Risk Factors Comparison 2024-02-28 to 2023-03-01 Form: 10-K

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

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results: Risks Related to Our Business and Our Strategy • We may not be able to generate sufficient revenue from our existing tests or develop new tests to be profitable. • Our strategic growth plan may not achieve the anticipated results, and we may not be able to achieve or maintain revenue growth or operate our business on a profitable basis. • ~~Our financial condition~~ **If the government** and ~~results of operations could~~ **other third- party payors fail to provide coverage and adequate payment for our existing and future tests, if any, our revenue and prospects for profitability will** be **harmed** ~~further adversely affected by the ongoing coronavirus pandemic or any other adverse public health development~~ . • If we do not generate sufficient cash flow from operations and are unable to secure additional funding, we may have to reduce our operations. • We are subject to debt covenants that impose operating and financial restrictions on us and if we are not able to comply with them, it could have a material adverse impact on our operations and liquidity. • If our ~~current operating plan changes and we find that our~~ existing capital resources ~~will~~ **and expected net cash to be generated from sales of our tests is** not ~~meet~~ **sufficient for us to maintain** our ~~needs~~ **currently planned operations** , we may find it necessary to raise additional funding, which may not be available **on favorable terms, or at all** . • We ~~are currently~~ **have been** subject to, and in the future may be subject to, securities class action lawsuits and stockholder derivative actions, as well as product or professional liability claims. These, and potential similar or related litigation, could result in substantial losses and have a material adverse effect on our business, cash position, operating results or financial condition. • An inability to attract and retain experienced and qualified personnel, including key management personnel, could adversely affect our business. • We have acquired and we may continue to acquire technologies, assets or other businesses that could cause us to incur significant expense and expose us to a number of unanticipated operational and financial risks, which could adversely affect our financial condition, results of operations and business prospects **. • Failure to comply with laws and regulations related to submission of claims for our services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs. • Our financial condition and results of operations could be adversely affected by adverse public health developments** . • If our SneakPeek Early Gender DNA Test does not perform as expected, we may not realize the expected benefits of our acquisition of Gateway **(as defined below)** . • Security breaches, loss of data and other disruptions, including from cyberattacks, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation. • If we experience a significant disruption in our information technology systems, our business operations and financial condition could be adversely affected. • Each of our tests is processed in a single one of our laboratory facilities, and any loss or prolonged interruption of our ability to use these laboratories or failure to maintain their operation in compliance with applicable regulations would seriously harm our business. • **Our inability to, or delay in, transitioning certain of our laboratory operations to new laboratory facilities in west Salt Lake City, Utah and South San Francisco, California could adversely affect our business. •** We depend on a limited number of third parties, or, in some cases, single- source suppliers, for equipment, reagents and other supplies. If these supplies become unavailable or are disrupted ~~, including as a result of COVID- 19 or another disease and responses to it~~ , then we may not be able to successfully perform our research or operate our business on a timely basis or at all. • Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. • Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests. • We rely on commercial courier delivery services to transport biological materials to our facilities in a timely and cost- efficient manner and if these delivery services are disrupted, our business will be harmed. • We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results. **• Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition. • Our estimates of actionable market size and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates. • Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.** Risks Related to the Development and Commercialization of Our Tests and Test Candidates • Our tests in development may not be clinically effective or may never achieve significant commercial market acceptance and our test offerings that we have recently launched or acquired may not be commercially successful. • If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully commercialize our tests, increase our revenue or achieve and sustain profitability. • If our current research collaborators or scientific advisors terminate their relationships with us or develop relationships with a competitor, our ability to discover genes, proteins, and biomarkers, and to validate and commercialize tests could be adversely affected. Risks Related to ~~Reimbursement • If the government and third- party payors fail to provide coverage and adequate payment for our existing and future tests, if any, our revenue and prospects for profitability will be harmed. • Failure to comply with laws and regulations related to submission of claims for our services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs. Risks Related to~~ Our Intellectual Property • If we **fail** ~~are not able~~ to protect our proprietary technology, others could compete against us more directly, which would harm our business. • If we are subject to litigation or other proceedings arising from a claim of infringement of the intellectual property of a third party, we might incur significant costs and delays in test introduction or we could be prevented from using technologies incorporated in our tests. • If we fail to

comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business. • We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets. • If we fail to adequately protect our trademarks, service marks, trade names and trade dress, we may lose goodwill and brand equity associated with our business. Risks Related to Government Regulation • If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer consequences that could materially and adversely affect our operating results and financial condition. • Our actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation, and / or adverse publicity and could negatively affect our business. • We may from time to time be subject to government investigation (s), the unfavorable outcome of which may have a material adverse effect on our financial condition, results of operations and cash flows. • Changes in health care policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our tests. • Our business could be harmed by the loss, suspension, or other restriction on a license, certification, or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations. • Changes in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future. • FDA regulation of our GeneSight Psychotropic test could be disruptive to our business. • Companion and complementary diagnostic tests require FDA approval, and we may not be able to secure such approval in a timely manner or at all. • Our companion diagnostic tests are subject to ongoing regulatory compliance obligations and continued regulatory review and the failure to comply with such obligations could result in regulatory enforcement and / or penalties. • Our business involves environmental risks that may result in liability for us. **General Risks and** Risks Related to Our Common Stock • Our stock price is highly volatile, and our stock may lose all or a significant part of its value. • ~~Our inability~~ **If we are unable** to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting **,** ~~could adversely affect~~ our results of operations, our stock price and investor confidence in us **could be adversely affected** . • Anti- takeover provisions of Delaware law, provisions in our charter and bylaws and re- adoption of our stockholders' rights plan, or poison pill, could make a third- party acquisition of us difficult. • Future sales and issuances of our common stock would result in dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline. • We do not intend to pay dividends ~~on our common stock~~ so any returns will be limited to changes in the value of our common stock. • If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. • **Increasing scrutiny and evolving expectations from regulators, business partners, investors, and other stakeholders with respect to our ESG practices may impose additional costs on us or expose us to new or additional risks. •** Our restated **certificate of incorporation and our restated** bylaws **designate specific** ~~provide that a~~ state **or federal** ~~court~~ **courts as** ~~located within~~ the ~~State of Delaware is the sole and~~ exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. We believe our future success is dependent upon our ability to successfully market our existing tests to additional patients within the United States, to expand into new markets ~~within and outside the United States~~ , ~~and~~ to develop and commercialize new **tests and to maintain or obtain reimbursement for our** tests. However, we may not be able to generate sufficient revenue, from our existing tests and launching and commercializing new tests, to be profitable. The demand for our existing tests may decrease or may not continue to increase at historical rates due to sales of new tests that may replace or cannibalize our existing product portfolio, or for other reasons such as the introduction of competing testing products by competitors. For example, because most of our tests are only utilized once per patient, we will need to sell our products to new patients or develop new tests in order to continue to generate revenue. Our average reimbursement rate per test may also decline, which may cause our revenues to decrease. Our pipeline of new test candidates, such as FirstGene and Precise MRD, are in various stages of development, some of which may take many more years to develop ~~,~~ and must undergo extensive clinical validation. We may be unable to discover or develop any additional tests through the utilization of our technologies or technologies we license or acquire from others. Even if we develop tests for commercial use, we may not be able to develop tests that: • meet applicable regulatory standards, in a timely manner or at all; • successfully compete with other technologies and tests; • avoid infringing the proprietary rights of others; • are adequately reimbursed by third- party payors; • can be performed at commercial levels or at reasonable cost; or • can be successfully marketed. We must generate significant revenue to achieve profitability. Even if we succeed in marketing our existing tests to physicians for use in new patients and in developing and commercializing any additional tests, we may not be able to generate sufficient revenue to be profitable. We are currently executing upon a **multi-year** strategic growth plan in which we intend to ~~accelerate growth through launching new tests~~ **continue growing by articulating our clinical differentiation** , ~~utilizing a unified ordering portal to~~ **raising awareness with patients who we believe would benefit from our testing products, and innovation that** ~~improve~~ **improves clinical outcomes, ease of use, and** access ~~and ease of use for patients and providers, expanding reimbursement coverage for our tests, enhancing our commercial capabilities and deploying a new commercial model in our Women' s Health and Oncology businesses~~ . Our future performance and growth ~~depends~~ **depend** on the success of our growth plan, including management' s ability to execute upon that plan and the ability of our employees to respond quickly and effectively to strategic projects and changes in our operations and business practices. The implementation of our strategic growth plan has resulted, and is expected to continue to result, in changes to business priorities and operations, capital allocation priorities, operational and organizational structures, and increased demands on management. The execution of our strategic growth plan may take longer than anticipated, and we may not realize, in full or part, our anticipated growth targets in our testing volumes and revenue, or such growth may be realized more slowly than anticipated. **In** ~~Historically, our business operated profitably and provided a cash contribution to our funding and operational needs. However, in~~ recent years we have not operated our business profitably, and we may not be able to ~~operate~~ **achieve** ~~our~~

or maintain ~~business on a profitable~~ **profitability** ~~basis~~ in the future. Potential events or factors that may have a significant impact on our ability to achieve our growth targets and achieve and / or maintain revenue growth and profitability for our business include the following: • the efforts of third- party payors to limit or decrease the amounts that they are willing to pay for our tests, recoup amounts already paid **, not cover our tests** , or institute burdensome administrative requirements for reimbursement, such as prior authorization requirements **; • our ability to execute on our strategic growth plan** ; • increased costs of reagents and other consumables required for testing; • increased personnel and facility costs; • our inability to hire competent, trained staff, including laboratory directors required to review and approve all reports we issue in our business, and sales personnel; • our inability to obtain necessary equipment or reagents to perform testing; • our inability to increase production capacity to meet demand increases; • our inability to expand into new markets ~~within or outside the United States; • our ability to execute on our strategic growth plan~~ ; • increased licensing or royalty costs, and our ability to maintain and enforce the intellectual property rights underlying our tests and services; • changes in intellectual propriety law applicable to our patents or enforcement in the United States and foreign countries; • the expiration of the patents covering our products; • the outcome of outstanding or new litigation; • potential obsolescence of our tests; • our inability to obtain or increase commercial acceptance of our tests; • increased competition and loss of market share; • global or local economic conditions; • increased regulatory requirements; and • material litigation costs, settlements, and judgments. The failure to achieve our growth targets and achieve and / or maintain revenue growth and profitability for our business could have a material adverse effect on our business, prospects, financial condition, results of operations, cash flows, as well as the trading price of our common stock. Any further outbreaks of COVID- 19..... material adverse effect on our business. In both domestic and foreign markets, sales of our tests or any future tests will depend in large part ~~,~~ upon the availability of reimbursement from third- party payors. Such third- party payors include state and federal health care programs such as Medicare, managed care organizations, **other** private health insurers and other organizations. These third- party payors are increasingly attempting to contain health care costs by demanding price discounts and limiting both coverage regarding which tests they will pay for and the amounts that they will pay for existing and new tests. We have experienced coverage limitations and price reductions for many of our products, including for our GeneSight Psychotropic Mental Health Medication Test, and we may continue to experience future coverage limitations and price reductions from CMS, managed care organizations, and other third- party payors. The fact that a test has been approved for reimbursement in the past, for any particular indication or in any particular jurisdiction, does not guarantee that such a test will be approved or remain approved for reimbursement, that the reimbursement amount approved for such test will not be reduced in the future, or that similar or additional tests will be approved for reimbursement in the future. Historically, we have not received reimbursement from third- party payors or payment from patients for many of our tests. Moreover, there can be no assurance that any new tests we have launched or may launch will be reimbursed at rates that are comparable to the rates that we historically obtained for our existing product portfolio. As a result, third- party payors may not cover or provide adequate payment for our current or future tests to enable us to maintain past levels of revenue or profitability with respect to such tests. Further, third- party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development. In addition, under PAMA, Medicare reimbursement for any given test is based on the weighted- median of the payments made by private payors for such test, rendering private payor payment levels even more significant. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of tests generally and any given test individually. ~~On~~ **Since** December ~~10, 2021~~ **2019** , Congress **has** passed **a series of laws to modify PAMA' s statutory requirements related to the data reporting period and phase- in of payment reductions under the CLFS for CDLTs that are not ADLTs. Most recently, the Further Continuing Appropriations and** ~~the~~ **Other Extensions** ~~Protecting Medicare and American Farmers from Sequester Cuts~~ Act **of 2024 (Pub. L. 118- 22** , ~~which included a~~ **enacted on November, 16, 2023) further delayed the reporting requirement as well as the application of the 15 % phase- in reduction. Under these statutory** ~~provision~~ **provisions ,** ~~that delays~~ the next ~~PAMA~~ **data** reporting period for **CDLTs** ~~clinical laboratory tests~~ that are not **ADLTs will be** ~~advanced diagnostic tests to~~ January 1, ~~2023~~ **2025** through March 31, **2025. The same series of laws modified the phase- in of payment reductions resulting from private payor rate implementation so that a 0. 0 percent reduction limit was applied for calendar years 2021 through** 2023 **, as compared to the payment amounts for a test the preceding year** . The ~~Consolidated~~ **Further Continuing** Appropriations **and Other Extensions** Act ~~,~~ **of** ~~2023~~ **2024 further applied a 0. 0 percent reduction limit** ~~, enacted on December 29, 2022, delayed the next PAMA reporting period~~ for **calendar year** ~~clinical laboratory tests that are not advanced diagnostic tests to January 1,~~ 2024 ~~through March 31, 2024~~ . **Consequently** ~~In addition~~ , **payment may** ~~the next round of rate cuts will~~ not be **reduced by more than** ~~implemented until 2024, with tests receiving cuts of up to~~ 15 percent ~~a~~ **per** year ~~from~~ **for calendar years** ~~2024~~ **2025** through ~~2026~~ **2027 as compared to payment amount established for a test the prior year** . Any declines in average selling prices of our products due to pricing pressures may have an adverse impact on our business, results of operations and financial condition. Third- party payors may also **impose prior authorization requirements,** dispute our billing or coding and may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We have also experienced delays or denials of coverage for failure to adequately comply with procedural requirements imposed by third- party payors to obtain reimbursement. We also periodically receive and respond to requests for recoupment from third- party payors in the ordinary course of business. When a third- party payor denies payment for testing, we often are not able to collect payment from the patient, and therefore, we do not receive any revenue from our testing. In addition, if a third- party payor successfully proves that payment for prior testing was in breach of contract or otherwise contrary to law, they may recoup payment, which amounts could be significant and would impact our results of operations. We may also continue to negotiate and settle with third- party payers in order to resolve allegations of overpayment. Third- party payors, such as commercial health insurers and government payors and programs, may also adopt requirements,

