**Risk Factors Comparison 2025-02-28 to 2024-02-29 Form: 10-K**

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

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this report, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our consolidated financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. If any of the following risks actually occurs, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment. Risks Related to Our Business and Industry If we are unable to successfully grow revenues for our products or services, and if our efforts to further increase the use and adoption of our products or to develop new products and services in the future do not succeed, our business will be harmed. Our ability to successfully grow revenues for our products and services is uncertain and subject to many risks, as further described in these Risk Factors. In particular, the significant majority of our revenues are derived from sales of our Panorama NIPT, our Horizon carrier screening, or HCS, test, and our Signatera test, and we expect this to continue to be the case for the foreseeable future. As such, any adverse impact we experience with respect to these tests could result in an impact to our overall revenues, or a component of such overall revenues. For example, a decline in our reimbursement rates for, and therefore our average selling price of, Horizon, could result in a decline in our overall blended average selling price. Continued and additional market demand for our tests, and reimbursement for our tests, particularly for NIPT for the average- risk population and for microdeletions, are key elements to our future success. The market demand for NIPTs, carrier screening tests and our other tests continue to evolve. We cannot guarantee that physicians will recommend and order our tests, and our laboratory distribution partners and licensees may not actively or effectively market our tests. Our ability to increase sales and establish significant levels of adoption and reimbursement for our tests is uncertain, and it may be challenging for us to achieve profitability for many reasons, including, among others: • the market for our tests may not grow as we expect; in particular, NIPTs may not gain acceptance for use as a screen for microdeletions, which would limit the market for Panorama, and we may fail to compete successfully in this market, whatever its size; • if we are unable to demonstrate that our tests are superior to competing tests, laboratories, clinics, clinicians, physicians, payers and patients may not adopt the use of our tests on a broad basis, and may not be willing to pay the price premium over competing tests that we have, to date, been able to achieve; • third- party payers, such as commercial insurance companies and government insurance programs, may decide not to reimburse for our tests, such as for the screening of microdeletions, may set the amounts of any reimbursements at prices that do not allow us to cover our expenses, or may otherwise adopt regulations, programs, policies or procedures that restrict or harm our business; for example, with respect to Panorama, many third- party payers currently have negative coverage determinations or otherwise do not reimburse for microdeletions screening and we expect low reimbursement rates for microdeletions screening to continue, at least in the near term; also, most state Medicaid programs currently either reimburse at low rates or do not reimburse for our tests; • billing operations, including managing various requirements by third- party payers to obtain reimbursement for our tests, are complex and time- consuming, and if we are unable to successfully manage such requirements, we may experience reduced and / or delayed reimbursement for our tests, which may impact our results of operations, as has happened in the past with respect to evolving prior authorization requirements; • the results of our SMART Study evaluating the performance of Panorama may fail to convince laboratories, clinics, clinicians, physicians or patients of the benefits of utilizing Panorama for microdeletions and may not increase reimbursement for Panorama; • the results of our clinical trials and any additional clinical and economic utility data that we may develop, present and publish in the future, or that comes from the commercial use of our tests, may be inconsistent with our existing data and may raise questions about the performance of our tests, or may fail to convince laboratories, clinics, clinicians, physicians, payers or patients of the value of our tests; • we may experience supply constraints, including those due to the failure of our key suppliers to provide required sequencers and reagents in sufficient amounts or of adequate quality or disputes with our key suppliers, including those with respect to the required sequencers and reagents from our supplier, Illumina, Inc., or Illumina, who is also one of our main NIPT competitors through its subsidiary, Verinata Health Inc., or Verinata, and with whom we have historically been involved in patent proceedings; • we may experience increased cost of product revenues, and cost of licensing and other revenues, as a percentage of total revenues, as has been the case in previous fiscal periods; • the U. S. Food and Drug Administration, or the FDA, or other U. S. or foreign regulatory or legislative bodies may adopt new regulations or policies, or take other actions that impose significant restrictions on our ability to market and sell our tests, including requiring FDA clearance or approval for the sale of our tests ~~(for example, the VALID Act or a proposed rule published by the FDA in September 2023)~~, as further discussed in the risk factor entitled " Regulatory and Compliance Risks — If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket 510 (k) clearance, de novo classification, or premarket approval and incur costs associated with complying with ~~30post~~ -- **post** market controls ") or of the sequencers, reagents, kits and other consumable products that we purchase from third parties in order to perform our testing **; • changes in the funding of the FDA or other government agencies or comparable foreign regulatory authorities could hinder, prevent or delay their regulatory review and approval processes or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely** ; • our laboratory partners may choose to develop their own tests that are competitive with ours or offer tests provided by our competitors due to pricing or other reasons as has happened in the past, or otherwise fail to effectively market our tests; and competitors may develop and commercialize more effective and / or less expensive tests that

deliver comparable results to our tests; • we may fail to adequately protect or enforce our intellectual property relating to our tests, leading to increased competition; or other parties may claim that the practice of our technology by us or our licensees and collaborators infringes such other party' s intellectual property rights, as certain of our competitors have ~~claimed~~ **31claimed** in lawsuits filed against us, as discussed further in " Note 8 — Commitments and Contingencies — Legal Proceedings " in the Notes to Consolidated Financial Statements; if we are required to pay litigation judgments or settlements or pay license fees in order to license third- party intellectual property rights due to actual or alleged infringement based on our running our tests, our results of operations or financial condition could be adversely impacted; • we may be unable to dedicate adequate resources to the maintenance and further technological advancement of our current tests that are necessary for such tests to be competitive in the marketplace because of the demands placed on our research and development and product teams with respect to our continuously expanding portfolio of products and programs, in particular our efforts and focus on developing our oncology and organ health product offerings; • in the event that it is in our commercial or financial interest or we are forced to transition sequencing platforms for Panorama, we may be unable to do so in a commercially sustainable way and that could survive claims of infringement of intellectual property rights of Illumina and other competitors, in a timely manner or at all; and • we may not be successful in commercializing our cloud- based distribution model. If we are not able to increase adoption of and grow revenues for our products or services, our business, operating results and financial condition will be harmed. We have incurred net losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects. We have incurred net losses each year since our inception in 2003. To date, we have financed our operations primarily through convertible debt and other debt instruments, our initial public offering, and our registered public equity offerings. Our net loss for the years ended December 31, **2024,** 2023, **and** 2022 ~~and 2021~~ was $ **190. 4 million, $** 434. 8 million, **and** $ 547. 8 million, ~~and $ 471. 7 million,~~ respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ 2. ~~4~~ **6** billion. We may continue to experience such losses in the future as we continue to devote a substantial portion of our resources to efforts to increase the adoption of, and reimbursement for, our products, improve these products, and research and develop and commercialize new products. In addition, the rate of growth in our revenues has fluctuated in the past, and may continue to do so in future periods. In particular, such rate of growth may be negative, flat, or may grow more slowly than we expect, including if the rate of growth of our test volumes slows. **Furthermore, although there** ~~A significant element of our business strategy~~ is ~~to maintain increased in- network coverage with third- party payers; however, the negotiated fees under our contracts with third- party payers are typically lower than the list price of our tests, and in some cases the third- party payers that we contract with have negative coverage determinations for some of our offerings, in particular Panorama for microdeletions screening. Therefore, being in- network with third- party payers has in the past had, and may in the future have, an adverse impact on our revenues and gross margins, especially if we are unable to increase the adoption of, and obtain favorable coverage determinations for reimbursement for, our products. Furthermore,~~ a CPT code **in place** for microdeletions **testing, we** ~~went into effect beginning in January 2017. We~~ have experienced low average reimbursement rates for microdeletions testing under this **CPT** code, and our microdeletions ~~31reimbursement~~ -- **reimbursement** may continue to remain low, at least in the near term, either due to reduced reimbursement, or third- party payers declining to reimburse, under the microdeletions code, which has had and will likely continue to have an adverse effect on our revenues ~~. In addition, a CPT code for expanded carrier screening went into effect beginning in January 2019, and has had, and may continue to have, an adverse effect on our reimbursement rates for our broader Horizon carrier screening panel, for which we previously primarily received reimbursement on a per condition basis, as those tests may be reimbursed as a combined single panel instead of as multiple individual tests. As further discussed in the risk factor entitled " — We may not be successful in commercializing our cloud- based distribution model, " our results of operations may be adversely affected if we do not sell a sufficient volume of tests under our cloud- based distribution model to offset the lower revenues per test performed under that model~~ . Our ability to forecast our future operating results, including revenues, cash flows and profitability, is limited and subject to a number of uncertainties. We have also encountered and will continue to encounter risks and uncertainties frequently experienced by rapidly growing companies in the life sciences and technology industry, such as those described in this report. If our assumptions regarding these risks and uncertainties are incorrect or these risks and uncertainties change, or if we do not address these risks successfully, our operating and financial results may differ materially from our expectations, and our business may suffer. Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations. Our success will depend in part on our ability to effectively introduce and increase market adoption of enhanced or new offerings. In recent years we have developed and launched several new products or enhanced versions of existing products, including our first offerings **and subsequent updated offerings** in oncology and in organ health, and we expect to ~~continue~~ **32continue** our efforts in all of these areas. The development and launch of enhanced or new tests requires the completion of certain clinical development and commercialization activities that are complex, costly, time- intensive and uncertain, and requires us to accurately anticipate the preferences and needs of patients, clinicians, payers, and other counterparties, as well as emerging technology ~~and~~ **,** industry trends **, and the competitive environment** . This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. We may not be successful in our current or future efforts to develop and commercialize cell- free DNA tests in industries that are newer to us. Moreover, we have limited experience forecasting our future financial performance from our new products in these industries that are newer to us, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our common stock to decline. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests and result in increased costs and the diversion of management' s attention and resources from other business matters, such as from our existing product offerings. For example, any tests that we may enhance or develop may not prove to 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 sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our test performance in commercial experience may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or through collaborative arrangements; healthcare providers may not order or use, or third- party payers may not reimburse for, any tests that we may enhance or develop; or we may otherwise have to abandon a test or service in which we have invested substantial resources. In particular, we are subject to the risk that the biological characteristics of the genetic mutations we seek to target, and upon which our technologies rely, are uncertain and difficult to predict. For example, in our efforts to detect and analyze circulating tumor DNA in plasma for MRD assessment and recurrence surveillance, our success depends on tumors shedding mutant DNA into the bloodstream in sufficient quantities such that our technology can detect such mutations, as well as patients having sufficient tumor tissue to design our custom ctDNA test for each patient. As further discussed in the risk factor entitled " If our products do not perform as expected, our operating results, reputation and business will suffer, " we may also experience unforeseen difficulties when implementing updates to our processes, as we have occasionally experienced with Panorama, Horizon, and our other tests. We cannot assure you that we can successfully complete the clinical development of any new or enhanced product, or that we can establish or maintain the collaborative relationships that may be essential to our clinical development and ~~32commercialization~~ -- **commercialization** efforts. Clinical development requires large numbers of patient specimens and, for certain products, requires 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, which we experienced in the past with our SNP- based Microdeletions and Aneuploidy RegisTry, or SMART, Study, or due to changes in study design or other unforeseen circumstances, such as our decisions in the past to expand our SMART Study; or we may be unable to afford or manage the large- sized clinical trials that some of our planned future products may require. The publication of clinical data in peer- reviewed journals is a crucial 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. Further, the data collected from any studies we complete in the future may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical community or to third- party payers seeking such data for purposes of determining coverage for our tests. For example, while we have published results from our SMART Study, we cannot assure you that such results or publications will convince laboratories, clinics, clinicians, physicians or patients of the benefits of utilizing Panorama for microdeletions. We also cannot be certain whether, or to what extent, the SMART Study may impact insurance coverage and reimbursement for microdeletions testing. Similarly, certain results of the CIRCULATE- Japan study have recently been published, and we cannot assure you that such results ~~will~~ **33will** impact professional society or practice guidelines, or coverage and reimbursement determinations from third- party payers, as we anticipate. In addition, as further described in the risk factor entitled " —If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post- market controls, " development of the data necessary to obtain regulatory clearance and approval of a test is time- consuming, requires us to incur significant costs, and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA premarket clearance or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier- stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, or could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, any of which could have a material adverse effect on our business, operating results or financial condition. These and other factors beyond our control could result in delays or other difficulties in the research and development, approval, production, launch, ongoing commercialization or distribution of enhanced or new tests and could adversely affect our competitive position and results of operations. Our quarterly results may fluctuate from period to period, which could adversely impact the value of our common stock. Our quarterly results of operations, including our revenues, gross margin, net loss and cash flows, have varied and may continue to vary from period to period as a result of a variety of factors, many of which are outside of our control, including those listed elsewhere in this " Risk Factors " section, and as a result, period- to- period comparisons of our operating results may not be meaningful. Our quarterly results should not be relied upon as an indication of future performance. In addition, to the extent that we continue to spend considerably on our internal sales and marketing and research and development efforts, we expect to continue to incur costs in advance of achieving the anticipated benefits of such efforts. Fluctuations in quarterly results and key metrics may cause our results to fall below our financial guidance or other projections or goals, or the expectations of analysts or investors, which could adversely affect the price of our common stock. We also face competitive pricing and reimbursement pressures, and we may not be able to maintain our premium pricing in the future, which would adversely affect our operating results. ~~33Competition~~ -- **Competition** in our industry is intense; if we are unable to compete successfully with respect to our current or future products or services, we may be unable to increase or sustain our revenues or achieve profitability. We compete primarily in the molecular testing field, which is characterized by rapid technological changes, 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 principal competition in women' s health comes from existing testing methods, technologies and products that are used by OB / GYNs, MFM specialists or IVF centers. These include other NIPTs and carrier screening tests offered by our competitors, as well as established, traditional first- line prenatal screening methods, such as serum protein measurement, where doctors measure certain hormones in the blood, and invasive prenatal diagnostic tests like amniocentesis, which have been used for many years and are therefore difficult to displace or supplement. We also face competition in the fields of oncology and organ health from other companies, which may be larger, more established, or have more experience or more resources than we do. In addition, new testing methods may be developed which may displace or be preferred over ~~NIPTs~~ **our current methods** , such as whole genome sequencing or single cell analysis with respect to NIPTs, or tracking more tumor- specific variants and / or other biomarkers in addition to ctDNA, or testing without the need for a sample of the tumor tissue, with respect to MRD testing. We cannot assure you that research, discoveries or other advancements by other companies will not render our existing or potential products and services uneconomical or result in products and services that are superior or otherwise preferable to our current or future products and services. It is possible that competition in all of the markets in which we operate will continue to increase. Some of our competitors' products and services are sold at a lower price than ours, which could cause sales of our tests and services to decline or force us to reduce our prices. Our current and future competitors could have greater technological, financial, reputational and market access advantages than us, and we may not be able to compete effectively ~~against~~ **34against** them. Increased competition is likely to result in pricing pressures, which could harm our revenues, operating income or market share. We have increasingly been subject to litigation with our competitors; for example, as disclosed elsewhere in these risk factors, we are or have recently been in active litigation with competitors in each of the women' s health, oncology and organ health fields, which involve considerable costs to us as well as management time and attention. If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve profitability. See the section entitled " Business – Overview – Competition " for additional information on our competitors. We ~~may not be successful in commercializing our cloud- based distribution model. We utilize a cloud- based distribution model to deploy our bioinformatics technology for use by other laboratories. Under this model, clinical laboratories around the world, including in the U. S., license our technology to develop and run their own NIPT or other molecular testing assays in their own facilities as LDTs, and then access our proprietary algorithms through our cloud- based Constellation software to analyze the assay results. In the diagnostics industry, the market for cloud- based solutions and services is not as mature as the market for on- premise enterprise software, and it remains uncertain whether and to what extent our cloud- based distribution model will achieve and sustain high levels of customer demand and market acceptance. The rate of adoption of our cloud- based distribution model continues to be slower than we anticipated, and depends on a number of factors, including the cost, performance and perceived value associated with our solution, as well as our ability to address security, privacy and regulatory requirements or concerns. In particular, all of our licensees under our cloud- based distribution model are required to use Illumina sequencers and reagents to run their tests that they develop based on our technology. As further described in the risk factor entitled " — We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers, " we are aware that Illumina has required our licensees to pay an additional license fee in certain jurisdictions in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud- based distribution model. Furthermore, Illumina competes with us through its subsidiary Verinata, and may not charge a similar license fee for Verinata' s licensed- based offering to other laboratories. As a result, our potential or current licensees may be unable to commercially launch their tests under our cloud- based distribution model in a financially viable manner, which has dissuaded and could continue to dissuade potential or current licensees from licensing from us or launching a test based on our technology. In addition, if a test developed by any of our licensees under our cloud- based distribution model in the United States is found not to be an LDT, the licensee may not be able to market its test, and we would not receive the anticipated revenues from that licensee. We also do not know whether, over the long term, this model will result in benefits or cost savings at the levels that we anticipate or at all. For example, to the extent that any of our laboratory customers for whom we currently perform 34our tests entirely in our laboratory transition to our cloud- based distribution model, our revenues from such customers will decrease because we are not able to charge as high an amount per test as when we perform the entire test ourselves. If the lower revenues per test performed is not offset by a sufficient increase in volume of tests sold, our overall revenues will be lower, and our results of operations may be adversely affected. Among the risks to our business and results of operations from our Constellation model are the following: • our and our licensees' ability to obtain required regulatory authorizations from the FDA and international regulatory agencies as further described in the risk factor entitled " Regulatory and Compliance Risks — Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue commercializing our cloud- based distribution model; " • supply constraints, including with respect to the blood collection tubes that are used for many of our tests, such as Panorama, Signatera and Prospera, and that are supplied by Streck, Inc., or Streck, as further described in the risk factor entitled " — We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers; " • allegations or potential third- party claims that the tests, based on our technology, developed by our licensees violate such third parties' intellectual property rights; • licensing portions of our proprietary technology to third parties that may not take the same security precautions as we do to protect this information; and • an inability to achieve anticipated benefits and costs savings. If we or other cloud- based solution providers experience security incidents, loss of customer data or disruptions in delivery or other problems, the market for cloud- based solutions in the diagnostics industry, including our solutions, may be adversely affected. Such events could also result in potential lawsuits and liability claims, or, as further described in the risk factor entitled " — Security breaches, loss of data and other disruptions, including with respect to cybersecurity, could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could~~

