

## Risk Factors Comparison 2024-02-22 to 2023-02-23 Form: 10-K

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Our operations and financial results are subject to various risks and uncertainties including those described below. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. ~~Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.~~ If any of the following risks or others not specified below materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline. Risks related to our business and strategy We have incurred significant losses since inception, we may continue to incur losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability. We have incurred significant losses since our inception. For the years ended December 31, **2023**, ~~2022~~, ~~and 2021 and 2020~~, we incurred net losses of \$ **479.4 million**, \$ 654.6 million, ~~and~~ \$ 384.8 million ~~and \$ 246.3 million~~, respectively. As of December 31, **2022-2023**, we had an accumulated deficit of \$ **2.17** billion. To date, we have financed our operations principally from the sale of stock or convertible securities, and revenue from precision oncology testing, ~~and our development services~~ **and other**. We have devoted substantially all of our resources to the development and commercialization of our current products and to research and development activities related to our future products, including clinical and regulatory initiatives to obtain marketing approval and sales and marketing activities. We will need to generate substantial revenue to achieve and then sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock. We may not be able to generate sufficient revenue to achieve and maintain profitability and our current or future products may not achieve or maintain sufficient commercial market acceptance. We are currently not profitable. Even if we succeed in increasing adoption of our existing products and services by physicians, obtaining additional coverage decisions from commercial and government payers, maintaining and creating relationships with our existing and new biopharmaceutical partners, and developing and commercializing additional products and services, we may not be able to generate sufficient revenue to achieve or maintain profitability. We believe our commercial success is dependent upon our ability to continue to successfully market and sell our current and future products, to continue to expand our current relationships and develop new relationships with clinicians and biopharmaceutical customers and to develop and commercialize new products. Our ability to achieve and maintain sufficient commercial market acceptance of our existing and future products will depend on a number of factors, including:

- our ability to increase awareness of our tests and the benefits of liquid biopsy;
- the rate of adoption and / or endorsement of our tests by clinicians, KOLs, advocacy groups and biopharmaceutical companies;
- the timing and scope of any approval or certification by regulatory agencies, including the FDA, or notified bodies for our tests;
- our ability to obtain positive coverage decisions for our tests from additional commercial payers and to broaden the scope of indications included in such coverage decisions;
- our ability to obtain reimbursement and expanded coverage from government payers, including Medicare;
- the impact of our investments in product innovation and commercial growth;
- negative publicity regarding ours or our competitors' products resulting from defects or errors; and
- our ability to further validate our technology through clinical research and accompanying publications.

We cannot assure that we will be successful in addressing each of these criteria or other criteria that might affect the market acceptance of our products. If we are unsuccessful in achieving and maintaining market acceptance of our products, our business and results of operations will suffer. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for any of our products, which may vary significantly;
- the timing and cost of, and level of investment in, research, development, regulatory approval or certification and commercialization activities relating to our products, which may change from time to time;
- the volume and customer mix of our precision oncology testing;
- the start and completion of projects in which our development services **and other** are utilized;
- the introduction of new products or product enhancements by us or others in our industry;
- coverage and reimbursement policies with respect to our products and products that compete with our products;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- changes in governmental regulations or in the status of our regulatory approvals or certifications or applications;
- future accounting pronouncements or changes in our accounting policies;
- developments or disruptions in the business and operations of our clinical, commercial and other partners;
- the impact of natural disasters, political and economic instability, including wars, terrorism, and political unrest, epidemics or pandemics, ~~including the ongoing coronavirus pandemic~~, boycotts, curtailment of trade and other business restrictions; and
- the effects of high inflation or other general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

Additionally, it is difficult to predict the amount we are able to collect for our tests from commercial payers. We receive reimbursement for our tests from several commercial payers for whom we are not a participating provider. Because we are not contracted with these payers, they determine the amount they are willing to reimburse us for tests. We have provided testing services to patients with many cancer types and indications, some of the time as a non-participating provider through **2022-2023**. When we have received payment as a non-participating provider, the amounts, on average, were significantly lower than for participating providers. Even when these payers have paid a claim, they