programs or policies that may restrict or adversely affect our business. For example, in September 2022, the California Department of Public Health (CDPH) promulgated certain regulatory amendments to the California Prenatal Screening (PNS) Program that made the PNS Program the exclusive means of obtaining cfDNA trisomy screening in California. These regulatory amendments set a price that participating laboratories would receive for each cfDNA test that was substantially lower than laboratories had previously charged, and prohibited laboratories that did not contract with CDPH from participating in the PNS Program and from offering or performing cfDNA trisomy screening in California. As we are not ~~currently~~ a participating laboratory under the PNS Program, we would ~~be~~ **have been** prohibited from offering or performing our Prequel screening test in California. On September 16, 2022, we filed jointly with Laboratory Corporation of America Holdings (Labcorp) a writ petition in the Superior Court of the State of California, County of San Francisco, against the CDPH and its Director challenging CDPH' s ability to make the PNS Program the exclusive means of obtaining cfDNA trisomy screening in California. On September 16, 2022, we also moved jointly with Labcorp for a preliminary injunction to enjoin the implementation and enforcement of the new exclusivity regulation. On November 2, 2022, the Superior Court granted our motion for a preliminary injunction, which allowed us to continue to offer our Prequel screening test in California. On December 17, 2022, we filed jointly with Labcorp a motion for judgment on our writ, through which we **sought** ~~are seeking~~ a permanent injunction to enjoin the implementation and enforcement of the new exclusivity regulation. **On April 28** ~~A hearing on that motion is scheduled for March 21~~, 2023 ~~. CDPH has also commenced the process of appealing the preliminary injunction~~, ~~though no hearing date has been set, and that appeal may be mooted by~~ the Superior Court ~~' s decision on~~ **issued an order granting** our motion for **a permanent injunction to enjoin the implementation and enforcement of the new exclusivity regulation. On June 1, 2023, the Superior Court issued a final** judgment **and** ~~on the~~ writ ~~prior to any hearing. Pending the outcome~~ of ~~this~~ **mandate enjoining the implementation and enforcement of the new exclusivity regulation. The CDPH did not file a notice of appeal. As a result of the** ~~ongoing~~ **foregoing** ~~litigation~~, we **expect to continue to** ~~cannot be certain that we will~~ be able to ~~continue offering~~ ~~---~~ **offer** ~~or~~ **and** ~~performing~~ ~~---~~ **perform** our Prequel screening test in California. ~~If~~ **However,** the **possibility that we might not** ~~exclusivity regulation is ultimately determined to~~ be ~~valid and we are either not~~ able **to continue** to offer our Prequel screening test in California ~~at all, or must do so through the PNS Program at lower rates than we currently charge, our financial and operating results will likely be adversely affected. In addition, although the implementation and enforcement of the exclusivity regulation has been preliminarily enjoined, the possibility that we may be unable to continue to offer our Prequel screening test in California has~~ had a chilling effect on sales of our Prequel screening test in California. U. S. and foreign governments continue to propose and pass legislation designed to reduce the cost of health care. For example, in some foreign markets, the government controls the pricing of many health care products. We expect that there will continue to be federal and state proposals to implement governmental controls or impose health care requirements. In addition, the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on product pricing. Cost control initiatives could decrease the price that we would receive for any tests in the future, which would limit our revenue and profitability **.While we believe that our existing cash,cash equivalents and marketable securities,future cash flow from operations,and amounts available** for borrowing under our ~~Amended~~ **ABL** Facility (as defined below) will be sufficient to ~~fund~~ **meet** our ~~current operations~~ **anticipated cash requirements** for **at least** the ~~foreseeable future~~ **next 12 months** ,changes could occur that would consume available capital resources more quickly than we currently expect and we may need or want to raise additional financing.On ~~December 23~~ **June 30** , ~~2016~~ **2023** ,we entered into ~~a senior secured~~ **an asset- based** revolving credit facility **(the " ABL Facility ") with an initial maximum principal amount of $ 90.0 million with JPMorgan Chase Bank,N.A.** as ~~borrower~~ **administrative agent and issuing bank** , ~~with~~ **and the** ~~the~~ **other** ~~lenders~~ **lender parties** ~~from time to time party~~ thereto **.On October** ~~,which was amended on July~~ 31, ~~2018,May 1,2020~~ **2023** , **we entered into** ~~February 22,2021 and~~ **an amendment to** ~~July 26,2022 (~~ the **ABL** ~~" Amended~~ Facility ~~")~~ **to increase the maximum principal amount of the available revolving line of credit under the ABL Facility by $ 25.0 million for a total maximum principal commitment under the ABL Facility of $ 115.0 million** .As of December 31, ~~2022~~ **2023** ,we ~~have no~~ **had $ 40.0 million of** outstanding borrowings under ~~our Amended~~ **the ABL** Facility ~~and our revolving commitment amount was $ 150.0 million~~ .The ~~Amended~~ **ABL** Facility ~~restricts~~ **limits** our ability to **incur additional indebtedness** ~~make future borrowings if unrestricted cash,cash equivalents~~ and **requires us to comply** ~~marketable securities exceed $ 150.0 million,unless such borrowings are used in connection~~ with certain **minimum liquidity** ~~permitted acquisitions.Unrestricted cash,cash equivalents~~ and **minimum availability covenants** ~~marketable securities totaled $ 169.7 million as of December 31,2022.As our total unrestricted cash,cash equivalents,and marketable securities under the Amended Facility exceeded $ 150.0 million as of December 31,2022,we are currently unable to make future borrowings under the Amended Facility unless related to a permitted acquisition~~ .In addition, **during November 2023,we completed an underwritten public offering of our common stock in which we sold 7,441,176 shares of our common stock at a price of $ 17.00 per share for proceeds of $ 117.6 million,net of offering expenses and underwriting discounts.If we do not generate sufficient cash from operations,if our capital resources are consumed more rapidly than expected,** ~~our~~ **or** ~~Amended~~ **if we no longer have access to additional funds under our ABL** Facility ~~expires on July 31,2023,~~ and **are** ~~there is no guarantee that the Amended Facility will be extended or that we will be able~~ **unable** to secure additional funding **,** ~~or other financing options in a timely manner or~~ on ~~favorable~~ **acceptable** terms **or** ~~,if~~ at all ~~.We are also subject to financial covenants as part of our Amended Facility that could limit our ability to incur additional indebtedness.Without additional funds~~ ,we may be forced to delay,scale back or eliminate some of our sales and marketing activities,research and development activities,or other operations,and potentially delay development of our tests in an effort to provide sufficient funds to continue our operations.If any of these events occur,our ability to achieve our development and commercialization goals could be adversely affected.Our future capital requirements will depend on many factors that are currently unknown to us,including:• the scope,progress,results and cost of development,clinical testing and pre- market studies of any new tests that we may develop or acquire;• the progress,results,and costs to develop additional tests;• our ability to