~~adversely affect our business and reputation, " could subject us to federal and state privacy laws and regulations or expose us to regulatory action or liability, any of which could have a material adverse effect on our business. If there is a reduction in demand for cloud- based solutions caused by technological challenges, weakening economic conditions, security or privacy concerns, competing technologies and products or other challenges, we may not be successful in executing our Constellation business model, and our results of operations may be adversely affected. We~~ rely on internal and third- party data centers and platforms to host our laboratory and cloud- based software, and any interruptions of service or failures may impair our ~~laboratory~~ operations ~~or the delivery of our cloud- based services~~ and harm our business. We currently maintain a data center at our laboratory facilities in San Carlos, California. In addition, our proprietary bioinformatics algorithms are a crucial component of our test processing, and combine information derived from our mmPCR assay workflows with publicly available data from the broader scientific community to analyze and return test results. We host the significant majority of these algorithms on a cloud-based software platform pursuant to an agreement with DNAnexus, Inc., or DNAnexus, and both we and our Constellation licensees access our algorithms through the DNAnexus platform. The DNAnexus platform is hosted on third- party data center hosting facilities operated by Amazon Web Services, or AWS, located primarily in the United States and in the European Union. We also host our algorithms on AWS platforms directly. Our algorithms are currently used to run many of our tests and certain of our research and development activities, as well as for our Constellation licensees. In the event of any technical problems that may arise in connection with our on- site data center, the DNAnexus platform or the AWS servers on which the DNAnexus platform is hosted, or the AWS servers that host our data directly, or difficulties in or termination of our relationship with DNAnexus, we could experience interruptions in our laboratory operations or our cloud- based services, and we and our Constellation licensees may be unable to access our proprietary algorithms and therefore be unable to process tests or conduct any other activities that require access to such algorithms. These types of problems may be caused by a variety of ~~35factors~~ **factors**, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. We do not have any backup platform, server or other means to host our algorithms, and may be unable to find and implement an alternative platform that is satisfactory for our needs on commercially reasonable terms, in a timely manner, or at all. Interruptions in our operations or service may reduce our revenue, cause us to issue refunds, result in the loss of customers, cause laboratory licensees to terminate their contracts with us, adversely affect our ability to attract new laboratory licensees, or harm our reputation. We could also be exposed to potential lawsuits and liability claims. If our products do not perform as expected, our operating results, reputation and business will suffer. Our success depends on the market' s confidence that we can provide reliable, high- quality testing results. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our test volumes continue to increase and our product portfolio continues to expand. We believe that our customers are particularly sensitive to test limitations and errors, including inaccurate test results and the need on occasion to perform second blood draws, or redraws, on patients, for which Panorama has in the past experienced a higher rate than advertised for other NIPTs. As a result, if our tests do not perform as expected or favorably in comparison to competitive tests, our operating results, reputation, and business will suffer. We may also become subject to legal claims arising from such limitations, errors, or inaccuracies. Our tests use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes, or fluctuations in external variables, may result in sensitivity or specificity rates that are lower than we anticipate or that vary between test runs, a higher than anticipated number of tests that require redraws or fail to produce results, or longer than expected turnaround times, which we have experienced and will likely continue to experience on occasion as a result of issues with laboratory equipment, components or materials or otherwise. In addition, we regularly evaluate and refine our testing processes, and any refinements we make may not improve our tests as we expect and may result in unanticipated issues that may adversely affect our test performance as described above, which we have experienced in the past. Such operational, technical and other difficulties may impact the commercial attractiveness of our products, may increase our costs or divert our resources, including management' s time and attention, from other projects and priorities, or may subject us to legal claims. Furthermore, any changes to our testing process may require us to use new or different suppliers or ~~materials~~ **35materials** with whom or which we are unfamiliar, and which may not perform as we anticipate, and could cause delays, downtime or other operational issues. We rely on third- party laboratories to perform portions of our service offerings. Certain of our tests, or components of our tests, are performed by third- party laboratories. These third- party laboratories are subject to contractual obligations to perform these services for us but are not otherwise under our control. We therefore do not control the capacity and quality control efforts of these third- party laboratories other than through our ability to enforce contractual obligations on volume and quality systems, and we have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also have no control over the timeliness of such laboratories' performance of their obligations to us. Third- party laboratories that we have contracted with have in the past had, and occasionally continue to have, issues with delivering results to us or resolving issues with us, including within the time frames we expected or established in our contracts with them, which sometimes results in longer than expected turnaround times for, or negatively impacts the performance of, these tests and services. We have had to review and, in some cases, revise our processes, procedures and agreements with our business partners to address unforeseen operational issues and other contingencies, and will likely continue to do so as our business grows. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of our third- party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. We may not have sufficient alternative backup if one or more of the third- party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness. Changes to or termination of our agreements or inability to renew our agreements with these third- party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these tests and services. In the event of any adverse developments with these third- party laboratories or their ability to

perform their obligations to us in a timely manner and in accordance with the standards that we and our customers expect, ~~36our~~ -- **our** ability to service our customers may be delayed, interrupted or otherwise adversely affected, which could result in a loss of customers and harm to our reputation. Furthermore, when these issues arise, we have had to expend time, management attention and other resources to address and remedy such issues. In addition, certain third- party payers, including some state Medicaid payers, that we are under contract with may take the position that sending out testing to third- party laboratories and billing for such tests is contrary to the terms of our provider agreement and may refuse to pay us for the testing. If any of these events occur, our business, financial condition and results of operations could suffer. Further, some state laws impose anti-markup restrictions that prevent an entity from realizing a profit margin on outsourced testing. If we or our subsidiaries are unable to markup outsourced testing, our revenues and operating margins may suffer. If either of our CLIA- certified laboratory facilities becomes inoperable, we will be unable to perform our tests and our business will be harmed. We currently operate laboratory facilities in Austin, Texas and in San Carlos, California, both of which process Panorama, Horizon, and Signatera tests, which together represent the significant majority of our revenues. Our other tests that we perform are currently only able to be performed at one, but not both, of our laboratories, and are primarily performed at our San Carlos location, and we currently otherwise have no backup or redundant facility to perform these tests. Our San Carlos laboratory is situated near active earthquake fault lines, and both of our laboratories are located in areas that have in recent years experienced, and are likely to experience in the future, severe weather events. Either of our laboratories may be harmed or rendered inoperable, or samples could be damaged or destroyed, by natural or manmade disasters, including earthquakes, severe weather, flooding, power outages and contamination, including as a result of a health pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. An inability to perform our tests or the backlog of tests that could develop if either our San Carlos or Austin laboratory is inoperable for even a short period of time may result in the loss of customers and an adverse effect on our revenues or harm our reputation. We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers. We have sourced and will continue to source components of our technology, including sequencers, reagents, tubes and other laboratory materials, from third parties. In particular, our sequencers, many of our reagents, including for Panorama, Horizon and Signatera as described below, and our blood collection tubes, are sole sourced. ~~For~~ **36For** example, our molecular diagnostics tests are currently only validated to perform on Illumina' s sequencing platform; in addition, Illumina is currently the sole supplier of our sequencers and related reagents for Panorama, Horizon, Signatera and Prospera, along with certain hardware and software, pursuant to a supply agreement that expires in August 2033. Without sequencers and the related reagents, we would be unable to run our tests and commercialize our products. **All** ~~In addition, all~~ of the licensees under our Constellation cloud- based distribution model **also** do not have alternatives other than to use Illumina sequencers and reagents to run the tests that they develop based on our technology. In addition, Illumina and Sequenom, which was acquired by LabCorp, have entered into a patent pooling agreement pursuant to which both parties have pooled their intellectual property directed to NIPT. We understand from public filings that under the patent pooling agreement, Illumina has the exclusive worldwide rights to, among other things, license third- party laboratories to develop and sell NIPTs utilizing the pooled intellectual property and to enforce the pooled intellectual property against suspected infringers. Illumina has granted us certain rights to Illumina' s intellectual property related to NIPT, including the pooled intellectual property, for running our own tests; however, we do not have an express license to grant rights under the pooled intellectual property to the licensees under our Constellation cloud- based distribution model. We are aware that Illumina has required our licensees, in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud- based distribution model, to pay an additional fee for a license under the pooled intellectual property in jurisdictions in which Illumina believes certain of the pooled intellectual property is enforceable. This additional fee has dissuaded and could continue to dissuade potential or current licensees from licensing from us or launching a test based on our technology. In addition, we have in the past been involved in patent infringement litigation against Illumina, which we and Illumina have settled. In addition, Illumina competes with us in the NIPT market through its subsidiary, Verinata. We understand Illumina supplies the same or similar sequencers and consumables to Verinata. Because of Illumina' s ownership of Verinata, we face increased risk and uncertainty regarding continuity of a successful working relationship with Illumina under our supply agreement, as well as in our ability to compete with Verinata in the marketplace in view of economic advantages enjoyed by Verinata with respect to the cost of sequencers and related ~~37consumables~~ -- **consumables** . Our failure to maintain a continued supply of the sequencers and reagents, along with the right to use certain hardware and software, would adversely impact our business, financial condition, and results of operations. Validating alternative sequencing platforms requires significant resources, expenditures and time and attention of management, and there is no guarantee that we will be successful in implementing any alternative sequencing platforms in a commercially sustainable way. We also cannot guarantee that we will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts, in particular given our limited product and research and development resources and various business initiatives, which could result in increased costs and delayed timelines or otherwise impact our business and results of operations. In addition, our Panorama test is currently only validated to be performed using Streck' s blood collection tubes, and we use only Streck tubes for the primary analysis of Signatera results, and for our Prospera test. Streck is the sole supplier of the blood collection tubes included in Panorama and our other cell- free DNA tests under a supply arrangement with Streck under which we are required to exclusively use Streck tubes for Panorama. Similarly, all of the licensees under our cloud- based distribution model also have no current alternative but to use these blood collection tubes to run the tests that they develop based on our technology. Furthermore, our sequencers, sourced from Illumina, as well as certain other reagents we use for Panorama and our other tests, are intended for research use only and are labeled as RUO. As discussed further in the risk factor entitled " Regulatory and Compliance Risks — Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing

our tests to market or performing such tests for our customers, " the FDA may determine that a product labeled RUO is, nonetheless, intended to be used diagnostically, and could take enforcement action against the manufacturer of the product. If this were to occur with respect to Illumina or any of our other suppliers of RUO products, we could be required to obtain one or more alternative sources of these products, and we may not be able to do so on commercially reasonable terms, a commercially reasonable timeframe, or at all. In addition, Streck' s blood collection tubes have not been registered as a medical device in all countries in which we market our Panorama test. As discussed in the risk factor entitled " Regulatory and Compliance Risks — Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue commercializing our cloud- based distribution model, " the regulatory authorities in some of these countries may determine that such registration is required, which could impact our ability to offer Panorama in such countries. Furthermore, because our licensees under our cloud- based distribution model also exclusively use such sole- sourced components to run the tests they develop based on our technology, and our laboratory distribution partners must use certain of such sole- sourced components in order to ~~utilize~~ **37utilize** our tests, any enforcement action against the supplier by the FDA or any other regulatory authority in the jurisdictions in which our licensees and laboratory distribution partners are located could have an adverse impact on our business. Because we rely on third- party manufacturers, we do not control the manufacture of these components, including whether such components will meet our quality control requirements, nor the ability of our suppliers to comply with applicable legal and regulatory requirements. In many cases, our suppliers are not contractually required to supply these components to the quality or performance standards that we require. If the supply of components we receive does not meet our quality control or performance standards, we may not be able to use the components, or if we use them not knowing that they are of inadequate quality, our tests may not work properly or at all, or may provide erroneous results, and we may be subject to significant delays caused by interruption in production or manufacturing or to lost revenue from such interruption or from spoiled tests. This occasionally occurs with respect to certain reagents. In addition, any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at our third- party manufacturers' facilities that cause a loss of manufacturing capacity would heighten the risks that we face. In the event of any adverse developments with our sole suppliers, or if any of our sole suppliers modifies any of the components they supply to us, our ability to supply our products may be interrupted, and obtaining substitute components could be difficult or require us to re- design or re- validate our products. In addition, if we obtain FDA clearance, approval or de novo classification for any of our tests as an in vitro diagnostic, or IVD, such issues with suppliers or the components that we source from suppliers could affect our commercialization efforts for such an IVD, as further described in the risk factor entitled " Regulatory and Compliance Risks — If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs ~~38associated~~ -- **associated** with complying with post- market controls. " Our failure to maintain a continued supply of components, or a supply that meets our quality control requirements, or changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers, particularly in the case of sole suppliers such as Streck and Illumina, could result in the loss of access to important components of our tests and impact our test performance or affect our ability to perform our tests in a timely manner or at all, which could impair, delay or suspend our commercialization activities. In the event that we transition to a new supplier from any of our sole suppliers, doing so could be time- consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance of our tests or could require that we re- validate our affected tests using replacement equipment and supplies, which could delay the performance of our tests and result in increased costs. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations. We rely on commercial courier delivery services to transport samples to our facilities in a timely and cost- efficient manner and if these delivery services are disrupted, our business may be harmed. Our core business depends on our ability to quickly and reliably deliver test results to our customers. We typically receive blood samples for analysis at our laboratory facilities within days of collection from the patient. Disruptions in delivery service – whether due to error by the courier service, labor disruptions, bad weather, natural disaster, terrorist acts or threats or for 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. Security breaches, loss of data and other disruptions, including with respect to cybersecurity, could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and reputation. In the ordinary course of our business, we collect and store sensitive data, including legally- protected personal information, such as test results and other patient health information, credit card and other financial information, insurance information, and personally identifiable information. We also store sensitive intellectual property and other proprietary business information, including that of our customers, payers and collaboration partners. We are highly dependent on information technology networks and systems, including a combination of on- site systems, managed data center systems and cloud- based data center systems, and the Internet, to securely process, transmit, and store a wide variety of ~~business~~ **38business** - critical information, including research and development information, commercial information and business and financial information. We also communicate sensitive data, including patient data, telephonically, through our website, through facsimile, through integrations with third- party electronic medical records systems, and through relationships with third- party vendors and their subcontractors, both in the United States and internationally. The laws of some foreign countries do not protect data privacy to the same extent as the laws of the United States. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized access, use or disclosure, our information technology and infrastructure, and that of our technology and other third- party service providers and their subcontractors, are nevertheless inherently vulnerable to, and from time to time experience,

cyber- attacks by hackers or viruses or breaches due to employee error, technical error, malfeasance or other disruptions. Any such breach or interruption, whether of our systems or that of our third- party service providers or their subcontractors, could compromise our data security, and the information we store could be inaccessible by us or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure, modification, or other loss of information could result in legal claims or proceedings, liability or penalties under laws and regulations that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, European data privacy regulations, such as the General Data Protection Regulation, or GDPR, or state privacy regulations, such as the California Consumer Privacy Act. We may be required to comply with state breach notification laws, become subject to mandatory corrective action, or be required to verify the correctness of database contents. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial ~~39information~~ -- **information** , provide information about our tests, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may compound these adverse consequences. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position. We are also subject to the risks described above as a result of our relationships with third- party vendors and their subcontractors, whose systems may be breached and may cause our sensitive data, including patient data, to be compromised. We have on occasion experienced such disruptions by way of third- party vendors. For example, in 2020 we were notified of a data security incident that affected a third- party vendor, which affected a number of our patients whose protected health information was stored in such third- party vendor' s systems. The third- party vendor notified the affected individuals as required by HIPAA. Our cloud- based distribution model adds additional data privacy risk, as certain personal health and other information may be sent to and stored in the cloud by our laboratory licensees, many of which are located outside of the United States. We contractually prohibit our licensees from sending personally- identifiable information to our cloud servers, and the vendor that hosts our software in the cloud is contractually required to comply with data privacy laws, such as HIPAA and GDPR. However, we cannot be certain that these third parties will comply with the terms of our agreements, nor that they will not experience security breaches or other disruptions. The marketing, sale, and use of our tests could result in substantial damages arising from product liability, professional liability, or other claims that exceed our resources. The marketing, sale and use of our tests could lead to product liability claims against us if someone were to allege that our test failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results or our test failed to produce a result, or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with our marketing and promotional activities or as part of the results generated by our tests. For example, Panorama could provide a low- risk result which a patient or physician may rely upon to make a conclusion about the health of the fetus, which may, in fact, have the condition for which we delivered a low- risk result because the Panorama result was a so- called false negative. Similarly, Panorama could provide a so- called false positive, which is a high- risk result for ~~a~~ **39a** fetus that may not, in fact, have the relevant condition. Even though Panorama and our other tests are highly accurate, they are not 100 % accurate and we may report false negative or false positive results, which may subject us to lawsuits claiming product or professional liability or other claims, as has happened in the past and may happen in the future. A product liability or professional liability claim could result in substantial damages and be costly and time- consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated, or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our services, or cause our partners to terminate our agreements with them, any of which could adversely impact our results of operations. If we are unable to successfully scale our operations, our business could suffer. Our overall test volumes grew from approximately ~~1, 570, 000 to~~ 2, 066, 500 **to 2, 496, 100** and further to ~~2~~ **3** , ~~496~~ **064** , ~~100~~ **600** tests processed during the years ended ~~2021,~~ 2022 ~~and ,~~ 2023 **, and 2024** , respectively, and since 2009 we have launched over 15 product offerings **, enhancements,** or indications. In addition, we regularly evaluate and refine our testing process, often significantly updating our workflows. As our test volumes and product portfolio continue to grow, we will need to continue to ramp up our testing capacity and implement increases in scale, such as increased headcount, additional or new equipment, laboratory space and qualified laboratory personnel, increased office and laboratory space, expanded customer service capabilities, billing and systems process improvements, enhanced controls and procedures, and an expanded internal quality assurance program and technology platform. The value of our tests to patients and physicians depends on our ability to perform the ~~40tests~~ -- **tests** on a timely basis and at an exceptionally high standard of quality, and on maintaining our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new facilities, equipment or processes or to hire the necessary personnel in a timely and effective manner could result in higher processing costs or an inability to meet market demand, or could otherwise affect our operating results, as we have experienced in the past. In addition, our efforts to scale our operations may be unable to keep pace with an increase in the frequency of our launches of new or enhanced products and services. Particularly in recent years, we have expanded into markets or industries new to us with new products, significant product enhancements, and expanded indications. As we continue to launch additional offerings and product enhancements, we will need to manage our resources among various initiatives, and such competing priorities could lead to delays in one or more of our business initiatives.

Conversely, to the extent that we scale our operations, infrastructure and other resources but do not ultimately meet our anticipated timelines in our product development efforts, we will experience higher costs and expenses than necessary until our project timelines and operational resources become aligned. We may also, intentionally or unintentionally, allocate resources to new products or initiatives in a manner disproportionate to the amount of revenue that such initiatives generate compared to our existing or core offerings. We cannot assure you that our efforts to scale our commercial operations will not negatively affect the quality of our test process or results, or that we will be successful in managing the growing complexity of our business operations. To execute our growth plan, we must attract and retain highly qualified personnel. Competition for these personnel is intense, especially for sales, scientific, medical, laboratory, research and development and other technical personnel, and especially in the San Francisco Bay Area where we have an office and laboratory facilities, and the turnover rate of such personnel can be high. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for highly qualified personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached their legal obligations to their former employers, which occurs from time to time. In addition, job candidates and existing employees in the San Francisco Bay Area often consider the value of the equity awards they receive in connection with their employment. To the extent that our current or potential employees perceive the value of our equity awards to be low, our ability to recruit, retain and motivate highly skilled employees may be adversely affected, which could then have an adverse effect on our business and future growth prospects. Furthermore, to the extent that we are unable to retain our employees and they leave our company to join one of our competitors, we cannot assure you that any invention, non- disclosure or non- compete agreements we have in place will provide meaningful protection against a departing employee' s unauthorized ~~use~~ **40use** or disclosure of our confidential information, as further discussed in " — Risks Relating to our Intellectual Property — If we are not able to adequately protect our trade secrets and other proprietary information, the value of our technology and products could be significantly diminished. " In addition, our growth may place a significant strain on our operating and financial systems and our management, sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate faster than we anticipate, we may face difficulties in obtaining additional office or laboratory space, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow successfully or we may grow at a slower pace, and our business could be adversely affected. If our sales, distribution, development or other partnerships are not successful and we are not able to offset the resulting impact through our own efforts or through agreements with new partners, our commercialization activities may be impaired and our financial results could be adversely affected. Part of our business strategy is to develop relationships with laboratory and other partners to develop or sell our products, both in the United States and internationally. For example, we have entered into an agreement with BGI Genomics pursuant to which, among others, ~~we will~~ **BGI Genomics** ~~commercialize~~ **commercializes** ~~Signatera~~ **our MRD test** in China on **its** ~~BGI Genomics' s~~ sequencing platform ~~; and an agreement with Foundation Medicine to develop and commercialize personalized circulating tumor DNA monitoring assays for use by biopharmaceutical and clinical customers who order Foundation Medicine' s companion diagnostic cancer test~~ . Developing and commercializing products with third parties reduces our control over such development and commercialization efforts and subjects us to the various risks inherent in a joint effort with a third party, such as delays, operational issues, technical difficulties and other contingencies outside of our influence or control. Distributing Panorama, Signatera and our other products through partners reduces our control over our revenues, our ~~41market~~ -- **market** penetration and our gross margin on sales by the partner if we could have otherwise made that sale through our direct sales force. The financial condition of these third parties could weaken, or they could terminate their relationship with us and / or stop selling our products, as has happened in the past; reduce their marketing efforts in respect of our products; develop and commercialize or otherwise sell competing products in addition to or in lieu of our tests, as has also occurred; merge with or be acquired by a competitor of ours or a company that chooses to de- prioritize or cease the efforts to develop, sell or otherwise partner with us on our products; or otherwise breach their agreements with us. ~~For example, as further described in " Note 3 — Revenue Recognition — Licensing and Other Revenues — Qiagen " of our consolidated financial statements, we had entered into a license, distribution and development agreement with Qiagen pursuant to which, among others, Qiagen would distribute an NIPT based on our Panorama test on a sequencer to be developed by us and Qiagen; however, Qiagen thereafter discontinued the development of its Next Generation Sequencing Platform and instead partnered with Illumina to develop next- generation sequencing based tests.~~ Furthermore, our laboratory partners may misappropriate our trade secrets or use our proprietary information in such a way as to expose us to litigation and potential liability; and our compliance risk may increase to the extent that we are responsible, or deemed responsible, for our partners' sales and marketing activities. Disagreements or disputes with our partners, including disagreements over customers, proprietary rights or our or their compliance with contractual obligations, might cause delays or impair the commercialization of ~~Panorama, Signatera or~~ **our** ~~our other~~ tests, lead to additional responsibilities for us with respect to new tests, or result in litigation or arbitration, any of which would divert management attention and resources and be time- consuming and expensive. As is typical for companies in our industry, we are continually evaluating and pursuing various strategic or commercial partnerships, relationships, or collaborations, some of which may involve the sale and issuance of our common stock, which could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline. If our partnerships are not successful, our ability to increase sales of our products and to successfully execute our strategy could be compromised. Our financial condition and results of operations may be adversely affected by international regulatory and business risks. As we expand our operations, including by offering our tests in other countries, we are increasingly subject to varied and complex foreign and international laws and regulations due to operating, offering our products, or contracting with employees, contractors and other service providers in various other countries. Compliance with these laws and regulations often involves significant costs and may