may elect at any time to review previously paid claims for overpayment against these claims. In the event of an overpayment determination, the payer may offset the amount they determine they overpaid against amounts they owe us on current claims. We have limited leverage to dispute these retroactive adjustments and we cannot predict when, or how often, a payer might engage in these reviews. A significant amount of these offsets by one or more payers in any given quarter could have a material effect on our results of operations and cause them to fall below expectations or guidance we may provide. Our efforts to become a participating provider of a number of commercial payers may not be successful. Even when we have obtained positive coverage decisions for our tests from commercial payers and entered into agreements with them, such agreements typically are standard form contracts and may allow payers to terminate coverage on short notice, impose significant obligations on us and create additional regulatory and compliance hurdles for us. As part of our reimbursement operations, we appeal denials from payers, and if successful, we receive payments from these appeals. However, due to the inherent variability of the insurance landscape, we cannot guarantee future success of, or any payments from, appeals of reimbursement denials by payers. Historic success and payments are not indicative of future success of and payments from such appeals. Due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our tests, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received for a test differs from the revenue recorded for the test. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. New product development and commercialization involve a lengthy and complex process and we may be unable to develop or commercialize new products on a timely basis, or at all. Products that are under development have taken time and considerable resources to develop, and we may not be able to complete the development and commercialization of ~~the~~ such products for clinical use on a timely basis, or at all. For example, there can be no assurance that we will be able to produce commercial products for early detection of cancer. Before we can commercialize any new products, we will need to expend significant funds in order to: • conduct substantial research and development, including validation studies and clinical studies; • further develop and scale our laboratory processes to accommodate different products; and • further develop and scale our infrastructure to be able to analyze increasingly large amounts of data. Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including: • failure of the product to perform as expected, including defects and errors; • lack of validation data; or • failure to demonstrate the clinical utility of the product. Our development plan involves using data and analytical insights generated from our current products as a force multiplier of returns on research and development investment in our future products. However, if we are unable to generate additional or compatible data and insights, then we may not be able to advance our products under development as quickly, or at all, or without significant additional investment. As we develop products, we have made and will have to make significant investments in product development, marketing and selling resources, including investing heavily in clinical studies, which could adversely affect our future cash flows. Our current revenue is primarily generated from sales of our tests and we are highly dependent on them for our success. Our ability to execute our growth strategy and become profitable is highly dependent on the continued adoption and use of our tests, which accounted for **almost all 91 %, 87 % and 81 %** of our revenue in the years ended December 31, **2023, 2022, and 2021 and 2020, respectively**. Continued adoption and use of our tests will depend on several factors, including the prices we charge for our tests, the scope of coverage and amount of reimbursement available from third- party payers for our tests, the availability of clinical data that supports the value of our tests and the inclusion of our tests in industry treatment guidelines. In addition, many biopharmaceutical companies have existing relationships with companies that develop molecular diagnostic tests, including our competitors, and may continue to use their tests instead of ours. Despite our business development efforts, it could be difficult, expensive and / or time- consuming for biopharmaceutical companies to switch diagnostic tests for their products, and our tests may not be widely accepted by biopharmaceutical companies, if at all, which could in turn hinder the growth of sales of our tests. If we are unable to achieve commercial success for our tests, our business, results of operations and financial condition would be materially and adversely affected. We cannot assure that our tests will continue to maintain or gain market acceptance, and any failure to do so would materially harm our business and results of operations. If our products do not meet the expectations of patients and our customers, our operating results, reputation and business could suffer. Our success depends on the market' s confidence that we can provide reliable, high- quality precision oncology products that will improve clinical outcomes, lower healthcare costs and enable better biopharmaceutical development. We believe that patients, clinicians and biopharmaceutical companies are likely to be particularly sensitive to product defects and errors in the use of our products, including if our products fail to detect genomic alterations with high accuracy from samples or if we fail to list or inaccurately include certain treatment options and available clinical studies in our test reports, and there can be no guarantee that our products will meet their expectations. Furthermore, if our competitors' products do not perform to expectations, it may result in lower confidence in our tests as well. As a result, the failure of our products to perform as expected could significantly impair our operating results and our reputation. In addition, we may be subject to legal claims arising from any defects or errors in our products. If we are unable to support demand for our current and future products, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage our anticipated growth, our business could suffer.