operate our business on a profitable basis;• the costs of preparing,filing and prosecuting patent applications,maintaining and enforcing our current issued patents,and defending intellectual property- related claims;• our ability to enter into collaborations,licensing or other arrangements favorable to us;• the costs of acquiring technologies or businesses,and our ability to successfully integrate and achieve the expected benefits of our business development activities and acquisitions;• the progress,cost and results of our international efforts;• the costs of expanding our sales and marketing functions and commercial operation facilities in the United States and in new markets;• the costs,timing and outcome of any litigation against us;and • the costs to satisfy our current and future obligations.Covenants in the ~~Amended~~ **ABL** Facility impose operating and financial restrictions on us.These restrictions may prohibit or place limitations on,among other things,our ability to incur ~~additional~~ **liens,incur** indebtedness, ~~create~~ **dispose of assets,make investments,make** certain **restricted payments** ~~types of liens~~ , ~~and complete mergers~~ -- **merge** ,consolidations,or change in control transactions.Under the Amended Facility,a change in control of the Company,which means that a stockholder or a group of stockholders is or becomes the beneficial owner,directly or indirectly,of more than 35 % of the total voting power of the voting stock of the Company,would require mandatory prepayment of any outstanding debt.The Amended Facility may also prohibit or place limitations on our - **or consolidate and enter into certain speculative hedging arrangements** ~~ability to sell assets,pay dividends or provide other distributions to stockholders.These restrictions could also limit our ability to take advantage of business opportunities~~ .We are also required to **maintain** ~~comply with certain financial covenants,including a~~ minimum liquidity ~~covenant~~ **of $ 60.0 million and minimum availability of $ 25.0 million at all times before achieving a fixed charge coverage ratio of 1.0 to 1.0 and thereafter , to maintain a fixed charge coverage ratio of 1.0 to 1.0 until achieving availability** under the ~~Amended~~ **ABL** Facility **of greater than the greater of (a) $ 10.6 million and (b) 12.5 % of the lesser of the maximum commitment amount and the borrowing base for a period of 30 consecutive days.In addition,the ABL Facility includes a number of customary events of default** .If **any event of default occurs (subject, ~~we are unable to comply with these financial covenants~~** in **certain instances,to specified grace periods),the principal,premium,if any,interest and any other monetary obligations on all the ~~the~~ then** ~~Amended~~ **outstanding amounts under the ABL** Facility ~~,we~~ may **become due** ~~be in default under the agreement.A default would result in an~~ **and payable immediately** ~~increase in the rate of interest and limits on our ability to incur certain additional indebtedness and it could potentially cause any loan repayment to be accelerated~~ , ~~any of~~ which could have a material adverse impact on our operations and liquidity.We ~~anticipate~~ **believe** that our existing ~~capital resources~~ **cash,cash equivalents** and **marketable securities of $ 140.9 million as of December 31,2023,our** expected ~~net~~ cash **flow from operations,and our availability** to **borrow will** be **sufficient** ~~generated from sales of our tests will enable us~~ to ~~maintain~~ **meet** our ~~currently planned operations~~ **anticipated cash requirements** for **at least** the ~~foreseeable future~~ **next 12 months** .However,we base this expectation on our current operating plan,which may change.We have incurred,and ~~will~~ **may** continue to incur,significant ~~costs in the development and marketing of current and prospective~~ **losses.We may not be able to generate sufficient revenue from our existing** tests **and launching and commercializing new tests,to be profitable** . ~~Our~~ **In addition,our** ongoing efforts to develop tests and expand our business,which may be through internally developed products,partnerships,in- licensing and mergers and acquisitions,will **continue to** require substantial cash resources.In addition,we have incurred,and may continue to incur,substantial costs in defending and settling legal proceedings. **In connection with the settlement of the Ravgen (as defined below) litigation,we may be required to pay Ravgen $ 21.25 million in five annual installments beginning no earlier than January 1,2026 if certain conditions are satisfied.** We may also be required to pay an additional $ ~~32~~ **25** . ~~5~~ **0** million to the former equity and vested incentive unit holders of Gateway,if certain revenue,volume and earnings targets set forth in the acquisition agreement are achieved.If adequate funds are not available,we may be required to raise additional funds.Sources of potential additional capital resources may include,but are not limited to,public or private equity financings, ~~expanding or supplementing our Amended Facility,~~ or selling convertible or non- convertible debt securities. ~~This~~ **Any** additional funding,if necessary,may not be available to us on reasonable terms,or at all ~~.If we issue shares of stock or other securities to acquire new companies or technologies,the ownership interests of our existing stockholders may be significantly diluted and the price of our common stock may decrease~~ .Because of our potential long- term capital requirements,we may access the public or private equity or debt markets whenever conditions are favorable,even if we do not have an immediate need for additional capital at that time.Under Securities and Exchange Commission rules,we currently qualify as a well- known seasoned issuer (WKSI),and can at any time file a registration statement registering securities to be sold to the public which would become effective and available for use upon filing.If additional funds are raised by issuing equity or equity- based securities,existing stockholders may suffer significant dilution.Debt financing,if available,may involve agreements that include covenants limiting or restricting our ability to take specific actions,such as incurring debt,making capital expenditures or declaring dividends.If we raise additional funds through collaborations,strategic alliances,partnerships and licensing arrangements with third parties,we may have to relinquish valuable rights to our technologies or tests or grant licenses on terms that are not favorable to us.We ~~are currently~~ **have been** subject to a variety of litigation,including a securities class action lawsuit filed in the United States District Court for the District of Utah,and stockholder derivative actions filed in the Delaware Court of Chancery and the United States District Court for the District of Delaware. **On August 2,2023,we entered into a stipulation and agreement of settlement to resolve the securities class action lawsuit,which was subsequently approved by the United States District Court for the District of Utah on December 15,2023.Pursuant to the terms of the settlement,we paid a settlement amount of $ 77.5 million in cash.** We also may be subject to future securities class action and stockholder derivative claims.Such litigation may adversely impact our business,cash position,results of operations or financial condition and divert management' s time and attention from our business ~~.We cannot predict the outcome of these lawsuits,nor can we predict the amount of time and expense that will be required to resolve these lawsuits and the expense of resolving these lawsuits may be in amounts significantly above our insurance coverage~~ .In addition,the marketing,sale and use of our tests could subject us to liability for errors in,misunderstandings of,or inappropriate reliance on,information we provide to clinicians,geneticists or

patients,and lead to claims against us if someone were to allege that a test failed to perform as it was designed or marketed,if we failed to provide a correct test result to a patient,if we failed to correctly interpret the test results,if we failed to update the test results due to a reclassification of the variants according to new published guidelines,or if the ordering physician or patient were to misinterpret test results or improperly rely on them when making a clinical decision.We could also be subject to claims,lawsuits or liability if the biological materials we receive for analysis were not properly attributed to the correct patient or if we failed to maintain custody of or properly track the biological materials.A product liability or professional liability claim could result in substantial damages and be costly and time- consuming for us to defend ~~.For example,on January 24,2022,we paid $ 14.0 million to settle a lawsuit that alleged negligence,breach of contract and associated torts in connection with an alleged error in testing performed by us in 2004~~ .Although we maintain liability insurance for certain claims,including director and officer' s insurance and insurance for errors and omissions,we cannot assure you that such insurance would fully protect us from the financial impact of defending against outstanding or future claims or any judgments,fines or settlement costs arising out of any outstanding or future claims.Any claim ~~,including the securities class action and stockholders derivative claims or an errors and omissions liability claim,~~ brought against us,with or without merit,could increase our insurance rates or prevent us from securing insurance coverage in the future.If we were successfully sued for product or professional liability claims or in connection with ~~current or~~ future securities class action and stockholder derivative claims,we could face substantial losses that exceed our insurance coverage and our other resources.For example, ~~although~~ we ~~maintain~~ **depleted our** director and officer' s insurance coverage **for** ~~and continue to engage in defense of~~ the ~~outstanding~~ **recently settled** securities class action **lawsuit** and **no** ~~stockholder derivative claims,our~~ insurance **proceeds were available** ~~coverage will only cover up~~ to **us to pay the settlement amount** ~~an aggregate of $ 20.0 million of liability in certain circumstances after we have paid a significant deductible~~ .If we are not successful in our defense of ~~these~~ **any future** ~~litigations~~ **litigation** ,we could be forced to make significant payments to or other settlements with our stockholders and their lawyers outside of our insurance coverage,and such payments or settlement arrangements could have a material adverse effect on our business,cash position,operating results or financial condition.Additionally,any lawsuit could cause injury to our reputation or cause us to suspend sales of our tests.The occurrence of any of these events could have a materially adverse effect on our reputation,cash position,and results of operations.Because of the specialized scientific nature of our business,we are highly dependent upon our ability to attract and retain highly qualified and experienced personnel,including key management personnel.Competition for these personnel is intense,especially for management,sales,scientific,medical,information technology,research and development and other technical personnel.We may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions.We have from time to time experienced,and we expect to continue to experience,difficulty in hiring and retaining employees with appropriate qualifications.Our compensation arrangements,such as our short- term incentive and equity award programs,may not be successful in attracting new employees and retaining and motivating our existing employees.Our agreements with our employees generally provide for employment that can be terminated by either party without cause at any time,subject to specified notice requirements.Further,the non- competition provision that certain key employees are subject to may not be enforceable under certain state laws,particularly California,or federal laws or such provisions may be prohibitively expensive to enforce.Our growth and commercial activities have placed a greater workload and strain on our existing employees,increasing the risk that our employees experience fatigue or burnout or terminate their employment with us.In addition,inflation has had ~~,and we expect that it will continue to have,~~ an impact on the costs that we incur to attract and retain qualified personnel ~~,~~ and may make it more difficult for us to attract and retain such personnel.Our success also depends on the skills,experience and performance of key members of our senior management team,who are critical to directing and managing our growth and development in the future.The loss of any member of our senior management team may cause us to experience difficulties in competing effectively,developing our technologies,and implementing our business strategies.Furthermore,the loss of the services of or failure to recruit key scientific and technical personnel and other qualified personnel who are necessary to operate our business would adversely affect our business and it may have a material adverse effect on our business as a whole.In addition to organic growth,we intend to continue to pursue growth through the acquisition of technology,assets or other businesses that may enable us to enhance our technologies and capabilities,expand our geographic market and sales channels,add experienced management personnel and increase our test offerings.For example,on ~~November~~ **February** 1, ~~2022~~ **2024** ,we acquired ~~Gateway,which markets and sells~~ the **Precise Tumor** ~~SneakPeek Early Gender DNA~~ Test **,the Precise Liquid Test,and a CLIA certified laboratory from Intermountain Healthcare** .However,these acquisitions may not generate a positive return on our investment.Additionally,we may be unable to implement our growth strategy if we cannot identify suitable acquisition candidates,reach agreement on potential acquisitions on acceptable terms,successfully integrate personnel or assets that we acquire or for other reasons.We may also experience increased expenses,distraction of our management,and personnel and customer uncertainty as a result of our acquisition activities.Our acquisition efforts may involve certain risks,including:• we may have difficulty integrating **products,** operations and systems of any acquired business;• key personnel and customers of the acquired company may terminate their relationships with the acquired company as a result of the acquisition;• we may not be successful in launching newly acquired tests,or if those tests are launched,they may not prove successful in the marketplace;• we may experience additional financial and accounting challenges and complexities in areas such as tax planning and financial reporting;• we may assume or be held liable for risks and liabilities as a result of our acquisitions,including for legal,compliance,recoupment,and environmental- related costs and liabilities,some of which we may not discover during our due diligence;• we may incur significant additional operating expenses **and such acquisition may not be profitable** ;• we may experience inconsistencies in standards,controls,procedures,policies and compensation structures;• we may encounter risks and limitations on our ability to consolidate our corporate and administrative infrastructures;• our ongoing business may be disrupted or receive insufficient management attention;and • we may not be able to realize synergies,the cost savings or other financial