require changes in our business practices that may result in reduced revenues and adversely affect our operating results. We are subject to the Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, 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. Our reliance on independent laboratories to sell Panorama and other products internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other U. S. companies in the medical device and pharmaceutical field have faced ~~criminal~~ **41criminal** penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with foreign government officials. We are also subject to similar anti- bribery laws in the jurisdictions in which we operate, including the United Kingdom' s Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far- reaching in nature. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and we could be subject to severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures, any of which could result in a material adverse effect on our business, prospects, financial condition, or results of operations. In addition, our international activities are subject to U. S. economic and trade sanctions, which restrict or otherwise limit our ability to do business in certain designated countries. Other limitations, such as restrictions on the import into the United States or the export to other countries of tissue or genetic data necessary for us to perform our tests, or restrictions on importation and circulation of blood collection tubes or other equipment or supplies by countries outside of the United States, may limit our ability to offer our tests internationally. We may also face competition from companies located in the countries in which we or our partners or licensees offer our tests, and in which we may be at a competitive disadvantage because the country may favor a local provider or for other reasons. ~~42By~~ **By** operating internationally, we may experience longer accounts receivable payment cycles and difficulties in collecting accounts receivable; realize lower margins due to lower pricing in many countries; incur potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings; experience financial accounting and reporting burdens and complexities; experience difficulties in staffing and managing foreign operations, including under labor and employment laws and regulations that are new or unfamiliar to us; be subject to trade barriers such as tariffs, quotas, preferential bidding or import or export licensing requirements; be exposed to political, social and economic instability abroad, including terrorist attacks and security concerns; be exposed to fluctuations in currency exchange rates; and experience reduced or varied protection for intellectual property rights and practical difficulties in enforcing intellectual property and other rights, including with respect to assignment of inventions to us by our consultants in foreign jurisdictions. Outside of the United States we enlist local and regional laboratories, contract employees and other contracted service providers to assist with various aspects of our business operations, including blood draws, engineering, sales, marketing, billing and customer support. Subject to regulatory clearance where required, we also contract with international licensees to run the molecular portion of our tests in their own labs and then access our algorithm for analysis of the resulting data through our cloud- based Constellation platform. Locating, qualifying and engaging additional distribution partners and local laboratories with local industry experience and knowledge is necessary to effectively market and sell our tests outside of the United States. We may not be successful in finding, attracting and retaining such distribution partners or laboratories, or we may not be able to enter into such arrangements on favorable terms. Sales practices and other activities utilized by our distribution partners, contract employees and other service providers, some of which may be locally acceptable, may not comply with relevant standards required under United States laws that apply to our operations overseas, including through third parties, which could create additional compliance risk. Our training and compliance program and our other internal control policies and procedures, and our contractual terms with these third parties, may not always protect us from acts committed by our employees, contractors, partners or agents abroad. Non- compliance by us or our employees, contractors, partners or agents, whether maliciously or in error, of any applicable laws or regulations could result in fines or penalties, or adversely affect our ability to operate and grow our business. Even if we are able to effectively manage our international operations, if our distribution partners and local and regional laboratory licensees are unable to effectively manage their businesses, our business and results of operations could be adversely affected. Furthermore, the legal landscape governing advertising, promotional and other marketing activities can vary widely from jurisdiction to jurisdiction, and is often more complex, less clear or less developed than in the United States. If our marketing activities are found to be in violation of local laws, regulations or practices, we may be subject to fines and other penalties, and may be required to cease marketing or commercialization activities in such jurisdiction. If our sales and marketing efforts are not successful outside of the United States, we may not achieve market acceptance for our tests outside of the United States, which would harm our business. ~~Operating~~ **42Operating** internationally requires significant management attention and financial resources. We cannot be certain that the investment and additional resources required to increase international revenues or expand our international presence will produce desired levels of revenues or profitability. If we lose the services of our founder and Executive Chairman, our Chief Executive Officer, or other members of our senior management team, we may not be able to execute our business strategy. Our success depends in large part upon the continued service of our senior management team. In particular, our founder and Executive Chairman, Matthew Rabinowitz, as well as Steve Chapman, our Chief Executive Officer, are critical to our vision, strategic direction, culture, products and technology. In addition, we do not maintain key- man insurance for Dr. Rabinowitz, Mr. Chapman or any other member of our senior management team. The loss of our founder and Executive Chairman, our Chief Executive Officer, or one or more other members of our senior management team could have an adverse effect on our business. We may engage in acquisitions, dispositions or other strategic transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. From time to time, we may enter into transactions to acquire or dispose of businesses, products or technologies or to engage in other strategic transactions, such as our recent acquisition of certain

reproductive health assets related to ~~43Invitae~~ -- **Invitae** Corp.' s NIPT and carrier screening business. We may not be able to complete such transactions on favorable terms or at all. Any acquisitions or other strategic transactions we consummate may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue shares of our common stock or other equity securities to the stockholders of the acquired company, which would cause dilution to our existing stockholders. We could incur losses resulting from such strategic transactions, including undiscovered liabilities of an acquired business that are not covered by any indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non- disruptive manner. Any dispositions may also cause us to lose revenue and may not strengthen our financial position. Strategic transactions may also divert management attention from day- to- day responsibilities, increase our expenses, result in accounting charges, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future strategic transactions or the effect that any such transactions might have on our operating results. We are involved in legal proceedings, regulatory investigations and inquiries and other legal matters, which may have an adverse effect on our business, financial condition, results of operations and prospects. We are involved in legal matters, including investigations, subpoenas, demands, disputes, litigation, requests for information, and other regulatory or administrative actions or proceedings, including those with respect to intellectual property, testing and test performance, billing, reimbursement, marketing, short seller and media allegations, employment, and other matters. See Note 8 — Commitments and Contingencies — Legal Proceedings for a description of our legal matters. An independent committee of our board of directors initiated and completed an internal investigation into the allegations made in a March 2022 short seller report, with the assistance of the law firm of WilmerHale LLP, or WilmerHale. WilmerHale had access to company executives, personnel, records, communications, and documents. Based on the investigation, the independent committee, on behalf of the board, concluded that the allegations of wrongdoing against the Company in the report were unfounded. We are responding to ongoing regulatory and governmental investigations, subpoenas and inquiries, and contesting our current legal matters, and cannot provide any assurance as to the ultimate outcome with respect to any of the foregoing. There are many uncertainties associated with these matters. Such matters may cause us to incur costly litigation and / or substantial settlement charges, divert management attention, result in adverse judgments, fines, penalties, injunctions or other relief, and may result in loss of customer or investor confidence regardless of their merit or ultimate outcome. For example, in January 2024, a jury verdict of $ 57 million was awarded against us in a patent infringement lawsuit filed by Ravgen, Inc. **, and in November 2024, a jury verdict of over $ 292 million was awarded against us in litigation with Guardant Health, Inc. Although we intend to appeal any adverse judgment, we cannot assure you that we will be successful.** In addition, the resolution of any intellectual property litigation may require us to make royalty ~~payments~~ **43payments** , which could adversely affect gross margins in future periods. If any of the foregoing were to occur, our business, financial condition, results of operations, cash flows, prospects, or stock price could be adversely affected. We may need to raise additional capital, and if we cannot do so when needed or on commercially acceptable terms, we will be required to slow or cease our investment in our product development and commercialization plans, which would have an adverse effect on our business. We have incurred net losses since our inception, and we anticipate net losses and negative operating cash flows for the near future. While we have introduced multiple products that are generating revenues, these revenues may not be sufficient to fund all of our operations, including our product development and commercialization plans. Consequently, we will need to generate additional revenues to achieve future profitability and may need to raise additional funds through public or private equity or debt financings, corporate collaborations or licensing arrangements to continue to fund or expand our operations. Our actual liquidity and capital funding requirements will depend on numerous factors, including: • our ability to achieve broader commercial success with our tests and product offerings; • the costs and success of our research, development, and commercialization efforts for potential new products and additional indications for, and enhancements to, current products; ~~44~~ • our ability to obtain more extensive coverage and reimbursement for our tests, including for microdeletions screening in NIPT, as well as in additional indications in **women' s health,** oncology **,** and organ health as we continue to invest in expanding our offerings in these fields ~~; • our ability to generate sufficient revenues from our cloud- based distribution model~~ ; • our ability to collect on our accounts receivable; • our need to finance capital expenditures and further expand our clinical laboratory operations; • our ability to manage our operating costs; • costs and expenses to protect or enforce our intellectual property rights or to defend against infringement claims brought against us, including any associated litigation settlements or judgments we are required to pay; and • the timing and results of any regulatory authorizations that we are required to obtain for our tests. Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity- linked securities, or grant of equity or equity- linked securities in connection with any debt financing, will dilute stockholders' ownership interests in us and may have an adverse effect on the price of our common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants, and may impose other constraints on us and our operations. To the extent that we raise capital through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us. If we are not able to obtain adequate funding when needed, we may be required to delay or slow our investment in the development and commercialization of our products and significantly scale back our business and operations, which would have an adverse effect on our business. In addition, we may have to work with a partner on one or more of our tests or programs, which could lower the economic value of those programs to our company. ~~We~~ **44We** have incurred ~~substantial~~ indebtedness that may decrease our business flexibility, access to capital, and / or increase our borrowing costs, which may adversely affect our operations and financial results. **As** ~~In April 2020, we issued $ 287. 5 million aggregate principal amount of 2. 25 % Convertible Senior Notes due 2027, or the Convertible Notes. Our indebtedness may: • limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes; • limit our ability to~~

~~use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes; • require us to use a substantial portion of our cash flow from operations to make debt service payments; • limit our flexibility to plan for, or react to, changes in our business and industry; • place us at a competitive disadvantage compared to our less leveraged competitors; and • increase our vulnerability to the impact of adverse economic and industry conditions. Further, the indenture governing the Convertible Notes does not restrict our ability to incur additional indebtedness and we and our subsidiaries may incur substantial additional indebtedness in the future, subject to the restrictions contained in any future debt instruments existing at the time, some of which may be secured indebtedness. 45As~~ of December 31, ~~2023~~ **2024** , we have $ 80. 4 million of outstanding balance of the Credit Line including accrued interest. The Credit Line is secured by a first priority lien and security interest in the Company' s money market and marketable securities held in its managed investment account with UBS. The Company is required to maintain a minimum of at least $ 150. 0 million in its UBS accounts as collateral. UBS has the right to demand full or partial payment of the Credit Line obligations and terminate the Credit Line, in its discretion and without cause, at any time. Recent macroeconomic pressures resulting from ongoing geopolitical or other matters may have an adverse impact on our business, financial results and prospects. The COVID- 19 pandemic ~~has~~ had a significant negative impact on the macroeconomic environment, such as decreases in per capita income and level of disposable income, inflation, rising interest rates, and supply chain issues. Ongoing geopolitical matters **in recent years** have also contributed to difficult macroeconomic conditions and exacerbated supply chain issues, resulting in significant economic uncertainty as well as volatility in the financial markets, particularly in the United States. Such conditions may adversely impact our business, financial results, and prospects. In addition, such macroeconomic conditions could impact our ability to access the public markets as and when appropriate or necessary to carry out our operations or our strategic goals. We cannot predict the ongoing extent, duration or severity of these conditions, nor the extent to which we may be impacted. In the event of health epidemics or outbreaks in the future, our operations could be disrupted and our business adversely impacted. Such disruptions or impacts may be similar to those we faced during the COVID- 19 pandemic, such as mandated business closures in impacted areas, limitations with employee resources due to stay at home orders or sickness of employees or their families, reduced demand for certain of our products, or supply constraints. Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests. DNA testing, like that conducted using Panorama, Horizon, Signatera, and our other products, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons such as religious concerns; 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. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for services and products enabled by our technology platform, either of which could harm our business. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. We have a significant amount of net operating loss, or NOL, carryforwards that can be used to offset potential future taxable income and related income taxes. As of December 31, ~~2023~~ **2024** , we had federal, state, and foreign NOL carryforwards of approximately $ 1. 6 billion, $ 1. 1 billion and $ ~~3~~ **4** . ~~8~~ **1** million, respectively, which, if not utilized, begin to expire in **2033,** ~~2027~~ **2025** ~~, 2024~~ , and 2027, respectively. Approximately $ 1. 3 billion of these federal NOLs can be carried forward indefinitely. We also had federal research and development credit carryforwards of approximately $ ~~64~~ **83** . 3 million, which begin to expire in 2027, and state research and development credit carryforwards of approximately $ ~~36~~ **45** . ~~7~~ **6** million, which begin to expire in 2031. Under Section 382 of the Internal Revenue Code of 1986, as amended, 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. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which may not be within our control. Our ability to use these carryforwards could be limited if we experience an " ownership change ~~.~~ " **or if the tax laws are amended or otherwise changed.** ~~46Our~~ **45Our** estimates of total addressable market opportunity 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. Total addressable market opportunity estimates and growth forecasts 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 our market may prove to be inaccurate. Even if a market in which we compete meets our size estimates and forecasted growth for such market, our business could fail to grow at similar rates. Risks Related to ReimbursementIf we are unable to expand, maintain or obtain third- party payer coverage and reimbursement for Panorama, Horizon and our other tests, or if we are required to refund any reimbursements already received, our revenues and results of operations would be adversely affected. Our business depends on our ability to obtain and maintain adequate coverage and reimbursement from third- party payers and patients. Third- party reimbursement for our testing represents a significant portion of our revenues, and we expect government and commercial third- party payers to continue to be our primary source of payments. In particular, we believe that in order for us to continue to achieve commercial success, we will need to achieve insurance coverage for microdeletions screening, and obtain positive coverage determinations and favorable reimbursement rates from commercial third- party payers, the Centers for Medicare & Medicaid, or CMS, and state reimbursement programs for our tests. Historically, we have not received reimbursement for a significant number of Panorama tests that we have performed for microdeletions; we have published data from our SMART Study, but we cannot be certain whether, or to what extent, the SMART Study may impact insurance coverage and reimbursement for Panorama for microdeletions. In addition, while we have received positive coverage determinations for certain specified uses and indications of our Signatera test from

