange Act for the purpose of effecting sales of our common stock. Any sales of securities by directors and executive officers, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our common stock, particularly if the trading volume of our common stock is relatively low at the time of these sales. ~~In addition, as of February 15, 2023, the holders of 1, 277, 220 shares of common stock and holders of warrants to purchase 409, 108 shares of common stock are entitled to rights with respect to registration of such shares under the Securities Act pursuant to an investors' rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.~~ Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following: • a classified board of directors with three- year staggered terms,

which may delay the ability of stockholders to change the membership of a majority of our board of directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause; • the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings; • the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. We are also subject to the anti- takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. Our amended and restated certificate of incorporation ~~provide~~ **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 provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, the stockholders will not be deemed to have waived our compliance with the Federal Securities laws and rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval. Based on their most recent publicly filed beneficial ownership reports, our greater than 5 % stockholders collectively own approximately ~~69~~ **64** % of our outstanding capital stock and our greater than 5 % stockholders, directors and executive officers collectively own (without duplication) approximately ~~70~~ **65** % of our outstanding capital stock as of February 15, ~~2023~~ **2024** . As a result, such persons, acting together, have the ability to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock. We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in the foreseeable future. We currently intend to retain any future earnings to fund the growth of our business. In addition, our Amended Loan Agreement restricts our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future. An active, liquid trading market for our common stock may not be maintained. Prior to our **initial public offering (** IPO **)** , there had been no public market for our common stock. Our common stock began trading on ~~the~~

The Nasdaq Global Market (Nasdaq) relatively recently, but we can provide no assurance that we will be able to develop and sustain an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. During ~~2022~~ **2023** , our average daily trading volume has been approximately ~~54~~ **25** , ~~446~~ **040** shares. ~~General Risk Factors~~ Our failure to meet the continued listing requirements of ~~the~~ Nasdaq ~~Global Market~~ or The Nasdaq Stock Market LLC could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. If securities or industry analysts **downgrade our common stock or otherwise** issue ~~an~~ adverse ~~opinion~~ **opinions or commentary** regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that equity research analysts publish about us and our business. Currently, we have limited analyst coverage and we do not have any control over such analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline . We are an emerging growth company..... litigation, reputational harm and other consequences . We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because ~~pharmaceutical~~ **life sciences and diagnostics** companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business.