and operational benefits we anticipated,or such synergies,savings or benefits may take longer than we expected.The process of negotiating acquisitions and integrating acquired tests,services,technologies,personnel or businesses might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business,whether or not any such transaction is ever consummated.Moreover,we might never realize the anticipated benefits of any acquisition such as increase in our scale,diversification,cash flows and operational efficiency and meaningful accretion to our diluted earnings per share.Future acquisitions could result in the use of our available cash and marketable securities,potentially dilutive issuances of equity securities,the need to incur additional debt,contingent liabilities,or impairment expenses related to goodwill,and impairment or amortization expenses related to other intangible assets,which could harm our financial condition.In addition,if we are unable to integrate any acquired businesses,tests or technologies effectively,our business,financial condition and results of operations may be adversely affected.We may also seek to divest assets from time to time,including but not limited to,large capital equipment,diagnostic tests,intellectual property,business units,or corporate affiliates.For example,we divested Myriad RBM,Inc.,which provided pharmaceutical and clinical services,on July 1,2021,and we completed the sale of select operating assets and intellectual property,including the Vectra test,from the Myriad Autoimmune business unit,on September 13,2021.The prices that we receive for such assets may not be high and,in some cases,have been and may be lower than the amount we invested in or paid for such **assets** . We are subject to laws and regulations governing the submission of claims for payment for our services, such as those relating to: coverage of our services under Medicare, Medicaid and other state, federal and foreign health care programs; the amounts that we may bill for our services; and the party to which we must submit claims. Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or in attempts by state and federal health care programs, such as Medicare and Medicaid, to recover payments already made. Submission of claims in violation of these laws and regulations can result in recoupment of payments already received, substantial civil monetary penalties, and exclusion from state and federal health care programs, and can subject us to liability under the federal False Claims Act and similar laws. The failure to report and return an overpayment to the Medicare or Medicaid program within 60 days of identifying its existence can give rise to liability under the False Claims Act. Further, a government agency could attempt to hold us liable for causing the improper submission of claims by another entity for services that we performed if we were found to have knowingly participated in the arrangement at issue. ~~challenges~~ **Any outbreak of contagious disease or adverse public health development could have a material** and **adverse effect on our business operations,** ~~complexities in areas such as tax planning and~~ financial ~~reporting;• we~~ **condition,or results of operations.Such adverse effects have included,and** may ~~assume or be held liable~~ **in the future include,diversion** ~~for~~ **or prioritization** ~~risks and liabilities as a result~~ of **health care resources away from the conduct of testing,limitations on patients' access to our products,and disruptions** ~~our~~ **or** ~~acquisitions,including for legal,compliance,recoupment,and environmental~~ **restrictions affecting the ability of our laboratories to process our tests.Future surges in COVID - 19 cases or any other outbreak of contagious disease and** related **employee absences** ~~costs and liabilities,some of which we~~ may **strain** ~~not discover during~~ our **workforce and impact our ability to process tests in a timely way** due ~~diligence;• we may incur significant additional operating expenses;•~~ **to reduced staff availability.To the extent that any disease affects individuals and businesses around the globe,** we may experience ~~inconsistencies in standards~~ **disruptions from time to time that could severely impact our business** , ~~controls,procedures,policies~~ **including:• decreased volume of testing as a result of disruptions to health care providers** and ~~compensation structures~~ **limitations on the ability of providers to administer tests,including the suspension of non- emergency appointments and services** ;• ~~we may encounter risks~~ **disruptions or restrictions on the ability of our customers,our collaborators',or our suppliers' personnel to travel,including as a result of shelter- in- place or stay- at- home orders from state** and **local governments,and temporary closures of our facilities or the facilities of our collaborators or suppliers;•** limitations on **employee resources that would otherwise be focused on the development of our products,processing our tests,and the conduct of our clinical trials,including because of sickness of employees** ~~our~~ **or their families** ~~ability to consolidate our~~ **or** ~~corporate and administrative infrastructures~~ **requirements imposed on employees to avoid contact with large groups of people** ; **and** • **delays in necessary interactions with local regulators,ethics committees and other important agencies and contractors due to limitations in employee resources** ~~our~~ **or** ~~ongoing business~~ **access.In addition,the continued spread of COVID- 19 or the spread of another disease globally could continue to adversely affect our manufacturing and supply chain.Parts of our direct and indirect supply chain are located overseas and both international and domestic components have been,and** may **in the future** be **,subject to disruption as a result of COVID- 19 or another disease and responses to it.If the supplies and components necessary to manufacture our products become unavailable or are** disrupted ~~or receive insufficient management attention;~~ **as a result of a disease** and ~~•~~ **responses to it,then** we may not be able to **successfully perform** ~~realize synergies,the cost savings or~~ **our** ~~other financial and operational benefits~~ **research,sell our tests,or operate our business on a timely basis or at all.If our SneakPeek Early Gender DNA Test does not perform as expected,** we ~~anticipated,or such synergies,savings or benefits may take longer than we expected.The process of negotiating acquisitions and integrating acquired tests,services,technologies,personnel or businesses might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business,whether or not any such transaction is ever consummated.Moreover,we might never realize the anticipated benefits of any acquisition such as increase in our scale,diversification,cash flows and operational efficiency and meaningful accretion to our diluted earnings per share.Future acquisitions could result in the use of our available cash and marketable securities,potentially dilutive issuances of equity securities,the need to incur additional debt,contingent liabilities,or impairment expenses related to goodwill,and impairment or amortization expenses related to other intangible assets,which could harm our financial condition.In addition,if we are unable to integrate any acquired businesses,tests or technologies effectively,our business,financial condition and results of operations may be adversely affected.We may also seek to divest assets from time to time,including but not limited to,large~~

~~capital equipment,diagnostic tests,intellectual property,business units,or corporate affiliates.For example,we divested Myriad RBM,Inc.,which provided pharmaceutical and clinical services,on July 1,2021,and we completed the sale of select operating assets and intellectual property,including the Vectra test,from the Myriad Autoimmune business unit,on September 13,2021.The prices that we receive for such assets~~ may not **realize** ~~be high and,in some cases,have been and may be lower than~~ the **expected benefits of** ~~amount we invested in or~~ **our acquisition of Gateway** ~~paid for such assets~~ .On November 1,2022,we acquired Gateway **Genomics,LLC (" Gateway")** ,a personal genomics company and developer of consumer genetic tests that gives families insight into their future children.Gateway offers and sells the SneakPeek Early Gender DNA Test in the U.S.direct to consumers via sneakpeektest.com and Amazon.com ~~and~~ **,** through various clinical channels,such as OBGYN offices,midwives,birth centers and ultrasound clinics and laboratories **,and in certain retail locations** .The SneakPeek Early Gender DNA Test is also sold internationally through distributors in the United Kingdom,Canada,Australia and certain other countries.The SneakPeek Early Gender DNA Test competes against other gender DNA tests and other methods of determining fetal sex (such as non- invasive prenatal testing and ultrasounds) based on a variety of factors,including accuracy,how early the sex of the fetus can be determined,price,ease of use,convenience,and the speed in which test results are delivered.We believe that the SneakPeek Early Gender DNA Test currently outperforms competing tests and methods of fetal sex determination on a number of these factors,including accuracy,ease of sample collection with the at- home SNAP blood collection device,and the test' s ability to reveal a baby' s sex at six weeks into pregnancy,the earliest method available.However,there can be no guarantee that the SneakPeek Early Gender DNA Test will continue to outperform other early fetal sex determination tests in these areas or that we will be able to continue to enhance and improve the SneakPeek Early Gender DNA Test in ways that would allow it to remain the market- leading early fetal sex determination test.The success of our acquisition of Gateway depends in part on the continued growth of the SneakPeek Early Gender DNA Test,including our ability to sell the SneakPeek Early Gender DNA Test in retail stores while continuing to increase sales volumes in existing channels,and our ability to cross- sell our Prequel prenatal screening test to SneakPeek Early Gender DNA Test customers.Historically,we have limited experience with marketing non-clinical,consumer products directly to consumers or with retail- based marketing strategies,and there can be no guarantee that we will be successful in doing so.In addition,we may not be able to continue to grow the SneakPeek Early Gender DNA Test at the rate at which it was growing prior to our acquisition of Gateway,and we may not be successful at selling the SneakPeek Early Gender DNA Test in retail stores.We may also face a number of obstacles to cross- sell our Prequel prenatal screening test to SneakPeek Early Gender DNA Test customers,including persuading physicians of our SneakPeek Early Gender DNA Test customers to use our Prequel prenatal screening test and navigating patient consent and data privacy laws.In the ordinary course of our business,we collect and store sensitive data,including legally protected patient health information,credit card information,personally identifiable information about our employees and customers,intellectual property,and proprietary business information,including that of our customers,payors and collaboration partners.We manage and maintain our applications and data utilizing on- site,remote,or cloud- based systems.These applications and data encompass a wide variety of business- critical information including research and development information,commercial information and business and financial information.The secure processing,storage,maintenance and transmission of this critical information ~~are~~ **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 has been,and may continue to be,vulnerable to attacks by hackers,or viruses,malware,including ransomware,breaches or interruptions due to employee error,malfeasance or other disruptions,or lapses in compliance with privacy and security mandates.Any such malicious cyberattack,virus,breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties,publicly disclosed,held for ransom, **altered,** lost or stolen.We have measures in place that are designed to prevent,and if necessary,to detect and respond to such cybersecurity incidents and breaches of privacy and security mandates.While we have experienced unauthorized accesses to our information technology systems and infrastructure in the past,which may occur again in the future,our security measures have been able to detect,respond to and prevent any material adverse effect to our information systems and business operations from such breaches.However,in the future,any such access,disclosure or other loss **,or alteration** of information could result in legal claims or proceedings,liability under laws that protect the privacy of personal information,such as HIPAA,government enforcement actions and civil or even criminal penalties.Unauthorized access,loss **,alteration,** or dissemination could also disrupt our operations,including our ability to process samples,provide test results,bill payors or patients,provide customer support services,conduct research and development activities,process and prepare company financial information,and manage various general and administrative aspects of our business,and may damage our reputation,any of which could adversely affect our business,financial condition and results of operations.In addition,we face increased cybersecurity risks and potential disruption to our technology infrastructure due to the number of employees that are working remotely as a result of remote work policies and other hybrid work arrangements.Increased levels of remote access create additional opportunities for cybercriminals to exploit vulnerabilities,and employees may be more susceptible to phishing and social engineering attempts.Information technology (IT) and communication systems are an important part of our business operations.These IT and communications systems support a variety of functions,including sample processing,tracking,quality control,customer service and support,billing,research and development activities,and various general and administrative activities.The availability of our products and services and fulfillment of our customer contracts depends on the continuing operation of our IT and communication systems.Our IT and communication systems may be susceptible to damage,disruptions or shutdowns due to power outages,hardware failures,computer viruses,attacks by computer hackers,telecommunication failures,user errors,catastrophes or other unforeseen events.Our IT and communication systems also may experience interruptions,delays or cessations of service or produce errors in connection with system implementation,integration,upgrades or system migration work that takes place from time to time. **In addition,we may not be able to maintain operational effectiveness of our IT and**

communication systems due to insufficient technology infrastructure,aging components,accumulated technical debt and gaps in our software release processes. If we were to experience a prolonged system disruption in the IT and communication systems that involve our interactions with customers,providers or suppliers,it could result in the loss of sales and customers and significant incremental costs,which could adversely affect our business.In addition,security breaches of our IT systems could result in the misappropriation or unauthorized disclosure of confidential information belonging to us or to our employees,partners,customers or suppliers,which could result in our suffering significant financial or reputational damage.We rely on a CLIA- certified facility in Salt Lake City,Utah to perform most of our tests;a CLIA- certified laboratory in South San Francisco,California to perform our Foresight and Prequel tests;a **CLIA- certified laboratory in St.George to perform our Precise Tumor test;a** single laboratory facility in Cologne,Germany to perform and produce our EndoPredict test kits;a CLIA- certified laboratory in Mason,Ohio to perform our GeneSight test;and a laboratory in ~~La Jolla~~ **San Diego** ,California to perform our SneakPeek Early Gender DNA test ~~.We also plan to open new laboratories in South San Francisco,California,San Diego,California and west Salt Lake City,Utah~~ .Our laboratories and the equipment we use to perform our tests would be difficult to replace and may require significant lead time to replace and qualify for use if they become inoperable.Some of our laboratories are located near active earthquake fault lines and in a region affected by wildfires and flooding.We currently have no backup or redundant facility to perform each of our tests.In the event any of our testing facilities were to lose its CLIA certification or other required certifications or licenses or were affected by a pandemic or man- made or natural disaster,such as an earthquake,severe weather,flooding,rising sea levels,other physical effects of climate change,power outages or contamination,we would be unable to continue our business,with respect to the tests performed at the particular facility or overall,at current levels to meet customer demands for a significant period of time **.According to the U.S.Environmental Protection Agency,heat waves and large storms are likely to become more frequent or more intense with human-induced climate change,which could impact our operations** .Although we maintain insurance on these facilities,including business interruption insurance,it may not be adequate to protect us from all potential losses if these facilities were damaged or destroyed.In addition,any interruption in our business would result in a loss of goodwill,including damage to our reputation.If our business were interrupted,it would seriously harm our business. **We are** ~~The inability to open the planned facilities~~ in **the process of transitioning our laboratory operations in Salt Lake City,Utah,where most of our tests are performed,and** South San Francisco,California, **where our Foresight** ~~San Diego,California~~ and **Prequel tests are performed,to new laboratory facilities in** west Salt Lake City,Utah, **and South San Francisco,California,respectively.The inability to transition our existing laboratory operations to our new laboratories in South San Francisco,California and west Salt Lake City,Utah,** delays in ~~opening~~ **transitioning our laboratory operations to** such facilities or the failure to obtain any required permits,licenses,or certifications could result in increased costs,limit our ability to keep up with the demand for our products,and prevent us from realizing the intended benefits of these new facilities and our future laboratories.We currently rely on a small number of suppliers,or,in some cases,single- source suppliers,to provide our gene sequencing equipment,content enrichment equipment,multiplex protein analysis equipment,robots,and specialty reagents and other laboratory supplies required in connection with our testing and research and development activities.We believe that currently there are limited alternative suppliers of the equipment,robots,reagents and certain other supplies that we use in our business.The equipment,robots,reagents or other supplies may not remain available in commercial quantities at acceptable costs. **In addition,we rely upon a limited number of commercial delivery services to provide us with laboratory supplies,and the disruption of such delivery services could adversely impact our business.** If we are unable to obtain when needed additional or alternative equipment or robots,or an adequate supply of reagents or other ingredients or supplies at commercially reasonable rates,our ability to continue to identify genes and perform testing would be adversely affected.In addition,the loss of a single- source supplier or the failure to perform by a single- source supplier could have a disruptive effect on our business,including our ability to perform testing,and could adversely affect our results of operations.In addition,the ~~continued~~ spread of ~~COVID- 19 or the spread of another~~ disease globally could further adversely affect our manufacturing and supply chain.Parts of our direct and indirect supply chain are located overseas and both international and domestic components have been ~~,and may continue to be,~~ subject to disruption as a result of COVID- 19 ~~or another disease~~ and responses to it.We have experienced and may ~~continue to~~ **in the future** experience a shortage of certain laboratory supplies and equipment,and we may experience a suspension of services from other laboratories or third parties as a result of **a global pandemic** ~~COVID - 19 or another disease~~ and responses to it.Political,administrative,legislative,legal or regulatory actions in response to **a global pandemic** ~~COVID - 19 or another disease~~ could create additional supply shortages,disruptions or other uncertainties affecting our research and business.If the supplies and components necessary to manufacture our products become unavailable or are disrupted ~~,including as a result of COVID- 19 or another disease and responses to it~~ ,then we may not be able to successfully perform our research or operate our business on a timely basis or at all. **Further** ~~As part of our business strategy~~ , **disruption in the global supply chain related to hostilities in Ukraine and the Middle East could impact our supply chain.For example,Houthi forces have recently begun attacking freighters in the Red Sea due to the ongoing conflict between Israel and Gaza.While** we ~~operate in international markets and~~ have **not experienced material supply** ~~active sales operations in Germany,France,and Japan and production operations in Germany.We also distribute our SneakPeek Early Gender DNA Test through distributors in the United Kingdom,Australia,Canada and certain other countries.We may establish additional operations or acquire additional properties outside the United States in order to advance our international sales.Doing business internationally involves a number of risks,including:• multiple,conflicting and changing~~ --- **chain disruptions related to** ~~laws and regulations such as tax laws,export and import restrictions,employment laws,data privacy laws such as the~~ **these global hostilities** ~~EU GDPR,regulatory requirements and other governmental approvals,permits and licenses;• failure by us~~ to **date** ~~obtain regulatory approvals or adequate reimbursement for the use of our tests in various countries;• ineffective marketing campaigns leading to failure in establishing a viable~~ , ~~profitable,and sustainable presence in our international markets;• difficulty in staffing and managing~~