commercial third- party payers as well as the Molecular Diagnostic Services Program, or MolDx, which identifies and establishes Medicare coverage and reimbursement for molecular diagnostic tests, **as well as for our Prospera Kidney and Lung tests,** we cannot guarantee that our ~~test~~ **tests** will be reimbursed at the ~~rate~~ **rates** we expect ~~. Furthermore~~ , ~~while we have also received positive coverage decisions from MolDx for~~ - **or** ~~our Prospera Kidney and Lung tests, we cannot guarantee that our tests will continue to be reimbursed~~ at the same or ~~a~~ similar ~~rate~~ **rates** as we have received thus far. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in network status with, third- party payers for our existing or future tests, our ability to generate revenues will be limited. For example, physicians may be reluctant to order our tests due to the potential of a substantial out- of- pocket cost to the patient if reimbursement coverage is unavailable or insufficient. In making coverage determinations, third- party payers often rely on practice guidelines issued by professional societies. The practice guidelines issued by professional societies now generally acknowledge that NIPT is the most sensitive screening option for, and / or are generally supportive of NIPT in, average- risk pregnancies, in addition to high- risk pregnancies. However, while most third- party payers now reimburse for NIPT for average- risk patients, it remains the case that not all third- party payers, particularly state Medicaid payers, do so. Furthermore, many third- party payers do not reimburse for microdeletions screening. While we have published data on the performance of Panorama for the 22q11. 2 deletion syndrome, including most recently from our SMART Study, we have and may continue to experience low reimbursement rates for Panorama for microdeletions, and we may otherwise be unable to obtain positive coverage determinations for our test. If third- party payers do not reimburse for NIPT for microdeletions in the future, our future revenues and results of operations ~~would~~ **may** be adversely affected, particularly to the extent that we continue to perform large volumes of tests for which third- party payers do not reimburse. In addition, **although there is** a CPT code **in place** for microdeletions **testing, we** ~~took effect in January 2017. We~~ have experienced low average reimbursement rates for microdeletions under this **CPT** code, and we expect ~~that this code will continue to cause~~ our microdeletions reimbursement to remain low, at least in the near term, due to third- party payers declining to reimburse and as a result of reduced reimbursement, under the code, which has had, and we expect to continue to have, an adverse effect on our revenues. ~~Also, a CPT code for expanded carrier screening tests took effect in January 2019.~~ The ~~code has caused and may continue to cause reimbursement rates for our broader Horizon carrier screening panel to decrease because those tests may be reimbursed as a combined single panel instead of as multiple individual tests. 47The~~ reimbursement environment, particularly for molecular diagnostics, is continually changing and our efforts to broaden reimbursement for our tests with third- party payers may not be successful. Third parties, such as commercial health insurers and government programs, from whom we have received reimbursement may withdraw coverage or decrease the amount of reimbursement for our tests at any time and for any reason, or may otherwise adopt requirements, programs or policies that may restrict or adversely affect our business. In addition, in some cases, our tests or their uses ~~within~~ **46within** certain populations, such as for microdeletions, are considered experimental by third- party payers and, as a result, some payers have decided not to cover or reimburse for such tests. Some third- party payers bundle payment for multiple tests or tests that screen for multiple conditions, such as our Horizon test or our Panorama test and the separate Panorama screen for microdeletions, into a single payment rate, thereby limiting our reimbursement in those situations. Payers may also dispute our billing or coding. Based on any of the foregoing, third- party payers may also 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 deal with requests for recoupment from third- party payers from time to time in the ordinary course of our business, and it is likely that we will continue to do so in the future. See " Note 8 — Commitments and Contingencies — Third- Party Payer Reimbursement Audits " in the Notes to Consolidated Financial Statements. If a third- party payer denies payment for testing, reimbursement revenue for our testing could decline. If a third- party payer successfully proves that payment for prior testing was in breach of contract or otherwise contrary to law, they may recoup payment or bring legal action to do so, which amounts could be significant and would adversely impact our results of operations, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third- party payer in order to resolve an allegation of overpayment. Any of these outcomes might require us to restate our financials from a prior period, which would likely cause our stock price to decline. For example, in 2018 we reached a settlement with certain government payers regarding past reimbursement submissions; although the settlement involved no admission of fault by us and no corporate integrity agreement, we cannot guarantee that we will not be subject to similar claims, resulting in additional settlements or repayments, in the future. Furthermore, some of our contracts with third- party payers contain so- called most favored nation provisions, pursuant to which we have agreed that we will not bill the third- party payer more than we bill any other third- party payer. We must therefore monitor our billing and claims submissions to ensure that we remain in compliance with these contractual requirements with third- party payers. If we do not successfully manage these most favored nation provisions, we may need to forego revenues from some third- party payers or reduce the amount we bill to each third- party payor with a most- favored nation clause in its contract that is violated, which would adversely affect our revenues. This situation could also subject us to claims for recoupment, which could require the time and attention of our management, require the expense of engaging outside counsel or consultants, and may be a distraction from development of our business, adversely impacting our operations. Such recoupment demands could also ultimately result in an obligation to repay amounts previously earned. In addition, if a third- party payer denies coverage, it may be difficult for us to collect from the patient, and we may not be successful in doing so. In particular, we are often unable to collect the full amount of a patient' s responsibility where we are an out- of- network provider and the patient is left with a large balance, despite our good faith efforts to collect. As a result, we cannot always collect the full amount due for our tests when third- party payers deny coverage, cover only a portion of the invoiced amount or the patient has a large cost- sharing obligation, which may cause payers to raise questions regarding our billing policies and patient collection practices. We believe that our billing policies and our patient collection practices are compliant with applicable laws and reimbursement policies. However, from time to time we receive inquiries from

third- party payers regarding our billing policies and collection practices. We address these inquiries as and when they arise, but there is no guarantee that we will always be successful in addressing such concerns in the future, which may result in a third- party payer deciding to reimburse for our tests at a lower rate or not at all, seeking recoupment of amounts previously paid to us, or bringing legal action to seek reimbursement of previous amounts paid. Any of such occurrences could cause reimbursement revenue for our testing, which constitutes the large majority of our revenue, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, which would adversely impact our results of operations, and we might be required to restate our financials from a prior period, which would likely cause our stock price to decline. ~~48Our~~ -- **Our** revenues may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs. Medicare reimbursement impacts our revenues from our oncology and organ health products, as a large proportion of these patients are covered by Medicare. Medicare beneficiaries generally do not receive our women' s health testing. However, Medicare reimbursement can affect both Medicaid reimbursement, which is relevant to our NIPT, and reimbursement from commercial third- party payers. Specifically, fee- for- service Medicaid programs generally do not ~~reimburse~~ **47reimburse** at rates that exceed Medicare' s fee- for- service rates, and many commercial third- party payers set their payment rates at a percentage of the amounts that Medicare pays for such testing services. Medicare reimbursement rates are typically based on the Clinical Laboratory Fee Schedule, or CLFS, set by CMS. Our current Medicare Part B reimbursement for Panorama was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the certainty afforded by a formal national coverage determination by CMS. Thus, CMS could issue an adverse coverage determination as to Panorama which could influence other third- party payers, including state Medicaid programs, and could have an adverse effect on our revenues. It is estimated that nearly half of all births in the United States are to state Medicaid program beneficiaries. Each state' s Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide coverage for our testing. Even if our testing is covered by a state Medicaid program, we must be recognized as an enrolled Medicaid provider by the state in which the Medicaid beneficiary receiving the services resides in order for us to be reimbursed by a state' s Medicaid program, including under a Medicaid managed care plan. Furthermore, in certain states that have implemented managed care organizations, or MCOs, that are typically operated by commercial third- party payers, we would also need to contract with one or more MCOs as a participating provider for us to be reimbursed for testing services that we provide to a Medicaid beneficiary. Our San Carlos, CA laboratory is enrolled as a Medicaid provider in ~~50~~ **51** U. S. states or territories and our Austin, TX laboratory is enrolled as a Medicaid provider in ~~40~~ **43** states ~~, with additional applications underway for both laboratories~~ . However, even if we are recognized as a Medicaid provider in a state, if Medicare' s CLFS rate for our services and tests are low, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition, from time to time we receive requests from state Medicaid programs seeking information or documents to determine eligibility for and the amount of Medicaid reimbursement. As a result of all of these factors, many state Medicaid programs only reimburse our testing at a low dollar amount, or not at all. Low or zero- dollar Medicaid reimbursement rates for our tests could have an adverse effect on our business and revenues. Our revenues may be adversely impacted if third- party payers withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors. We are in- network, or under contract, with the significant majority of third- party payers from whom we receive reimbursement; this means that we have agreements with most third- party payers that govern test approval or payment terms. However, these contracts do not guarantee reimbursement for all testing we perform. For example, third- party payers with whom we have written agreements may have time- sensitive deadlines to file claims or may have policies that state they will not reimburse for the screening of microdeletions, or don' t have a policy in place to reimburse for microdeletions screening. In addition, the terms of certain of our payer agreements require the ordering physician or qualified practitioner' s signature on test requisitions or require other controls and procedures prior to conducting a test. In particular, third- party payers have increasingly required prior authorization to be obtained prior to conducting a test, as a condition to reimbursing for the test. This has placed a burden on our billing operations as we have to dedicate or source resources to ensuring that these requirements are met and to conduct follow- up and address issues as they arise, and has also impacted our results of operations, including our gross margins, since these requirements began to take effect. To the extent we or the physicians ordering our tests do not follow the prior authorization requirements, we may be subject to claims for recoupment of reimbursement amounts previously paid to us, or may not receive some or all of the reimbursement payments to which we would otherwise be entitled. This has occurred in some cases and may occur more frequently in the future, which does and would have an adverse impact on our revenues. Where we are considered to be an out of network provider, which is the case with some third- party payers from whom we receive reimbursement, such third- party payers could deny coverage and decline to reimburse for our tests ~~49according~~ -- **according** to each plan enrollee' s policy. Managing reimbursement on a case- by- case basis is time- consuming and contributes to an increase in the number of days it takes us to collect on accounts, which also increases our risk of non- payment. Negotiating reimbursement on a case- by- case basis also typically results in the receipt of reimbursement at a significant discount to the list price of our tests. Even if we are being reimbursed for our tests, third- party payers may review and adjust the rate of reimbursement, require patient cost- sharing, or stop paying for our tests. Government and commercial third- party payers continue to ~~increase~~ **48increase** their efforts to control the cost, utilization and delivery of healthcare services by demanding price discounts or rebates and limiting coverage of, and amounts they will pay for, molecular diagnostic tests. These measures have resulted in reduced payment rates and decreased utilization in the clinical laboratory industry. Because of these cost- containment measures, governmental and commercial third- party payers may reduce, suspend, revoke or discontinue payments or coverage at any time, including payors that currently provide reimbursement for our tests. Reduced reimbursement of our tests may harm our business, financial condition or results of operations. Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where

we expect to receive a fixed fee per test due to our reimbursement arrangements, we may nevertheless encounter disputes over pricing and billing. Among the factors complicating our billing of third- party payers are disparity in coverage among various payers; disparity in, and increasingly difficult, information and billing requirements among third- party payers, including with respect to prior authorization requirements and procedures and establishing medical necessity; and incorrect or missing billing information, which is required to be provided by the ordering healthcare practitioner. These billing complexities, and the associated uncertainty in obtaining payment for our tests, could result in reduced reimbursement of our tests, which could harm our business, financial condition and results of operations. A CPT code specific to NIPT for aneuploidies, and a CPT code for microdeletions, are in place, and CMS has established a pricing benchmark for aneuploidy and microdeletions testing. However, our microdeletions reimbursement has remained low because third- party payers are declining to reimburse, or reimbursing at low rates, under the microdeletions CPT code. Furthermore, we cannot guarantee that any data that we publish, such as from our SMART Study, will be sufficient to enable us to obtain positive coverage determinations for Panorama for microdeletions, negotiate favorable rates under the microdeletions CPT code, or receive reimbursement at all for this testing. ~~In addition, a CPT code for expanded carrier screening tests has been implemented, which has caused and may continue to cause reimbursement rates for our Horizon expanded carrier screening tests to decline.~~ We do not currently have assay- specific CPT codes assigned for all of our tests, and there is a risk that we may not be able to obtain such codes or, if obtained, we may not be able to negotiate favorable rates for such codes. We currently submit for reimbursement using CPT codes based on the guidance of outside coding experts and legal counsel. There is a risk that the codes we currently submit may be rejected or withdrawn or that third- party payers will seek refunds of amounts that they claim were inappropriately billed based on either the CPT code used, or the number of units billed. In addition, third- party payers may not establish positive coverage policies for our tests or adequately reimburse for any CPT code we may use, or seek recoupment for testing previously performed, which have occurred in the past. Regulatory and Compliance Risks We may be subject to increased compliance risks as a result of our rapid growth, including our dependence on our sales, marketing and billing efforts. **We are highly reliant on** ~~Approximately 91 % and 89 % of~~ our ~~total~~ **sales, marketing and billing activities to generate** revenues **in** ~~for each of the years ended December 31, 2023 and 2022, respectively, were attributable to~~ our **business** ~~U. S. direct sales~~. We maintain a heightened focus on our training and compliance efforts in line with our reliance on personnel in **these** ~~our sales, marketing and billing~~ functions, and the significance of these functions as components of our business. We continue to educate, train and monitor our personnel, but from time to time we experience situations in which employees fail to strictly adhere to our policies. In addition, sales and marketing activities in the healthcare space are subject to various rules and regulations, as described in the risk factor entitled " Reimbursement and Regulatory Risks Related to Our Business — If we or our laboratory distribution partners, consultants or commercial partners act in a manner that violates healthcare fraud and abuse laws or otherwise engage in misconduct, we may be subject to civil or criminal penalties. " Moreover, our billing and marketing messaging can be complex and ~~50nuanced~~ -- **nuanced** , and there may be errors or misunderstandings in our employees' communication of such messaging. Furthermore, we utilize text messaging, email, phone calls and other similar methods to communicate with patients who are existing or potential users of our products for various business purposes. These activities subject us to laws and regulations relating to communications with consumers, such as the CAN- SPAM Act and the Telephone Consumer Protection Act, violations of which could subject us to claims by consumers, who may seek actual or statutory damages, as has happened in the past, which could be material in the aggregate. As our sales and marketing efforts continue to be critical to our business, with respect to both our expanding product portfolio as well as continued geographical expansion, we will continue to face an increased need to remain vigilant in monitoring and improving our policies, processes and procedures to maintain compliance with a growing number and variety of laws and regulations, including with respect to consumer marketing. To the extent that there is any violation, whether actual, perceived or alleged, of our ~~policies~~ **49policies** or applicable laws and regulations, we may incur additional training and compliance costs; may, and from time to time do, receive inquiries, such as informal requests for documents, civil investigative demands, and subpoenas, from third- party payers or other third parties, including government entities; or may be held liable or otherwise responsible for such acts of non- compliance. Any of the foregoing could adversely affect our cash flow and financial condition. If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket 510 (k) clearance, de novo classification, or premarket approval and incur costs associated with complying with post- market controls. We currently offer a number of genetic tests, and each of those tests is an LDT. The FDA considers an LDT to be a test that is designed, developed, validated and used within a single laboratory. Our laboratories are currently regulated under CLIA and must comply with CAP requirements, and we are subject to extensive federal and state laws and regulations. The FDA has historically taken the position that it has the authority to regulate LDTs as medical devices under the FDC Act, but it ~~has~~ **had** generally exercised enforcement discretion with regard to such tests. **The final rule issued by FDA in May 2024, discussed in the section of** ~~This~~ **this** ~~means~~ **Annual Report on Form 10- K entitled " Business — Government Regulations — FDA ", could have a significant impact on our ability to market current LDTs and to develop new ones in the future. Although our LDTs marketed prior to May 6, 2024 may be eligible for enforcement discretion with respect to premarket review requirements, changes we make to such LDTs, as well as new LDTs we develop after** that ~~even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, de novo classification, or 510 (k) clearance, it has generally chosen not to enforce those requirements to~~ date ~~. The regulatory environment for LDTs is unstable -- in 2020 HHS directed FDA to stop regulating LDTs~~ , ~~but in 2021, HHS reversed its policy. Thereafter, the FDA resumed requiring submission of emergency use authorization, or EUA, requests, for COVID- 19 LDTs, but did not seek to regulate other, non- COVID, LDTs. Various legislation has been introduced seeking to substantially revamp the regulation of both LDTs and IVDs. In June 2021, legislation called the Verifying Accurate, Leading- edge IVCT Development Act, or VALID Act, which would have established a new risk- based regulatory framework for in vitro clinical tests, or IVCTs, a category that would have included IVDs, LDTs, collection devices, and instruments used with such tests was~~

~~introduced in Congress. This legislation was not enacted during that session of Congress but was reintroduced in 2023 and its prospects for enactment are unclear. In addition, the FDA announced a proposed rule regarding LDTs in September 2023, and has indicated that it plans to finalize the proposed rule in the second quarter of 2024, though we cannot be certain that the rule~~ will be **subject** ~~finalized on this timeline or at all. The proposed regulation would classify LDTs as medical devices, which would likely require us~~ to **various** ~~adhere to additional~~ regulatory requirements such as those described in this risk factor. If FDA premarket clearance, approval or de novo classification is required for any of our existing or future tests, or for any components or materials we use in **, or software that we or our customers use as part of, our** tests, we may be forced to stop selling our tests or we may be required to modify claims for or make other changes to our tests while we or our suppliers work to obtain FDA clearance, approval or de novo classification. Our business could be adversely affected while such review is ongoing and if we or our supplier are ultimately unable to obtain premarket clearance, approval or de novo classification. For example, the regulatory premarket clearance, approval or de novo classification process may involve, among other things, submitting a 510 (k) premarket notification, a request for de novo classification, or a PMA application to the FDA. As further described in the risk factor entitled " Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations, " completing such submissions requires the expenditure of time, attention and financial and other resources, and may not yield the desired results, which may delay, limit or prevent regulatory clearances, approvals or de novo classifications. In addition, we may require cooperation in our filings for FDA clearance, approval or de novo classification from third- party manufacturers of the components of our tests. If we are unable to obtain such required cooperation, we may be unable to achieve the desired regulatory clearances, approvals or de novo classifications or may be delayed or be required to expend additional costs ~~51and~~ -- **and** other resources in doing so. For example, Illumina currently is our sole sequencer and sequencing reagent supplier. If we seek to achieve regulatory clearance, approval or de novo classification for Panorama, to the extent that Panorama incorporates Illumina' s sequencer or sequencing reagents, we may require Illumina' s cooperation in the regulatory process. We may face difficulty obtaining cooperation from Illumina because Illumina is the parent company of Verinata, a direct competitor of ours in the NIPT field. In addition, we have been party to certain intellectual property proceedings with Illumina as described elsewhere in these Risk Factors. Moreover, if FDA premarket clearance, approval or de novo classification is required, our cash flows may be adversely affected until we obtain such clearance, approval or de novo classification, as most third- party payers, including Medicaid, will not reimburse for use of medical devices which are required to, but which do not, have marketing authorization. Furthermore, the FDA may conclude that ~~laboratories using~~ Constellation **is subject to regulation** ~~and related products from us do not meet the criteria for qualifying~~ as **CDS** ~~an LDT~~ , **which** ~~and require that such laboratories discontinue use of Constellation and related products. Such an FDA determination~~ could have an adverse impact on **our ability to commercialize our Constellation software. The need to obtain regulatory clearance, approval or de novo classification for Constellation could cause us to incur substantial costs and delays and interfere with our customers' ability to use** the **software in the development and** commercialization of ~~Constellation~~ **their diagnostic tests based on our technology** . The FDA has granted us Breakthrough Device designations for our Signatera test covering its use in various applications. While receiving such designations enables us to have increased interactions with FDA, we cannot assure you that these designations will lead to accelerated review or approval of our regulatory submissions for Signatera. ~~We~~ **50We** cannot assure you that, if we decide or are required to seek premarket clearance or approval or de novo classification for Panorama or any of our other tests, our efforts will succeed on a timely basis or at all. In addition, after a test has been cleared, approved or reclassified **through the de novo pathway** , certain kinds of changes that we may make to improve the test, or certain modifications by a supplier of a component upon which our approval relies, may result in the need for additional clearance, approval, or de novo classification by the FDA before we can implement them, which could increase the time and expense involved in implementing such changes commercially. The need for compliance with such FDA regulations would be time- consuming and expensive, potentially diverting resources from other aspects of our business, and we could be subject to legal actions, including fines and penalties, if we fail to comply with these requirements, any of which may adversely impact our business and results of operations. Furthermore, the FDA or the Federal Trade Commission, or FTC, as well as state consumer protection agencies, may object to the materials and methods we use to promote the use of our current tests or other LDTs we may develop in the future, including with respect to the product claims in our promotional materials, and may initiate enforcement actions against us. Enforcement actions by the FDA may include, among others, untitled or warning letters; fines; injunctions; civil or criminal penalties; recall or seizure of current or future tests, products or services; operating restrictions and partial suspension or total shutdown of production. Enforcement actions by the FTC and state consumer protection agencies may include, among others, injunctions, civil penalties, and equitable monetary relief. ~~If any of our software is determined by FDA to be non- exempt clinical decision support software, this could impede our ability to perform certain activities, and we could incur substantial costs and delays associated with trying to obtain premarket 510 (k) clearance, de novo classification, or premarket approval and incur costs associated with complying with post market controls. We may also need to obtain regulatory clearance, approval or de novo classification in the United States for our Constellation software in order for it to be used by third parties in the development and commercialization of their diagnostic tests based on our technology. The 21st Century Cures Act, enacted in 2016, includes a number of provisions relating to the FDA' s regulatory approach to software that may have bearing on the regulatory status of our Constellation software. We have discussed with the FDA the regulatory status of a portion of our Constellation software, the copy number calculator, or CNC. The FDA has indicated that the CNC may be appropriate for review under the de novo classification process, which is less burdensome than the PMA process. The FDA has stated that it would not prevent us from marketing Constellation in the United States; however, it is possible that the FDA may reverse itself either on the appropriate regulatory review path or regarding our ability to continue to market Constellation. We cannot assure you that, if we decide or are required to seek premarket clearance or approval or de novo classification for our software, our efforts will succeed on a~~

~~timely basis or at all. If we are unable to do so, we may be unable to commercialize our cloud based distribution model in the United States. If we are able to do so, we may be subject to ongoing FDA obligations and continued regulatory oversight and review. If we are not able to maintain regulatory~~  ~~compliance to the extent required, we may not be permitted to offer our Constellation software and may be subject to enforcement action by the FDA, such as the issuance of warning or untitled letters, fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and criminal prosecution.~~ Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue commercializing our cloud- based distribution model. An important part of our business strategy is to expand and offer our tests internationally, either by providing our testing services directly or through our laboratory partners, or through our licensees under our Constellation cloud- based distribution model. As we do so, we will become increasingly subject to or impacted by the regulatory requirements of foreign jurisdictions, which are varied and complex. Our tests, and certain components of our tests, may be subject to the regulatory approval requirements in each foreign country in which they are sold by us or a laboratory partner, or by our licensees under our cloud- based distribution model, and our future performance would depend on us or our partners or licensees obtaining any necessary regulatory approvals in a timely manner. For example, while we have entered into a license agreement with BGI Genomics to commercialize our Signatera test in China using BGI Genomics' s sequencing instruments and platform, such commercialization and development activities are subject to obtaining and maintaining necessary regulatory approvals in the relevant jurisdictions. In addition, we have obtained a CE Mark from the European Commission for our Constellation software and the key reagents for our licensees to run their NIPT based on our technology, as well as a CE Mark for our Panorama test as a whole. Therefore, we offer our Panorama test as an IVD both directly and through our Constellation model in these jurisdictions. We are occasionally required to address inquiries from regulatory authorities in various countries, such as those in the European Union, regarding the regulatory status of our Panorama or Constellation offerings. If we do not continue to satisfactorily address any such questions in the future, we may be required to cease offering our products, either directly or through our partners or licensees, in the relevant country. This may in turn result in similar concerns, and subsequent cessation of our sources of revenue, in other countries. In addition, as further described in the risk factor entitled " Risks Related to Our Business and Industry — We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers, " blood collection tubes sourced solely from Streck are required to run our tests. These blood collection tubes are CE Marked by the European Commission; however, if such blood collection tubes are not registered in jurisdictions that do not accept a CE Mark, we may be unable to expand our business in such jurisdictions. Regulatory approval can be a lengthy, expensive and uncertain process. In addition, regulatory processes are subject to change, and new or changed regulations can result in unanticipated delays and cost increases. For example, the European Commission ~~has~~ adopted revised in- vitro diagnostic regulations, or IVDR, which became effective in 2022. Among others, the new regulations ~~introduce~~ **introduced** risk- based classification for IVDs and ~~will~~ require notified body involvement for various classes of devices, including reproductive health tests such as Panorama, which **are** ~~will be~~ classified as a Class C product. As such, we **are** ~~will also be~~ required to submit clinical evidence and post- market performance data to regulators. We or our partners or licensees may not be able to obtain regulatory approvals on a timely basis, if at all, which may cause us to incur additional costs or prevent us from marketing our tests in the United States or in foreign countries. ~~Changes~~ **51Changes** in laws and regulations, or in their application, may adversely affect our business, financial condition and results of operations. The clinical laboratory testing industry is highly regulated, and failure to comply with applicable regulatory, supervisory, accreditation, registration or licensing requirements may adversely affect our business, financial condition and results of operations. In particular, the laws and regulations governing the marketing and research of clinical diagnostic testing are extremely complex and in many instances there are no clear regulatory or judicial interpretations of these laws and regulations, increasing the risk that we may be found to be in violation of these laws. Furthermore, the molecular diagnostics industry as a whole is a growing industry and regulatory bodies such as HHS or the FDA may apply heightened scrutiny to our products or to new developments in the field. While we have taken steps to ensure compliance with the current regulatory regime in all material respects, given its nature and our geographical diversity, there could be areas where we are non- compliant. Any change in the federal or state laws or regulations, ~~53including~~ -- **including** as a result of political pressure, relating to our business may require us to implement changes to our business or practices, and we may not be able to do so in a timely or cost- effective manner. Should we be found to be non- compliant with current or future regulatory requirements, we may be subject to sanctions which could include substantial financial penalties and criminal proceedings, which could result in changes to our operations, adverse publicity and other consequences, which may adversely affect our business, financial condition and results of operations by increasing our cost of compliance or limiting our ability to develop, market and commercialize our tests. While we have a compliance plan and policies to address compliance with federal and state laws and regulations, including applicable fraud and abuse laws and regulations such as those described in this risk factor, the evolving commercial compliance environment and the need to build and maintain robust and scalable systems to comply with laws and regulations in multiple jurisdictions with different compliance and reporting requirements increases the possibility that we could inadvertently violate one or more of these requirements. If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business. We are subject to CLIA, a federal law that, in partnership with the states, regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease or impairment of, or assessment of the health of, human beings. CLIA regulations require clinical laboratories to obtain a certificate and mandate specific standards in areas including personnel qualifications, administration, participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill federal health care programs, as well as many commercial third- party payers, for our tests. Our laboratories located in Austin, Texas and San Carlos, California are both CLIA