~~foreign operations;• managing multiple payor reimbursement regimes,government payors and self- pay systems;• complexities and difficulties in obtaining protection and enforcing our intellectual property;• logistics and regulations associated with shipping patient samples,including infrastructure conditions,customs and transportation delays,including compliance with the Office of Foreign Assets Control and other international trade sanctions;• limits in our ability to penetrate international markets if~~ we are **unable to predict how these conflicts will develop or guarantee that we will** not ~~able to process tests~~ **experience material supply chain disruptions in the future.** As **part** of ~~of~~ our business strategy,we operate in international markets and have active sales operations in Germany,France,and Japan and production operations in Germany.We also distribute our SneakPeek Early Gender DNA Test through distributors in the United Kingdom,Australia,Canada and certain other countries.We may establish additional operations or acquire additional properties outside the United States in order to advance our international sales.Doing business internationally involves a number of risks,including:• multiple,conflicting and changing laws and regulations such as tax laws,export and import restrictions,employment laws,data privacy laws such as the EU GDPR,regulatory requirements and other governmental approvals,permits and licenses;• failure by us to obtain regulatory approvals or adequate reimbursement for the use of our tests in various countries;• ineffective marketing campaigns leading to failure in establishing a viable,profitable,and sustainable presence in our international markets;• difficulty in staffing and managing foreign operations;• managing multiple payor reimbursement regimes,government payors and self- pay systems;• complexities and difficulties in obtaining protection and enforcing our intellectual property;• logistics and regulations associated with shipping patient samples,including infrastructure conditions,customs and transportation delays,including compliance with the Office of Foreign Assets Control and other international trade sanctions;• limits in our ability to penetrate international markets if we are not able to process tests locally;• financial risks,such as longer payment cycles,difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;• political and economic instability,including wars,terrorism,and political unrest,outbreak of disease,boycotts,curtailment of trade and other business restrictions;• regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S.Foreign Corrupt Practice Act,UK Bribery Act,anti- boycott laws and other anti- corruption laws;and • risks related to the disruptions caused by COVID- 19 or another disease and responses to it.Any of these factors could significantly harm our international operations and,consequently,our revenues and results of operations.In addition,any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include,but are not limited to,significant criminal,civil and administrative penalties,including imprisonment of individuals,fines and penalties,denial of export privileges,seizure of shipments,and restrictions on certain business activities.Also,the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.Our international operations could be affected by changes in laws,trade regulations,labor and employment regulations,and procedures and actions affecting approval,production,pricing,reimbursement and marketing of tests,as well as by inter- governmental disputes.Any of these changes could adversely affect our business.Our success internationally will depend,in part,on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business.Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.Genetic testing has raised ethical,legal and social issues regarding privacy rights and the appropriate uses of the resulting information.Governmental authorities could,for social or other purposes,limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions,particularly for those that have no known cure.Similarly,these concerns may lead patients to refuse to use,or clinicians to be reluctant to order,genomic tests even if permissible;they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance.Ethical and social concerns may also influence U.S.and foreign patent offices and courts with regard to patent protection for technology relevant to our business.Although the Genetic Information Non- discrimination Act has criminalized the disallowance of health insurance on the basis of genetic information,modification or retraction of this federal law could reduce public demand for genetic testing.These and other ethical,legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests,either of which could have an adverse effect on our business,financial condition or results of operations.Our core business depends on our ability to quickly and reliably deliver test results to our customers.We typically receive biological material for analysis at our laboratory facilities within days of collection from the patient.Disruptions in delivery service,whether due to errors by the courier service,labor disruptions,bad weather,natural disasters,terrorist acts or threats or other reasons,some of which we have experienced in the past,could adversely affect specimen integrity,our ability to process or store samples in a timely manner and to service our customers,and ultimately our reputation and our business.In addition,if we are unable to continue to obtain expedited delivery services on commercially reasonable terms,our operating results may be adversely affected.We also rely on commercial courier delivery services to transport **some of** our **tests** ~~SneakPeek Early Gender DNA Test~~ directly to customers and any disruptions in delivery service could adversely affect our ability obtain and process samples in a timely manner and to service our customers.We receive a portion of our revenues and pay a portion of our expenses in currencies other than the U.S.dollar,such as the **Japanese Yen,** Euro,the Swiss franc ~~,the Japanese yen~~ ,and the British pound.As a result,we are at risk for exchange rate fluctuations between such foreign currencies and the U.S.dollar,which could affect the results of our operations.If the U.S.dollar strengthens against foreign currencies,the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses. **During the year ended** December 31, ~~2022~~ **2023** ~~,and restrictions on certain business activities.Also,the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.Our international operations could be affected by changes in laws,trade regulations,labor and employment regulations,and procedures and actions affecting approval,production,pricing,reimbursement and marketing of tests,as well as by inter- governmental disputes.Any of these changes could adversely affect our business.Our success internationally will depend,in part,on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which~~

~~we do business.Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.Genetic testing has raised ethical,legal and social issues regarding privacy rights and the appropriate uses of the resulting information.Governmental authorities could,for social or other purposes,limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions,particularly for those that have no known cure.Similarly,these concerns may lead patients to refuse to use,or clinicians to be reluctant to order,genomic tests even if permissible;they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance.Ethical and social concerns may also influence U.S.and foreign patent offices and courts with regard to patent protection for technology relevant to our business.Although the Genetic Information Non- discrimination Act has criminalized the disallowance of health insurance on the basis of genetic information,modification or retraction of this federal law could reduce public demand for genetic testing.These and other ethical,legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests,either of which could have an adverse effect on our business,financial condition or results of operations.Our core business depends on our ability to quickly and reliably deliver test results to our customers.We typically receive biological material for analysis at our laboratory facilities within days of collection from the patient.Disruptions in delivery service,whether due to errors by the courier service,labor disruptions,bad weather,natural disasters,terrorist acts or threats or other reasons,some of which we have experienced in the past,could adversely affect specimen integrity,our ability to process or store samples in a timely manner and to service our customers,and ultimately our reputation and our business.In addition,if we are unable to continue to obtain expedited delivery services on commercially reasonable terms,our operating results may be adversely affected.We also rely on commercial courier delivery services to transport our SneakPeek Early Gender DNA Test directly to customers and any disruptions in delivery service could adversely affect our ability obtain and process samples in a timely manner and to service our customers.We receive a portion of our revenues and pay a portion of our expenses in currencies other than the U.S.dollar,such as the Euro,the Swiss franc,the Japanese yen,and the British pound.As a result,we are at risk for exchange rate fluctuations between such foreign currencies and the U.S.dollar,which could affect the results of our operations.If the U.S.dollar strengthens against foreign currencies,the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses.During the year ended December 31,2022~~ ,our revenues were ~~negatively~~ **not materially** impacted ~~by approximately $ 10.4 million~~ due to foreign currency fluctuations **,but may be in the future** .We may not be able to offset adverse foreign currency impact with increased revenues.We do not currently utilize hedging strategies to mitigate foreign currency risk and even if we were to implement hedging strategies to mitigate foreign currency risk,these strategies might not eliminate our exposure to foreign exchange rate fluctuations and would involve costs and risks of their own,such as ongoing management time and expertise,external costs to implement the strategies and potential accounting implications.We **record goodwill and intangible assets at fair value upon the acquisition of a business.Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired.Goodwill and indefinite- lived intangible assets are evaluated for impairment annually,or more frequently if conditions warrant,by comparing the carrying value of a reporting unit to its estimated fair value.Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable.Declines in operating results,divestitures,sustained market declines and other factors that impact the fair value of our reporting unit could result in an impairment of goodwill or intangible assets and,in turn,a charge to net income.Any such charges could have a material adverse effect on our results of operations or financial condition.Our actionable market size opportunity estimates and growth forecasts for our products are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate.Our publicly announced estimates and forecasts relating to the size and expected growth of the market for our products may prove to be inaccurate.Even if the markets in which we compete meet our size estimates and forecasted growth for such markets,our business could fail to grow at similar rates.As of December 31,2023,we have substantial deferred tax assets related to net operating loss (" NOLs ") and tax credit carryforwards.Pursuant to the Tax Cuts and Jobs Act (H.R.1) of 2017,federal NOLs arising in tax years beginning after December 31,2017 have an indefinite carryover period and may only be used to offset 80 % of current year taxable income.Federal NOLs prior to this enactment were subject to a 20- year carry- forward limitation.Further,under Section 382 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 % change,by value,in equity ownership over any three- year period),the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited.Given the Code' s broad definition,an ownership change could be the unintended consequence of otherwise normal market trading in our stock that is outside our control.An ownership change under Section 382 of the Code could also be triggered by certain strategic transactions.These limitations may result in our NOLs,tax credits,or other similar tax attributes expiring before we have the ability to use them.We** may not succeed in achieving significant commercial market acceptance of our test offerings that we have launched or acquired in recent years or are currently developing.Our ability to successfully develop and commercialize our current tests,as well as any future tests that we may develop or acquire,depend on several factors,including:• our ability to convince the medical community and consumers of the utility of our tests and their potential advantages over existing tests or other competing products or services;• our ability to market current and future products in new and existing channels,such as the launch of our SneakPeek Early Gender DNA Test in retail stores;• our ability to collaborate with biotechnology and pharmaceutical companies to develop and commercialize companion diagnostic tests for their therapeutic drugs and drug candidates;• the agreement by third- party payors to reimburse our tests,the scope and extent of which will affect patients' willingness or ability to pay for our tests and will likely heavily influence physicians' decisions to recommend our tests;and / or • the willingness of physicians to utilize our diagnostic tests,which can be difficult to interpret as our tests only predict as to a probability,not certainty,that a tested individual will develop the disease,will benefit from a particular therapy or