certified and accredited by the College of American Pathologists, or CAP, a third- party accreditation organization with deeming, or delegated, authority from CMS to determine compliance. To renew these certifications, we are subject to a formal external survey and inspection of each site at least every two years. Moreover, CLIA and / or state inspectors may conduct random inspections of our clinical laboratory or conduct an inspection as a result of a complaint or reported incident, as has occurred. Any failure to address identified deficiencies, or to otherwise comply with CLIA, CAP or state requirements, can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA and / or CAP certificate of accreditation or state laboratory permit, as well as a directed plan of correction, on- site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties, suspension or exclusion from the Medicare and Medicaid programs **,** and significant adverse publicity. Bringing our laboratory back into compliance with CLIA requirements could cause us to incur significant expenses and potentially lose revenues in order to address deficiencies and achieve compliance. Some U. S. states require that we hold licenses or permits to test samples from patients in those states, even if our laboratory facilities are not located in those states, and as a result we are also required to maintain standards related to those states' licensure requirements to conduct testing in our laboratories. California requires laboratories operating in or testing specimens from individuals located in California to hold state licensure in addition to CLIA certification. California laboratory registration is required for our San Carlos, California as well as for our Austin, Texas laboratory, because our Texas laboratory receives specimens originating from California. The State of Texas imposes CLIA requirements on laboratories operating within Texas but does not impose additional state licensure or registration requirements. ~~Additionally~~ **52Additionally** , all personnel involved in testing in our California laboratory must maintain a California state license or be supervised by licensed personnel. We maintain a license in good standing with the California Department of Public Health, or CDPH, for both our California and Texas laboratories. In addition, the New York State Department of Health, or NYSDOH, requires out- of- state laboratories that test specimens originating from New York to hold an NYSDOH permit and to comply with NYSDOH laboratory standards, including prior NYSDOH approval of LDTs. Both our Austin, Texas and San Carlos, California laboratories have received approval from the NYSDOH to offer certain of our tests to residents of New York, and we process samples originating from New York at each of these laboratories in accordance with the NYSDOH approvals. Our laboratory director must also maintain a license to perform testing issued by the CDPH as well as a Certificate of Qualification issued by NYSDOH. As under CLIA, we are subject to routine on- site inspections or inspections in response to a complaint under both California and New York state laboratory laws and regulations. If we are found to be out of compliance with either California or New York requirements, CDPH or NYSDOH may suspend, restrict or revoke our license or laboratory permit, ~~54respectively~~ -- **respectively** (and, with respect to California, may exclude persons or entities from owning, operating or directing a laboratory for two years following such license revocation), assess civil monetary penalties, or impose specific corrective action plans, among other sanctions. We cannot assure you that the regulators in any state from which we have obtained a required license or permit will find us to be in compliance with the applicable laws of their respective state at all times, which may result in suspension, limitation, revocation or annulment of our laboratory' s license for that state or negative impact to our CLIA certificate, censure, or civil monetary penalties, and would result in our inability to test samples from patients in that state. Any such consequences could materially and adversely affect our business by prohibiting or limiting our ability to offer testing. Changes in government **spending or** healthcare policy could increase our costs and negatively impact coverage and reimbursement for our tests by governmental and commercial third- party payers. The U. S. government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U. S. federal government and many U. S. state governments. As a result, our business could be affected by potentially significant and unanticipated changes in government healthcare policy, such as changes in reimbursement levels by government third- party payers, or in government- sponsored programs in which we may participate. Any such changes could substantially impact our revenues, increase costs and divert management attention from our business strategy. We cannot predict the impact, if any, of governmental healthcare policy changes on our business, financial condition and results of operations. In the U. S., the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or collectively, the PPACA expanded, among other things, the healthcare fraud and abuse laws such as the False Claims Act and the Anti- Kickback Statute, including but not limited to required disclosures of financial arrangements with physician customers, required reporting of discovered overpayments, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations ~~. There have been multiple attempts to repeal PPACA or significantly scale back its applicability, which if successful could negatively impact reimbursement for our testing, and could adversely affect our test volumes and, in turn, our business, financial condition, results of operations, and cash flows. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, repealed the requirement under PPACA that consumers buy insurance or pay a penalty unless they qualified for an applicable exemption. The repeal of this mandate means that fewer consumers may carry insurance coverage and therefore may be less likely to elect to receive our testing because they would be required to pay out of pocket for such tests, which could impact our test volumes and adversely affect our business, financial condition, results of operations, and cash flows~~ . The PPACA also created a system of health insurance " exchanges " designed to make health insurance available to individuals and certain groups through state- or federally- administered marketplaces in addition to existing channels for obtaining health insurance coverage. If Panorama or any of our other tests are not covered by plans offered in the health insurance exchanges, our business, financial condition and results of operations could be adversely affected. Furthermore, various proposed legislative initiatives with respect to the PPACA in the past, including possible repeal of the PPACA, have resulted in considerable uncertainty and concern regarding, for example, a patient' s election to undergo genetic screening and whether doing so may impact health insurance eligibility. Because it is unclear whether or how the PPACA may continue to evolve, be modified, or otherwise change, and whether and to what extent NIPT, cancer screening or other genetic screening may be affected, we are uncertain how our business may be impacted. In addition to the PPACA,

various healthcare reform proposals have also emerged from federal and state governments. Under PAMA, services payable by Medicare under the CLFS are adjusted based on negotiated payment rates paid by private payers for the same test. The implementation of the PAMA rates negatively impacted overall pricing and reimbursement for many clinical laboratory testing services. The PAMA rate reductions did not have a material impact on our business when they were implemented because our revenues from Medicare were very low at the time. The PAMA ~~reductions~~ **53reductions and reporting requirements** were suspended in 2021 and ~~are expected~~ **have continued** to ~~resume in~~ **be delayed, most recently until** ~~2025~~ **2026** . Due to our increased billing for our Signatera and Prospera testing, and in particular the significant and growing percentage of our revenues attributable to Signatera, any decrease in the reimbursement we receive under the CLFS due to PAMA may negatively impact our revenue when ~~they~~ **the PAMA rates** are implemented. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests and requirements that beneficiaries of federal health care programs pay for, or pay for higher portions ~~55of~~ **of** , clinical laboratory tests or services received, could substantially diminish the utilization of our tests, increase costs and adversely affect our ability to generate revenues and achieve profitability **. Statutory, regulatory, and policy changes, or government budget and funding levels, may also adversely impact the ability of the FDA, the NIH and other regulatory authorities to perform their regulatory functions. Additionally, over the last several years, the U. S. government has shut down multiple times and certain regulatory agencies have had to furlough critical government employees and stop critical activities. Inadequate funding for such organizations and / or potentially shifting priorities, including under the new administration, could prevent or delay regulatory review and approval processes, adversely affect their ability to hire and retain key personnel, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, any of which could negatively impact our business, including our ongoing research, development and commercialization initiatives** . We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or how any such future legislation, regulation or initiative may affect us. Current or potential future federal legislation and the expansion of government' s role in the U. S. healthcare industry, ~~as well as~~ changes to the reimbursement amounts paid by third- party payers for our current and future tests, **or limited or inadequate funding for regulatory authorities,** may adversely affect our test volumes and adversely affect our business, financial condition, results of operations, and cash flows. If we or our laboratory distribution partners, consultants or commercial partners act in a manner that violates healthcare fraud and abuse laws or otherwise engage in misconduct, we may be subject to civil or criminal penalties. We are subject to healthcare fraud and abuse regulation and enforcement by both the U. S. federal government and the states in which we conduct our business, including: • HIPAA, which created federal civil and criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and also imposes significant obligations with respect to maintenance of the privacy and security, and transmission, of individually identifiable health information; • federal and state laws and regulations governing **consumer protections, data privacy,** informed consent for genetic testing **,** and the use of genetic material; • federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services; • the federal Anti- Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as Medicare; • the federal False Claims Act which prohibits, among other things, the presentation of false or fraudulent claims for payment from Medicare, Medicaid, or other government- funded third- party payers; • federal laws and regulations governing the Medicare program, providers of services covered by the Medicare program, and the submission of claims to the Medicare program, as well as the manuals and guidance issued by CMS and the local medical policies promulgated by the Medicare Administrative Contractors with respect to the implementation and interpretation of such laws and regulations; **54** • the federal Stark law, also known as the physician self- referral law, which, subject to certain exceptions, prohibits a physician from making a referral for certain designated health services covered by the Medicare program (and according to case law in some jurisdictions, the Medicaid program as well), including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services; • the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration to a Medicare or state healthcare 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 a state healthcare program; • EKRA, which applies to items or services reimbursed by any health care benefits program, including commercial insurers, that, among other things, prohibits the knowing or willful payment or offer, or the solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing; ~~56~~ • the prohibition on reassignment by the **Medicare or Medicaid** program beneficiary of ~~Medicare~~ claims to any party; and • state law equivalents to the above laws, which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and state data privacy and security laws which may be more stringent than HIPAA. Furthermore, ~~in recent years~~ our industry has experienced increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act' s " whistleblower " or " qui tam " provisions ~~. The False Claims Act imposes liability for~~ , ~~among~~ **which are described in further detail in** ~~other~~ -- **the section of** ~~things~~ -- **this Annual Report** ~~, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to a federal governmental program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions~~ on ~~behalf of the federal~~ **Form 10- K entitled " Business —** ~~government~~ **Government Regulations — Healthcare Fraud** ~~for violations of the False Claims Act~~ and **Abuse Laws "** ~~permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement~~ . When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus mandatory civil penalties – up to approximately $ ~~27~~ **28** , ~~108~~ **619** in ~~2023~~ **2025** –

for each false claim or statement. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and in some cases go even further because many of these state laws apply where a claim is submitted to any third- party payer and not merely a governmental program. For example, in 2018 we reached a settlement with certain government payers regarding past reimbursement submissions. Although the settlement involved no admission of fault by us and no corporate integrity agreement, we cannot guarantee that we will not be subject to similar claims in the future. Many of these laws and regulations have not been fully interpreted by regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, there has been a recent trend of increased U. S. federal and state regulation, scrutiny and enforcement relating to payments made to referral sources, which are governed by these laws and regulations. We have adopted policies and procedures designed to comply with these laws, and in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. However, the rapid growth and expansion of our business both within and outside of the United States may increase the potential for violating these laws or our internal policies and procedures, and the uncertainty around the interpretation of these laws and regulations increases the risk that we may be found in violation of these or other laws and regulations, or of allegations of such violations, including pursuant to private qui tam actions brought by individual whistleblowers in the name of the government as described above. If our operations, including the conduct of our employees, distributors, consultants and commercial partners, are found to be in violation of any laws or regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement of profits, exclusion from participation in federal health care programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could materially and adversely affect our business, financial condition and results of operations. ~~Failure~~ **55Failure** to comply with privacy and security laws and regulations could result in fines, penalties and damage to our reputation and have a material adverse effect on our business. ~~The~~ **We are a covered entity and a business associate of other covered entities under the** federal HIPAA privacy and security regulations ~~establish comprehensive federal standards~~ **, which are described in further detail in the section of this Annual Report on Form 10- K entitled " Business — Government Regulations — HIPAA and Other Privacy Laws ". As a result, we must comply** with **certain requirements** ~~respect to the use~~ and **obligations regarding PHI** ~~disclosure of protected health information by health plans, healthcare providers, and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of protected health information. The regulations establish a complex regulatory framework on a variety of subjects~~ , including patient authorization of the use and disclosure of, administrative, technical and physical safeguards for, and analysis of security incidents and breach notification requirements with respect to, **PHI** ~~protected health information~~ . HIPAA provides for significant fines and other penalties for wrongful use or disclosure of protected health information in violation of privacy and security regulations, including potential civil and criminal fines and penalties. The HIPAA privacy and security regulations establish minimum requirements, and do not supersede state laws that are more stringent. A number of states include medical information in the definition of personal information and have implemented requirements or standards more stringent than HIPAA. Therefore, while we have implemented policies and ~~57procedures~~ -- **procedures** related to compliance with the HIPAA regulations, we are also required to comply with various state privacy and security laws and regulations, and could incur penalties, compliance costs as a result of non- compliance, or damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of confidential health information or other private personal information. In addition, other federal and state laws that protect the privacy and security of patient information may be subject to enforcement and interpretation by various governmental authorities and courts, resulting in complex compliance issues. The GDPR data privacy regulations **govern** ~~comprehensively reform the prior~~ data protection **in** ~~rules of~~ the European Union, and are more stringent, provide for higher potential liabilities, and apply to a broader range of personal data than those in the United States. The GDPR **applies** ~~is applicable~~ to **us as a** U. S.- based ~~companies~~ **company** ~~, such as ours,~~ that ~~do~~ **does** business or ~~offer~~ **offers** services in, or that ~~process~~ **processes** or ~~hold~~ **holds** personal data of data subjects in, the European Union. While our current processes and practices comply with the GDPR, we ~~have~~ **will** ~~needed~~ -- **need** to **continue** ~~expend considerable time and resources, including management attention,~~ to ~~revise~~ **monitor** our practices to ensure ongoing compliance with GDPR. Furthermore, the GDPR enables EU member states to enact jurisdiction- specific requirements in key areas, which could require us to implement multiple policies unique to the jurisdictions in which we operate, which could make it more difficult and resource- intensive to continue to operate in the European Union **. As discussed in more detail in " Business — Government Regulations — HIPAA and Other Privacy Laws, " state consumer protection and data privacy laws continue to evolve, with several states' privacy laws coming into effect in recent years, with more expected in the future. These state privacy laws dictate how we can collect, use, store, sell, share, analyze or process personal identifying information and / or consumer or health data received or generated by our business operations** . As we continue to expand and grow our business, our overall compliance with applicable laws and regulations may result in increased costs and attention of management, and failure to comply may result in significant fines, penalties and damage to our reputation. Additionally, the interpretation and application of health- related, privacy and data protection laws are often uncertain, contradictory and in flux, and it is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. As a result, we could be subject to government- imposed fines or orders requiring that we change our practices, which could cause us to incur substantial costs and may adversely affect our business and our reputation. Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers. Many of the sequencers, reagents, kits and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are labeled as for research use only, or RUO. In addition, we offer a version of our Signatera test as an RUO offering. Products that are intended for research use only and are labeled as RUO are exempt from

compliance with FDA requirements, including the approval, clearance or de novo classification and other product quality requirements for medical devices. A product labeled RUO but which is actually intended by the manufacturer for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and subject to FDA enforcement action. The FDA has issued guidance stating that when determining the intended use of a ~~product~~ **56product** labeled RUO, it will consider the totality of the circumstances surrounding distribution of the product, including how the product is marketed and to whom. In addition, many of the reagents used to perform our testing are offered for sale as analyte specific reagents, or ASRs. ASRs are medical devices and must comply with QSR provisions and other device requirements, but most are exempt from premarket review. The FDA could disagree with a manufacturer' s assessment that the manufacturer' s products are ASRs, or could conclude that products labeled as RUO are actually intended by the manufacturer for clinical diagnostic use, and could take enforcement action against the manufacturer, such as us with respect to Signatera (RUO), including requiring the manufacturer to cease offering the product while it seeks clearance, approval or de novo classification. Manufacturers of RUO products that we employ in our other tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business. The sequencers and reagents supplied to us by Illumina are labeled as RUO in the United States. We are using these sequencers and reagents for clinical diagnostic use. If the FDA were to require clearance, approval or de novo classification for the sale of Illumina' s sequencers and if Illumina does not obtain such clearance, approval or authorization, we would have to find an alternative sequencing platform for Panorama. We currently have not validated an alternative sequencing platform on which Panorama could be run in a commercially viable manner. If we were not successful in selecting, acquiring on commercially reasonable terms and implementing an alternative platform on a timely basis, our business, financial condition and results of operations would be adversely affected. ~~58Our~~ -- **Our** use of hazardous materials in the development of our tests exposes us to risks related to accidental contamination or injury and requires us to comply with regulations governing hazardous waste materials. Our research and development activities involve the controlled use of hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In addition, we are subject on an ongoing basis to federal, state and local regulations governing the use, storage, handling and disposal of these materials and specified hazardous waste materials. An increase in the costs of compliance with such laws and regulations could harm our business and results of operations. If the validity of an informed consent from a patient intake for Panorama or our other tests is challenged, we could be precluded from billing for such testing, forced to stop performing such tests, or required to repay amounts previously received, which would adversely affect our business and financial results. All clinical data and blood samples that we receive for genetic testing are required to have been collected from individuals who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. We seek to ensure that the individuals from whom the data and samples are collected do not retain or have conferred any proprietary or commercial rights to the data or any discoveries derived from them. Our partners operate in a number of different countries in addition to the United States, and, to a large extent, we rely upon them to comply with the individual' s informed consent and with U. S. and international laws and regulations. The collection of data and samples in many different U. S. states and foreign countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under different legal systems. The individual' s informed consent obtained could be challenged in the future in any particular jurisdiction, and those informed consents could be deemed invalid, unlawful or otherwise inadequate for our purposes. Any findings against us, or our laboratory distribution partners, could deny us access to, or force us to stop testing samples in, a particular country or could call into question the results of our clinical trials. We could also be precluded from billing third- party payers for tests for which informed consents are challenged, or could be requested to refund amounts previously paid by third- party payers for such tests. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our revenues and results of operations. ~~Risks~~ **57Risks** Related to Our Intellectual PropertyLitigation or other proceedings resulting from either third- party claims of intellectual property infringement, or asserting infringement by third parties of our technology, is costly, time- consuming, and could limit our ability to commercialize our products or services. Our success depends in part on our non-infringement of the patents or intellectual property rights of third parties, and our ability to successfully prevent third parties from infringing our intellectual property. We operate in a crowded technology area in which there has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the genetic diagnostics industry. Third parties, including our competitors, have asserted and may in the future assert that we are infringing their intellectual property rights; in particular, we are or have recently been engaged in patent infringement lawsuits and other intellectual property disputes against various competitors in each of the industries in which we operate, as described in " Note 8 — Commitments and Contingencies — Legal Proceedings " in the Notes to Consolidated Financial Statements. We may become subject to and / or initiate future intellectual property litigation as our product portfolio, and the level of competition in our industry segments, grow. Should we be unsuccessful defending against patent infringement claims, we may be required to pay substantial royalties, money damages, change our marketing practices, or be enjoined from offering certain products or services. For example, in January 2024, a jury verdict of $ 57 million was awarded against us in a patent infringement lawsuit filed by Ravgen, Inc. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non- infringing alternatives. Any of these or other adverse outcomes could prevent us from offering our tests or otherwise have a material adverse effect on our business, financial condition and our results of operations. ~~59We~~ **We** cannot predict whether, or offer any assurance that, the patent infringement claims we have initiated or may initiate in the future will be successful. We are and may become subject to counterclaims by patent infringement defendants. Our patents may be declared invalid or unenforceable, or narrowed in scope.

Even if we prevail in an infringement action, we cannot assure you that we would be adequately compensated for the harm to our business. If we are unable to enjoin third- party infringement, our revenues may be adversely impacted and we may lose market share; and such third- party product may continue to exist in the market, but fail to meet our regulatory or safety standards, thereby causing irreparable harm to our reputation as a provider of quality products, which in turn could result in loss of market share and have a material adverse effect on our business, financial condition and our results of operations. In addition, our agreements with some of our customers, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in patent infringement claims, including the types of claims described in this risk factor. We have agreed, and may in the future agree, to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, financial condition and results of operations. Any inability to effectively protect our proprietary technologies could harm our competitive position. Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and other countries; this becomes increasingly important as we expand our operations and enter into strategic collaborations with partners to develop and commercialize products. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter difficulties in establishing and enforcing our proprietary rights outside of the United States. In addition, the proprietary positions of companies developing and commercializing tools for molecular diagnostics, including ours, generally are uncertain and involve complex legal and factual questions. This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are protected by valid and enforceable patents or are effectively maintained as trade secrets. We have worked to procure patents protecting our technologies, but our procurement efforts may not always be successful, ~~and~~ **58and** any patents we successfully procure may be challenged in ways that lead to post- procurement scope reduction or invalidity. For example, certain of our intellectual property is, or recently has been, the subject of challenges instituted by our competitors, as described in " Note 8 — Commitments and Contingencies — Legal Proceedings " in the Notes to Consolidated Financial Statements. These challenges may impede our ability to protect our proprietary rights from unauthorized use. In addition, any finding that others have claims of inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms. Certain of our intellectual property was partly supported by a U. S. government grant awarded by the National Institutes of Health, and the government accordingly has certain rights in this intellectual property, including a non- exclusive, non- transferable, irrevocable worldwide license to use applicable inventions for any governmental purpose. Such rights also include " march- in " rights, which refer to the right of the U. S. government to require us to grant a license to the technology to a responsible applicant if we fail to achieve practical application of the technology or if action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U. S. industry. Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products. ~~60If~~ **If** we are not able to adequately protect our trade secrets and other proprietary information, the value of our technology and products could be significantly diminished. We rely on trade secret and proprietary know- how protection for our confidential and proprietary information and have taken security measures to protect this information. These measures, however, may not provide adequate protection. For example, we have a policy of requiring our consultants, advisors and collaborators, including, for example, our strategic collaborators with whom we seek to develop and commercialize products, to enter into confidentiality agreements and our employees to enter into invention, non- disclosure and non- compete agreements. However, breaches of our physical or electronic security systems, or breaches caused by our employees failing to abide by their confidentiality obligations during or upon termination of their employment with us, could compromise these protection efforts. Any action we take to enforce our rights may be time- consuming, expensive, and possibly unsuccessful. Even if successful, the resulting remedy may not adequately compensate us for the harm caused by the breach. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States or Europe. Any unauthorized use or disclosure of, or access to, our trade secrets, know- how or other proprietary information, whether accidentally or through willful misconduct, could have a material adverse effect on our programs and our strategy, and on our ability to compete effectively. If our trademarks and trade names are not adequately protected, we may not be able to establish or maintain name recognition in our markets of interest, and our business may be adversely affected. Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names that we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time- consuming, and possibly unsuccessful. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to infringe on other marks. Our pending trademark applications in the United States and in other foreign jurisdictions where we may file may not be successful. Even if these applications result in registered trademarks, third parties may challenge these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. ~~We~~ **59We** may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or diagnostic companies, including our competitors in the various markets in which we operate. We may be subject to claims that we or our employees, consultants or independent contractors have

inadvertently or willfully used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that our employees' former employers or other third parties have an ownership interest in our patents. 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, litigation could result in substantial costs to us and could divert the time and attention of our management and other employees. Risks Related to ~~our Convertible NotesServicing our debt will require a significant amount of cash. We may not have sufficient cash flow from our business to pay our outstanding debt, and we may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, which could adversely affect our business and results of operations. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the amounts payable under the Convertible Notes, depends on our future performance, which is subject to 61economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Further, holders of the Convertible Notes have the right to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of a " fundamental change " (as defined in the indenture governing the Convertible Notes) before the maturity date at a repurchase price equal to 100 % of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash, or be able to obtain sufficient financing, at the time we are required to repurchase the Convertible Notes. The conditional conversion feature of the Convertible Notes, when triggered, may adversely affect our financial condition and operating results. The conditional conversion feature of the Convertible Notes has been triggered for certain applicable periods beginning with the quarter ended September 30, 2020. During periods for which the conditional conversion feature has been or is triggered, holders of the Convertible Notes are entitled to convert their Convertible Notes at any time during such periods at their option. If one or more holders elect to convert their Convertible Notes, unless we choose to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would elect to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity. No holders have elected to convert their Convertible Notes. In addition, even if holders of Convertible Notes do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long- term liability, which would result in a material reduction of our net working capital. The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results. In August 2020, the FASB issued Accounting Standards Update ASU 2020- 06, or ASU 2020- 06, with the intent to simplify ASC 470- 20 and ASC subtopic 815- 40, Contracts in Entity' s Own Equity, or ASC 815- 40. Among the changes, ASU 2020- 06 removed the requirement to bifurcate the liability and equity components of convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion. In addition, ASU 2020- 06 precludes the use of the treasury stock method, when calculating diluted earnings per share, for convertible debt instruments that may be settled entirely or partially in cash upon conversion. We currently apply the " if- converted " method for calculating any potential dilutive effect of the conversion options embedded in the Convertible Notes on diluted net income per share, which assumes that all of the Convertible Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti- dilutive. The application of the if- converted method may reduce our reported diluted net income per share to the extent we are profitable, and accounting standards may change in the future in a manner that may otherwise adversely affect our diluted net income per share. 62Conversion of the Convertible Notes will dilute the ownership interest of existing stockholders, including holders who had previously converted their Convertible Notes, or may otherwise depress the price of our common stock. The conversion of some or all of the Convertible Notes will dilute the ownership interests of stockholders to the extent we deliver shares of our common stock upon such conversion. The Convertible Notes are currently convertible and may from time to time in the future be convertible at the option of their holders prior to their scheduled terms under certain circumstances. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock. Risks Related to~~ Ownership of Our Common StockThe market price of our common stock has been and may be volatile, which could subject us to litigation. The trading prices of the securities of life sciences companies, including ours, have been and may continue to be highly volatile; and financial markets in general, including our stock, experienced particularly high volatility as a result of the COVID- 19 pandemic and continued difficult macroeconomic conditions. Accordingly, the market price of our common stock is likely to be subject to wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this " Risk Factors " section and others including: • actual or anticipated variations in our and our competitors' results of operations, as well as how those results compare to analyst and investor expectations; • announcements by us or our competitors of new products, significant acquisitions, other strategic transactions, including strategic and commercial partnerships and relationships, joint ventures, divestitures, collaborations or capital commitments; • changes in reimbursement practices by current or potential

payers; • failure of analysts to initiate or maintain coverage of our company, issuance of new securities analysts' reports or changed recommendations for our stock; • negative publicity, including misinformation, about our company, our tests, or the commercial markets in which we operate; • forward- looking statements related to our financial guidance or projections, our failure to meet or exceed our financial guidance or projections or changes in our financial guidance or projections; • actual or anticipated changes in regulatory oversight of our products; • development of disputes concerning our intellectual property or other proprietary rights; • commencement of, or our involvement in, litigation and the outcomes of our litigation matters; • announcement or expectation of additional debt or equity financing efforts; • any major change in our management; • general economic conditions and slow or negative growth of our markets, including as a result of changes in the rate of inflation (including the cost of raw materials, commodities, and supplies) and interest rates; ~~and63~~ **and60** • changes in business, economic, and political conditions, including war, political instability and related military action. In addition, if the market for life sciences stocks or the stock market in general experiences uneven investor confidence, as has been the case in ~~recent months~~ **the past** , the market price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us. Some companies, including us, that have experienced volatility in the trading price of their stock have been the subject of securities class action litigation, and we may in the future become subject to such litigation. For example, we have in the past been subject to a purported securities class action lawsuit filed against us, our directors and certain of our officers and stockholders related to our initial public offering. Under certain circumstances, we have contractual and other legal obligations to indemnify and to incur legal expenses on behalf of current and former directors and officers, and on behalf of our former underwriters, in connection with any future lawsuits. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. 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. Defending against litigation is costly and time-consuming, and could divert our management' s attention and resources. 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. If we are unable to implement and maintain effective internal controls over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected. We are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes- Oxley Act requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal controls over financial reporting. The Sarbanes- Oxley Act also requires that our management report on internal controls over financial reporting be attested to by our independent registered public accounting firm. Although we determined that our internal controls over financial reporting were effective as of December 31, ~~2023~~ **2024** , we must continue to monitor and assess our internal controls over financial reporting. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal controls over financial reporting are effective, or ~~, when required in the future,~~ if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities. We do not intend to pay dividends on our capital stock so any returns will be limited to changes in the value of our common stock. We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain 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, our ability to pay cash dividends on our capital stock may be prohibited or limited by the terms of any current or future debt financing arrangement. Any return to stockholders will therefore be limited to the increase, if any, in the price of our common stock. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or in connection with acquisitions or strategic or commercial transactions, could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline. From time to time, we may issue additional securities or sell common stock, convertible securities, such as the Convertible Notes, or other equity securities in one or more transactions at prices and in a manner we determine. We also expect to continue to issue common stock to employees and directors pursuant to our equity incentive plans. If we sell or ~~64issue~~ **61issue** common stock, convertible securities, or other equity securities, or common stock is issued pursuant to equity incentive plans, investors in our common stock may be materially diluted. As we have done in the past, we may decide to issue common stock or other equity securities in connection with an acquisition or a strategic or commercial transaction, which could 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. Sales of a substantial number of shares of our common stock in the public markets could cause the price of our common stock to decline. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As we have done in the past, we may issue our shares of common stock or securities convertible into our common stock, such as our Convertible Notes, from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the price of our common stock to decline. If securities or industry analysts do not publish

research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. ~~Currently, only a small number of securities analysts cover our stock.~~ If ~~more analysts do not commence coverage of us, or if~~ industry analysts cease coverage of us or fail to publish reports on us regularly, the trading price for our common stock could be adversely affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. Provisions in our amended and restated certificate of incorporation, amended and restated bylaws, and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things: • authorize the issuance of " blank check " preferred stock that our board of directors could use to implement a stockholder rights plan; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • eliminate the ability of our stockholders to call special meetings of stockholders; • establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; • establish a classified board of directors so that not all members of our board are elected at one time; • permit the board of directors to establish the number of directors; • provide that directors may only be removed " for cause " and only with the approval of 75 % of our stockholders; 