has an aggressive form of the disease that the test is intended to predict.These factors present obstacles to commercial acceptance of our tests,which we would have to spend substantial time and money to overcome,if we can do so at all.Our inability to successfully do so would harm our business.In addition,we may experience research and development and regulatory challenges that could delay or prevent the development and commercialization of new test offerings,such as FirstGene and Precise MRD.The tests we enhance or develop may not be clinically effective in clinical trials or commercially,or may not ultimately meet our desired target product profile,be offered at acceptable cost and with the test performance metrics necessary to address the relevant clinical need or commercial opportunity.We also may experience difficulties completing the clinical development of any new or enhanced product,or establishing or maintaining the collaborative relations that may be essential to our clinical development and commercialization efforts.Clinical development requires large numbers of patient specimens and,for certain products,require large,prospective,and controlled clinical trials.We may not be able to enroll patients or collect a sufficient number of appropriate specimens in a timely manner,or we may experience delays during clinical development due to slower than anticipated enrollment,or due to changes in study design or other unforeseen circumstances,or we may be unable to afford or manage the large- sized clinical trials that some of our planned future products may require.In addition,the publication of clinical data in peer- reviewed journals is an important step in commercializing and obtaining reimbursement for tests such as ours,and our inability to control when,if ever,results are published may delay or limit our ability to derive sufficient revenues from any test that is the subject of a study.Peer- reviewed publications regarding our tests may be limited by many factors,including delays in the completion of,poor design of,or lack of compelling data from,clinical studies,as well as delays in the review,acceptance and publication process.If our tests or the technology underlying our current or future tests do not receive sufficient favorable exposure in peer- reviewed publications,the rate of clinician adoption of our tests and positive reimbursement coverage determinations for our tests could be negatively affected.The clinical laboratory and genetics testing fields are intense,highly competitive and characterized by rapid technological change,frequent new product introductions,reimbursement challenges,emerging competition,intellectual property disputes and litigation,price competition,aggressive marketing practices,evolving industry standards,and changing customer preferences.Our competitors in the United States and abroad are numerous and include,among others,major diagnostic companies,reference laboratories,molecular diagnostic firms,direct- to- consumer genetic companies,low- priced competitors,clinical laboratories,universities and other research institutions.Some of our competitors and potential competitors have larger customer bases,greater brand recognition and market penetration,better selling and marketing capabilities,more experience with third-party payors and considerably greater financial,technical,marketing and other resources than we do,which has allowed and may continue to allow these competitors to discover important genes and determine their function before we do,respond more quickly to changes in customer preferences,devote greater resources to the development,promotion and sale of their tests than we do,sell their tests at prices designed to win significant levels of market share,or obtain reimbursement from more third- party payors and at higher prices than we do.We could be adversely affected if we do not discover genes,proteins or biomarkers and characterize their function,develop tests based on these discoveries,obtain required regulatory and other approvals and launch these tests and their related services before our competitors.We may also not be able to keep pace with the rapid technological changes in our industry,or properly leverage new technologies to achieve or sustain competitive advantages in our tests,systems and processes.We also expect to encounter significant competition with respect to any tests that we may develop or commercialize.Those companies that bring to market new tests before we do may achieve a significant competitive advantage in marketing and commercializing their tests.We may not be able to develop additional tests successfully and we or our licensors may not obtain or enforce patents covering these tests that provide protection against our competitors.Moreover,our competitors may succeed in developing tests that circumvent our technologies or tests.Furthermore,our competitors may succeed in developing technologies or tests that are more effective or less costly than those developed by us or that would render our technologies or tests less competitive or obsolete.Increased competition and cost- saving initiatives on the part of governmental entities and third- party payors are likely to result in pricing pressures,which could harm our sales,profitability or ability to gain market share.We expect competition to intensify in the fields in which we are involved as technical advances in these fields occur and become more widely known and changes in intellectual property laws generate challenges to our intellectual property position.We have relationships with research collaborators at academic and other institutions who conduct research at our request.These research collaborators are not our employees.As a result,we have limited control over their activities and,except as otherwise required by our collaboration agreements,can expect only limited **amounts of their time to be dedicated to our activities.Our ability to discover genes,proteins,and biomarkers involved in human disease and validate and commercialize tests will depend in part on the continuation of these collaborations.If any of these collaborations are terminated,we may not be able to enter into other acceptable collaborations.In addition,our existing collaborations may not be successful.Our research collaborators and scientific advisors may have relationships with other commercial entities,some of which could compete with us.Our research collaborators and scientific advisors sign agreements which provide for the confidentiality of our proprietary information.We may not,however,be able to maintain the confidentiality of our technology and other confidential information related to all collaborations.The dissemination of our confidential information to third parties could have a material adverse effect on our business.As of December 31,2023** , our patent portfolio included issued patents owned or licensed by us and numerous patent applications in the United States and other countries with claims protecting our intellectual property rights. Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and protect our existing patent position, both in the United States and in other countries, for compositions, processes, methods and other inventions that we believe are patentable. Our ability to preserve our trade secrets, proprietary data bases and other intellectual property is also important to our long- term success. If our intellectual property is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. Patents may also issue

to third parties which could interfere with our ability to bring our tests to market. The laws of some foreign countries do not protect our proprietary rights to the same extent as U. S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries. The patent positions of diagnostic companies, including our patent position, are generally highly uncertain and involve complex legal and factual questions, and, therefore, any patents issued to us may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and any future tests are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or tests. In addition, any patents issued to us or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented. Where necessary, we may initiate litigation to enforce our patent or other intellectual property rights. Any such litigation may require us to spend a substantial amount of time and money and could distract management from our day- to- day operations. Moreover, there is no assurance that we will be successful in any such litigation. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: • we or our licensors were the first to make the inventions covered by each of our patent applications; • we or our licensors were the first to file patent applications for these inventions; • others will not independently develop similar or alternative technologies or duplicate any of our technologies; • any of our or our licensors' patent applications will result in issued patents; • any of our or our licensors' patents will be valid or enforceable; • any patents issued to us or our licensors and collaborators will provide a basis for commercially viable tests, will provide us with any competitive advantages or will not be challenged by third parties; • we will develop additional proprietary technologies or tests that are patentable; • the patents of others will not have an adverse effect on our business; or • our patents or patents that we license from others will survive legal challenges and remain valid and enforceable. If a third party files a patent application with claims to subject matter we have invented, the U. S. Patent and Trademark Office (USPTO) may declare interference between competing patent applications. If an interference is declared, we may not prevail in the interference. If the other party prevails in the interference, we may be precluded from commercializing services or tests based on the invention or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all. We also rely on trade secrets to protect our proprietary technologies and databases, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and others to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy if unauthorized disclosure of confidential information occurs. In addition, others may independently discover our trade secrets and proprietary information. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive position. Our tests may ~~also~~ conflict with patents that have been or may be granted to others. Our industry includes many organizations that have or are seeking to discern biomarkers and develop genomic, proteomic and other technologies. To the extent any patents are issued or have been issued to those organizations, the risk increases that the sale of our tests currently being marketed or under development may give rise to claims of patent infringement. Others may have filed and in the future are likely to file patent applications covering biomarkers that are similar or identical to our tests. Any of these patent applications may have priority over our patent applications and these entities or persons could bring legal proceedings against us seeking damages or seeking to enjoin us from testing or marketing our tests. Patent litigation is costly, and even if we prevail, the cost of such litigation could have a material adverse effect on us. If the other parties in any such actions are successful, in addition to any liability for damages, we could be required to cease the infringing activity or obtain a license. Any license required may not be available to us on commercially acceptable terms, if at all. Our failure to obtain a license to any technology that we may require to commercialize our tests could have a material adverse effect on our business. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non- infringing alternatives. We believe that there has been, and may continue to be, significant litigation in the industry regarding patent and other intellectual property rights. On December 21, 2020, Ravgen, Inc. **("Ravgen")** filed a lawsuit against us and our wholly owned subsidiary, Myriad Women' s Health **, Inc.** , in the U. S. District Court for the District of Delaware, alleging infringement of two patents relating to blood collection tubes and non- invasive prenatal testing analysis. ~~This litigation~~ **On October 23, 2023, we** and ~~any~~ **Ravgen entered into a settlement agreement pursuant to which** ~~other~~ -- **the parties agreed to settle the lawsuit. Pursuant to the terms of the settlement agreement, we agreed to pay Ravgen a minimum of $ 12. 75 million in three installment payments of $ 5 million, $ 5 million, and $ 2. 75 million on or before October 31, 2023, October 31, 2024, and October 31, 2025, respectively. We may also be required to pay Ravgen $ 21. 25 million in five annual installments beginning no earlier than January 1, 2026 if certain conditions are satisfied. Any** intellectual property litigation that we may become involved with in the future could consume a substantial portion of our managerial and financial resources. If any such litigation is resolved adversely to us, we could be required to pay damages, cease the infringing activity or pay an ongoing licensing fee ~~for our prenatal tests~~ , each of which could have a material adverse effect on our financial condition, results of operations or cash flows. Additionally, third parties may claim that the branding of our products infringes the trademarks, service marks, trade names or otherwise misappropriates or dilutes those third parties' rights. If we are found to be liable or to have infringed upon those third parties' rights, we may be required to pay damages and rebrand the infringing products. Rebranding can be expensive and time- consuming and may lead to the loss of brand equity or goodwill associated with the rebranded products. We license intellectual property that is important to our business, including licenses underlying the technology in our tests, and in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from distributing

our current tests, or inhibit our ability to commercialize future test candidates. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid, unenforceable or infringe upon third party patents, or if we are unable to enter into necessary licenses on acceptable terms. As is commonplace in our industry, we employ individuals who were previously employed at universities or genetic testing, diagnostic, biotechnology or other health care companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of a former employer or other third parties. Litigation may be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Our registered and unregistered trademarks, service marks, or trade names could be infringed by third parties. Enforcing our rights against such third parties can be expensive and distracting. If we fail to effectively enforce such rights against third parties, our trademark, service mark or trade name rights, and the associated goodwill and brand equity, could be lost. We file applications for registration of various marks associated with our brands in the United States and foreign jurisdictions. We may fail to successfully register these marks. Additionally, once a mark is registered, we may fail to pay all fees and attend to all formalities required to maintain the registration. Failure to obtain or maintain registration of our marks could make those marks harder to enforce and reduce the liability of an infringer even if we are able to successfully enforce such rights. Our operations are subject to extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among other things: • Clinical Laboratory Improvement Amendments of 1988 **and the implementing regulations** , which requires that laboratories obtain certification from the federal government, and state licensure laws **and regulations** ; • U. S. Food and Drug Administration laws and regulations that apply to medical devices such as our companion diagnostics **and other IVDs** ; • Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions; amendments to HIPAA under HITECH, which strengthened and expanded HIPAA privacy and security compliance requirements, increased penalties for violators, extended enforcement authority to state attorneys general and imposed requirements for breach notification; • state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators; • the federal Anti- Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program; • the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), which is an all- payor anti- kickback prohibition on, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to a clinical laboratory; • the federal physician self- referral prohibition (Stark Law or the Physician Self- Referral Law), which, absent an exception, prohibits a physician from making a **Medicare** referral for certain designated health services, including clinical laboratory services, if the physician or an immediate family member of the physician has an applicable financial relationship with the entity providing the designated health services; • the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government; • the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or **Medicaid** ~~state health care program~~ beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or **Medicaid** ~~a state health care program~~ , unless an exception applies; • other federal and state fraud and abuse laws, such as anti- kickback laws, prohibitions on self- referral **and fee- splitting** , and false claims acts, which may extend to services reimbursable by any third- party payor, including private insurers; • the federal Physician Payments Sunshine Act, which requires medical device manufactures to track and report to the federal government certain payments and other transfers of value made to physicians, other health care professionals, **and** teaching hospitals and ownership or investment interests held by physicians and their immediate family members; • Section 216 of the federal Protecting Access to Medicare Act of 2014, which requires the Centers for Medicare & Medicaid Services (CMS) to set Medicare rates for clinical laboratory testing based on private payor data reported by applicable laboratories; • the U. S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits companies and their intermediaries from making payments in violation of law to non- U. S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage; • state laws that impose reporting and other compliance- related requirements; and • similar foreign laws and regulations that apply to us in the countries in which we operate. We may also be subject to or affected by current or future federal, state, local and foreign laws and regulations, including laws relating to reproductive health care, which could restrict our business, reduce demand for our products, and adversely affect our operations, revenue, and results of operations. As a clinical laboratory, our business practices may face heightened scrutiny from government enforcement agencies such as the Department of Justice, the Office of Inspector General for the Department of Health and Human Services (OIG), and CMS. The OIG has issued fraud alerts in recent years, including a fraud alert relating to speaker programs in November 2020, that identify certain arrangements between medical device and drug companies and referring physicians as implicating the Anti- Kickback Statute. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the federal self- referral prohibition, commonly known as the Stark Law or the Physician Self- Referral Law, unless the arrangement meets all criteria of an applicable exception. The government has actively enforced these laws **, as well as the federal False Claims Act,** against

clinical laboratories in recent years. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratories' ability to provide or receive payment for our services. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third- party payors. The growth of our business and our ~~expansion~~ **continued business** outside of the United States may increase the potential of violating similar foreign laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. Any of the foregoing consequences could seriously harm our business and our financial results. Our actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and / or adverse publicity and could negatively affect our business. We are subject to domestic and international data protection laws and regulations that address privacy and data security and may affect our collection, use, storage, and transfer of personal information. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the U. S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health- related and other personal information. Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and / or adverse publicity and could negatively affect our operating results and business. For example, California has enacted the California Consumer Privacy Act, or CCPA, which went into effect in January of 2020. The CCPA ~~establishes~~ **established** a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for California residents, **requiring covered businesses to provide new disclosures to California residents,** and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Additionally in 2020, California voters passed the California Privacy Rights Act, or CPRA, **which went into** ~~effective~~ --- **effect on** January 1, 2023. The CPRA significantly amends the CCPA, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority. ~~Effective in~~ **In addition to California, more U. S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In** 2023, **comprehensive privacy laws in** Virginia, Colorado, Connecticut, and Utah **all took effect, and laws in Montana, Oregon, and Texas** will ~~have similar data protection~~ **take effect in 2024. In addition,** laws **in** ~~, and~~ other **U. S. states are set to take effect beyond 2024, and additional** U. S. states have proposals under consideration, **all of which are likely to** ~~increasing~~ **increase** ~~the~~ **our** regulatory compliance **costs and** ~~risk~~ **risks , exposure to regulatory enforcement action and other liabilities** . Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Union' s General Data Protection Regulation (GDPR), became effective in 2018 and imposed a broad data protection framework that expanded the scope of EU data protection law, including to non- EU entities meeting the jurisdictional requirements that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements for controllers and / or processors, as applicable, that must be complied with when handling the personal data of EU based data subjects, including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be " forgotten " and rights to data portability, as well as enhanced current rights (e. g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data are all classified as " special category " data under the GDPR and afford greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions — including restrictions — on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). The GDPR is applicable to part of our business and has increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional procedures to comply. The GDPR is complex and regulatory guidance continues to evolve. Furthermore, national GDPR variations, including the fields of clinical study and other health- related information may raise our costs of compliance and result in greater legal risks. We are also subject to evolving GDPR requirements on data export, because we transfer data to third countries outside of the EU that are not deemed " adequate. " The GDPR only permits exports of personal data outside of the EU to " non- adequate " countries where there is a suitable data transfer mechanism in place to safeguard personal data (e. g., the EU Commission approved Standard Contractual Clauses **or certification under the newly- adopted Data Privacy Framework**). On July 16, 2020, the Court of Justice of the EU, or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C- 311 / 18) (Schrems II). This decision calls into question certain data transfer mechanisms as

between the EU member states and the U. S. The CJEU is the highest court in Europe and the Schrems II decision ~~heightens~~ **heightened** the burden to assess U. S. national security laws on their business, and future actions of EU data protection authorities are difficult to predict at this time **. While the newly- adopted Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges** . Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to flow down or help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non- compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EU to us in the U. S. will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross- border transfers of personal data ~~,~~ or increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant penalties if we are found to be non- compliant. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation. We may from time to time be subject to government investigations, which may divert management resources and attention, cause us to incur substantial costs, and / or result in negative publicity, and any unfavorable outcome arising from such investigation may have a material adverse effect on our financial condition, results of operations and cash flows. For example, in June 2016, our wholly- owned subsidiary, Crescendo Bioscience, LLC (formerly known as Crescendo Bioscience, Inc.) (CBI), received a subpoena from the Office of Inspector General of the Department of Health and Human Services requesting that CBI produce documents relating to entities that received payment from CBI for the collection and processing of blood specimens for testing, including a named unrelated company, healthcare providers and other third- party entities. On January 30, 2020, the U. S. District Court for the Northern District of California unsealed a qui tam complaint, filed on April 16, 2016 against CBI, alleging violations of the federal and California False Claims Acts and the California Insurance Fraud Prevention Act (CIFPA). On January 22, 2020, after a multi- year investigation into CBI' s and the Company' s alleged conduct, the United States declined to intervene. On January 27, 2020, the State of California likewise filed its notice of declination. On April 1, 2022, we settled the qui tam lawsuit pursuant to which we paid a total of $ 45. 25 million to the United States and the State of California and $ 2. 75 million to relator' s counsel. The qui tam lawsuit was formally dismissed by the U. S. District Court for the Northern District of California on May 4, 2022. We may be subject to future claims or investigations under the Federal False Claims Act or a similar state law, and any unfavorable outcome arising from such claims or investigation could have a material adverse effect on our financial condition, results of operations and cash flows. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively called the ACA, became law. This law substantially changed the way health care is financed by both government and private third- party payors and continues to significantly impact our business and operations in ways we ~~cannot currently~~ **may not be able to** predict. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or were effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U. S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA' s constitutionality. Further legislative and regulatory changes under the ACA remain possible. The federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. Future changes or additions to the ACA or the Medicare and Medicaid programs, such as changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. Further, if reimbursement levels are inadequate, our business and results of operations could be adversely affected. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and private third- party payors to reduce costs while expanding individual health care benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests or the amounts of reimbursement available for our tests from governmental agencies or private third- party payors. Any future changes to legal or regulatory requirements or new cost containment initiatives could have a materially adverse effect on our business, financial condition, results of operation, and cash flows. The diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts. CLIA requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many private third- party payors, for laboratory testing services. As a condition of CLIA certification, each of our laboratories is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial

survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA certificate of accreditation, a CMS- approved accreditation organization. Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory' s CLIA certificate, which is necessary to conduct business, as well as the imposition of significant fines or criminal penalties. In addition, we are subject to regulation under state laws and regulations governing laboratory licensure. Some states have enacted state licensure laws that are more stringent than CLIA. We are also subject to laws and regulations governing our reference laboratory in Germany. Changes in state or foreign licensure laws that affect our ability to offer and provide diagnostic services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. If the CLIA certificate of any one of our laboratories is revoked, CMS could seek revocation of the CLIA certificates of our other laboratories based on their common ownership or operation, even though they are separately certified. Historically, the FDA has exercised enforcement discretion with respect to most **laboratory developed tests (** LDTs **)** and has generally not required laboratories that furnish LDTs to comply with the agency' s requirements for medical devices (e. g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). As of December 31, ~~2022~~ **2023** , none of our products other than MyChoice CDx and BRACAnalysis CDx are marketed by us under the FDA' s requirements for medical devices. In recent years ~~, however~~ , the FDA publicly announced its intention to regulate certain LDTs and issued two draft guidance documents that set forth a proposed phased- in risk- based regulatory framework that would apply varying levels of FDA oversight to LDTs. However, these guidance documents were not finalized, and **in 2017,** the **FDA issued** ~~framework was abandoned and replaced by~~ an informal discussion paper reflecting some of the feedback that FDA had received on the proposed LDT ~~regulation~~ **regulatory system. Subsequently, in October 2023, FDA issued a proposed rule to regulate LDTs under the current medical device framework and proposed to phase out the current enforcement discretion policy; the public comment period ended in early December 2023** . The **proposal envisions that the LDT enforcement policy phase- out process would occur in gradual stages over a total period of four years, with premarket approval applications for high- risk tests to be submitted by the 3. 5- year mark, although more details are expected to be provided with the upcoming final rule. The likelihood of the** FDA **finalizing** ~~acknowledged that~~ the ~~January 2017 discussion paper does not represent the formal position~~ **proposed rule in April 2024 (as currently projected), as well as potential litigation challenging its authority to take such action, is uncertain at this time. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight** of **LDTs by both** the FDA and **CMS, instead of implementation of the proposed administrative agency action, which may be disruptive to the industry and to patient access to certain diagnostic tests. Until any administrative rulemaking** is ~~not enforceable. Nevertheless~~ **finalized and regulatory changes become effective** , the FDA ~~wanted to share its~~ **is expected to** ~~synthesis of the feedback that it had received in the hope that it might advance public discussion on future LDT oversight. Notwithstanding the discussion paper, the FDA continues~~ **continue** to exercise enforcement discretion ~~and~~ **; although it** may attempt to regulate certain LDTs on a case- by- case basis at any time, which could result in delay or additional expense in offering our tests and tests that we may develop in the future. In addition ~~to potential enforcement priority changes from the FDA~~ , for several years bipartisan members of Congress have been negotiating legislation with the FDA and industry stakeholders to regulate in vitro clinical tests including LDTs under a shared FDA / CMS framework. Most recently, reform legislation entitled the Verifying Accurate, Leading- edge IVCT Development (VALID) Act ~~has~~ received increasing congressional support. ~~If enacted~~ **As drafted and re- introduced for consideration by the current Congress** , the VALID Act would codify into law the term " in vitro clinical test " (IVCT) to create a new medical product category separate from medical devices that includes products currently regulated as in vitro diagnostics (IVDs) as well as LDTs. ~~The~~ **If enacted, the VALID Act' s regulatory** framework would give the FDA the authority to ensure IVCTs are both analytically and clinically valid. **While** CMS would retain the authority to ensure the quality of operations within laboratories. All LDTs on the market prior to enactment of the legislation would be grandfathered and not subject to the new regulation. **The FDA' s recent publication of an LDT proposed rule that would apply the existing medical device framework to laboratory- developed products may renew stakeholder calls for a more targeted approach to modernizing federal 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.** It is unclear whether the VALID Act **or other diagnostic reform legislation** will be passed by Congress ~~in its current form~~ or signed into law by the President. Until the FDA finalizes its regulatory position regarding LDTs through formal notice- and- comment rulemaking, or the VALID Act or other legislation is passed reforming the federal government' s regulation of LDTs, it is unknown how the FDA may attempt to regulate our tests in the future and what testing and data may be required to support any required clearance or approval of our tests by the agency. If the VALID Act is implemented as drafted, or if the FDA were to **finalize** ~~promulgate regulations governing~~ the ~~development and marketing of~~ **proposed rule to regulate most** LDTs **as medical devices** , it could have a materially adverse impact on our results of operations. As described further above, the FDA has long claimed authority to regulate laboratory- developed tests but has exercised its " enforcement discretion " to limit enforcement of in vitro diagnostic regulatory requirements on this category of products. ~~The~~ **In October 2023, FDA issued a proposed rule to regulate LDTs under the current medical device framework and proposed to phase out the current enforcement discretion policy. Further, 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. In early 2019, we provided the FDA with clinical evidence and other information to support our GeneSight Psychotropic test. Later that year, the FDA requested changes to the GeneSight test offering. Although we disagreed that changes to the test were required, we submitted a proposal regarding the reporting of GeneSight test results to healthcare providers that we believed addressed the FDA' s principal concerns and would not affect the benefits that we believe are provided by the GeneSight test. Since submitting our proposal to the FDA, we engaged with our trade association in their efforts to defend the offering of pharmacogenomic tests as LDTs and to monitor broader developments across the stakeholder community. In response to 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 pharmacogenetic test offerings may be potentially dangerous, the agency also acknowledged that pharmacogenetic testing " offers promise for informing the selection or dosing of some medications for certain individuals ~~.~~" **when there is sufficient evidence demonstrating a relationship between how a person' s genes may impact their metabolism of a drug or how they may respond to the drug.** 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. Based on our discussions with the agency and these developments, we have not implemented our proposal to the FDA regarding the GeneSight test. While we see these developments as signaling 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 the ultimate form of the GeneSight Psychotropic Mental Health Medication test offering, if it must be changed, will have an adverse effect on our revenues from the test. Our companion and complementary diagnostic products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the federal Food, Drug, and Cosmetic Act (FDCA), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDCA, companion diagnostics must receive FDA clearance or approval before they can be commercially marketed in the U. S. The process of obtaining marketing approval or clearance from the FDA or by comparable agencies in foreign countries for new products could: • take a significant period of time; • require the expenditure of substantial resources; • involve rigorous pre- clinical testing, as well as increased post- market surveillance; • require changes to products; and • result in limitations on the indicated uses of products. Although we have successfully received FDA approval for some tests (e. g., our BRACAnalysis CDx and MyChoice CDx tests), we cannot predict whether or when we will be able to obtain FDA approval for other companion diagnostics that we are developing. Companion diagnostic tests such as BRACAnalysis CDx and MyChoice CDx are subject to ongoing FDA and comparable foreign regulatory authority requirements for manufacturing, labeling, packaging, storage, distribution, quality, safety, sale, marketing, advertising, promotion, sampling, record- keeping, export, import, conduct of post- marketing studies and submission of safety, efficacy or other post- market information. In addition, we are subject to continued compliance with regulatory requirements applicable to medical devices and in vitro diagnostics. The FDA or other regulatory authorities may take regulatory enforcement or other legal action or may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur with our marketed products. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and be subject to financial penalties or administrative action. In connection with our **laboratory operations and** research and development activities, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, including hazardous materials, biological specimens, chemicals and waste. The cost of compliance with these laws and regulations may become significant and could negatively affect our operating results. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Although we believe that our safety procedures for handling and disposing of controlled materials comply with the standards prescribed by state and federal regulations, accidental contamination or injury **to employees or third parties** from **the use, storage, handling or disposal of** these materials may occur. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources or any applicable insurance coverage we may have. The market prices for securities of relevant testing companies have been volatile. This volatility has significantly affected the market prices for these securities for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price for our common stock has fluctuated significantly since public trading commenced in October 1995, and it is likely that the market price will continue to fluctuate in the future. In the year ended December 31, ~~2022~~ **2023**, our stock price ranged from $ 13. ~~92~~ **82** per share to $ ~~28~~ **24**. ~~45~~ **21** per share. In addition, the stock market in general has experienced extreme price and volume fluctuations. Events or factors that may have a significant impact on our business and on the market price of our common stock include the following: • **failure to achieve and sustain revenue growth or margins in our business; •** major market events, such as the market' s reaction to the COVID- 19 pandemic generally and its specific impact on the Company; • failure of any of our recently launched tests and any new test candidates to achieve commercial success ~~; • failure to achieve and sustain revenue growth or margins in our business~~; • changes in the structure of healthcare payment systems and changes in governmental or private insurer

reimbursement levels for our tests; • introduction of new commercial tests or technological innovations by competitors; • termination of the licenses underlying our tests; • delays or other problems with operating our laboratory facilities; • failure of any of our research and development programs; • changes in intellectual property laws or the enforcement, validity or expiration of our patents in the United States and foreign countries; • developments or disputes concerning patents or other proprietary rights involving us directly or otherwise affecting the industry as a whole; • missing or changing the financial guidance we provide; • failure of analysts to initiate or maintain coverage of our company; • negative publicity, including misinformation, about our company, our tests or the industry in which we operate; • changes in the government regulatory approval process for our existing and new tests; • failure to meet estimates or recommendations by securities analysts that cover our common stock; • issuance of new securities analysts reports or changes in estimates or recommendations by securities analysts relating to our common stock or the securities of our competitors; • public concern over our approved tests and any test candidates; • litigation, including the outcome of existing and new litigation against us; • government and regulatory investigations; • our ability to raise additional funds if and when needed; • future sales or anticipated sales of our common stock by us or our stockholders; • the timing and amount of any repurchases of our common stock; • general market conditions, including as a result of changes in the rate of inflation and interest rates; • **potential** seasonal slowness in sales, particularly in the quarters ending September ~~30th~~ **30** and March ~~31st~~ **31** , the effects of which may be difficult to understand during periods of growth; • general perception of the industry and our products; • economic, health care and diagnostic trends, disasters or crises and other external factors; and • period- to- period fluctuations in our financial results. These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. ~~In addition, securities class action litigation such as the current stockholder suit pending against the Company discussed elsewhere in this Annual Report on Form 10- K and certain related matters may affect the market price and demand for our common stock. Such litigation may cause us to incur substantial costs defending the lawsuit regardless of the outcome and could also divert the time and attention of our management. We also may decide to settle lawsuits on unfavorable terms, including above any insurance coverage that may be available. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the market price of our common stock.~~ Section 404 of the Sarbanes- Oxley Act of 2002 requires that companies evaluate and report on the effectiveness of their internal control over financial reporting. Failure to have effective internal control over financial reporting and disclosure controls and procedures could impair our ability to produce accurate financial statements on a timely basis and could lead to a restatement of our financial statements. If ~~,~~ as a result of the ineffectiveness of our internal control over financial reporting and disclosure controls and procedures, we cannot provide reliable financial statements, our business decision processes may be adversely affected, our business and results of operations could be harmed, investors could lose confidence in our reported financial information, and our ability to obtain additional financing, or additional financing on favorable terms, could be adversely affected. Although we determined that our internal controls over financing reporting were effective as of December 31, ~~2022~~ **2023** , we may in the future identify internal control deficiencies that could rise to the level of a material weakness or uncover other errors in financial reporting. During the course of our evaluation of these material weaknesses, we may identify areas requiring improvement and may be required to design additional enhanced processes and controls to address issues identified through this review. There can be no assurance that such remediation efforts will be successful, that our internal control over financial reporting will be effective as a result of these efforts or that any such future deficiencies identified may not be material weaknesses that would be required to be reported in future periods. In addition, we cannot assure you that our independent registered public accounting firm will be able to attest that such internal controls are effective when they are required to do so. If we fail to **maintain effective disclosure controls and procedures or internal control over financial reporting or** remediate any future material weaknesses ~~and maintain effective disclosure controls and procedures or internal control over financial reporting~~ , you may not be able to rely on the integrity of our financial results, which could result in inaccurate or late reporting of our financial results, as well as delays or the inability to meet our reporting obligations or to comply with the rules and regulations of the Securities and Exchange Commission. Any of these **events** could result in delisting actions by the Nasdaq Stock Market, investigation and sanctions by regulatory authorities, **and** stockholder investigations and lawsuits, ~~and could~~ **in addition to** adversely ~~affect~~ **affecting** our business and the trading price of our common stock. Because we are a Delaware corporation, the anti- takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware, which prohibits us from engaging in certain business combinations, unless the business combination is approved in a prescribed manner. In addition, our restated certificate of incorporation and restated bylaws also contain certain provisions that may make a third- party acquisition of us difficult, including: • a classified Board of Directors, with three classes of directors each serving a staggered three- year term; • the ability of the Board of Directors to issue preferred stock; • a 70 % super- majority stockholder vote to amend our bylaws and certain provisions of our certificate of incorporation; ~~and~~ • the inability of our stockholders to call a special meeting or act by written consent **; and • only our Board of Directors can fill vacancies on the Board** . In the past, we implemented a stockholders' rights plan, also called a poison pill, which could make it uneconomical for a third party to acquire the Company on a hostile basis. Although the plan expired in July 2011, our Board of Directors could adopt a new plan at any time. The provisions in a stockholders' rights plan, as well as Section 203, may discourage certain types of transactions in which our stockholders might otherwise receive a premium for their shares over the then- current market price, and may limit the ability of our stockholders to approve transactions that they think may be in their best interests. From time to time, we may issue additional securities or sell common stock, convertible securities or other securities in one or more transactions at prices

and in a manner we determine. **For example, in November 2023, we sold approximately 7. 4 million shares of our common stock in an underwritten public offering.** We also plan to continue to grant equity awards that convert into **shares of** our common stock to employees and directors pursuant to our equity incentive plan. If we sell or issue common stock, convertible securities or other equity securities, or common stock is issued pursuant to equity incentive plans, holders of our common stock may be materially diluted. In addition, we may issue common stock or other equity securities in connection with an acquisition or other strategic transaction, which would cause dilution to our existing stockholders. New investors in such transactions could gain rights, preferences and privileges senior to those of holders of our common stock. We currently intend to retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of our ~~Amended~~ **ABL** Facility restrict our ability to pay dividends. 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. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If few analysts continue coverage of us, the trading of our stock would likely decrease. Even if we do maintain sufficient analyst coverage, there can be no assurance that analysts will provide favorable coverage. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. **Increasing scrutiny and evolving expectations from regulators, business partners, investors, and other stakeholders with respect to our environmental, social, and governance (" ESG ") practices may impose additional costs on us or expose us to new or additional risks. Companies across many industries are facing increasing scrutiny related to their ESG practices and disclosure. With this increased focus, public reporting regarding ESG practices is becoming more broadly expected. Any failure or perceived failure to accomplish or accurately track and report on our ESG initiatives on a timely basis or to meet stakeholder expectations could adversely affect our business, the willingness of our partners to do business with us, employee retention efforts, and our brand and reputation. In addition, we expect there will likely be increasing levels of regulation, disclosure- related and otherwise, with respect to ESG matters. For example, during 2022, the SEC proposed rules that require companies to provide significantly expanded climate- related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and Board of Directors. Furthermore, changing laws and regulations and evolving stakeholder expectations may further increase our compliance and other costs necessary to meet those expectations. In addition, California has recently enacted climate disclosure laws that may require us to report on our greenhouse gas emissions, climate- related financial risks, and other climate- related matters. Furthermore, industry and market practices, as well as requirements of our business partners, may further develop to become even more robust than what is required under any new laws and regulations, and we may have to expend significant efforts and resources to keep up with market trends, stay competitive among our peers, and comply with such requirements, which could result in higher associated compliance costs and penalties for failure to comply with such laws and regulations.** Our restated bylaws provide that a state court located within the State of Delaware (or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate of incorporation or our restated bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. ~~This~~ **Our restated certificate of incorporation provides that the federal district courts of the United States of America are the** exclusive forum **for the resolution of any claims under the Securities Act of 1933, as amended. These exclusive forum** ~~provision~~ **provisions** may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Alternatively, if a court were to find ~~the~~ **these** exclusive forum ~~provision~~ **provisions** ~~contained in our restated bylaws~~ to be inapplicable or unenforceable in an action, we might incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and results of operations.