As our volume of test sales grows, we will need to continue to increase our workflow capacity for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program and extend our platform to support comprehensive genomic analysis at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our precision oncology products. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities or process enhancements will be successfully implemented, if at all, or that we will have adequate space in our laboratory facility or be able to secure additional facility space to accommodate such required expansion. As we commercialize additional products, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business. If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced. Biopharmaceutical customers collaborate with us for analysis of whole blood or plasma samples for multiple applications primarily to support clinical studies, including patient identification, companion diagnostics and, retrospective testing and data services. In addition, we generate revenue from licensing our digital sequencing technologies to our domestic biopharmaceutical customers and international laboratory partners. In the years ended December 31, 2023, 2022, and 2021 and 2020, revenue from our top five biopharmaceutical customers, including their affiliated entities, accounted for 14 %, 18 %, and 18 % and 27 % of our total revenue, respectively. The revenue attributable to our biopharmaceutical customers may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue. Adverse speculation about our existing or potential relationships with biopharmaceutical companies may be a catalyst for adverse speculation about us, our products and our technology, which can adversely affect our reputation and business. Our future success depends in part on our ability to maintain relationships and to enter into new relationships with biopharmaceutical customers, including offering our platform to such customers for companion diagnostic development, novel target discovery and validation as well as clinical study enrollment, and growing into other business opportunities. This can be difficult due to many factors, including the type of biomarker support required and our ability to deliver it and our biopharmaceutical customers' satisfaction with our products or services, internal and external constraints placed on these organizations and other factors that may be beyond our control. Furthermore, our biopharmaceutical customers may decide to decrease or discontinue their use of our current products and tests, or our future products due to changes in their research and product development plans, failures in their clinical studies, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control. Continued usage of our tests by particular biopharmaceutical customers may also depend on whether the partner obtains positive data in its clinical studies, is able to successfully obtain regulatory approval and subsequently commercializes a therapy for which we have partnered with them to develop a companion diagnostic, or other administrative factors that are outside our control. Some of our biopharmaceutical customers have contracted with us to provide testing for large numbers of samples, which could strain our testing capacity and restrict our ability to perform tests for other customers. Furthermore, biopharmaceutical companies may decline to do business with us or decrease or discontinue their use of our tests due to their broad strategic collaboration with any of our competitors. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to research and clinical studies that facilitate the collection and incorporation of new information into our platform and tests. We engage in conversations with biopharmaceutical companies regarding potential commercial opportunities on an ongoing basis. There is no assurance that any of these conversations will result in a commercial agreement, that the resulting relationship will be successful, or that clinical studies conducted as part of the engagement will produce successful outcomes. If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our product development could be delayed and revenue and results of operations could be adversely affected. Our payer concentration may materially adversely affect our financial condition and results of operations. We receive a substantial portion of our revenue from a limited number of third- party commercial payers, most of which have not contracted with us to be a participating provider. If one or more of these payers were to significantly reduce, or cease to pay, the amount such payer reimburses us for tests we perform, or if such payer does not reach or maintain favorable coverage and reimbursement decisions for our tests, it could have a material adverse effect on our business, financial condition and results of operations. We have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. If commercial payers were to decide not to include us as a participating provider, cease paying us altogether, drastically reduce the amount they were willing to pay us or attempt to recover any amounts they had already paid, it could cause significant fluctuations in our quarterly results and could harm our business and results of operations. In September 2018, we began to receive reimbursement from Medicare for claims submitted with respect to Guardant360 clinical our precision oncology tests performed for NSCLC patients. In March 2020, we began to receive reimbursement from Medicare for claims submitted with respect to Guardant360 clinical tests performed for qualifying patients diagnosed with solid tumor cancers of non-central nervous system origin other than NSCLC. Revenue from clinical tests for patients covered by Medicare represented approximately 43 %, 45 %, and 45 % and 42 % of our precision oncology revenue from clinical customers for the years ended December 31, 2023, 2022, and 2021 and 2020, respectively. Revenue attributable to Medicare

accounted for more than 10 % of our total revenue in each of the years ended December 31, 2023, 2022, and 2021 and 2020. In addition, pursuant to CMS regulations, we cannot bill Medicare directly for tests provided for Medicare beneficiaries in some situations. CMS adopted an exception to its laboratory date of service regulation, and if certain conditions are met, molecular testing laboratories such as us can rely on that exception to bill Medicare directly, instead of seeking payment from the hospital. If this exception is repealed or curtailed by CMS, or its laboratory date of service regulation is otherwise changed to adversely impact our ability to bill Medicare directly, our revenue could be materially reduced. If we fail to obtain or maintain coverage and adequate reimbursement from third- party payers, we may be unable to increase our testing volume and revenue as expected. Retrospective reimbursement adjustments, such as deductions from further payments and clawbacks, can also negatively impact our revenue and cause our financial results to fluctuate. In addition, as part of our reimbursement operations, we appeal denials from payers, and if successful, we receive payments from these appeals. However, due to the inherent variability of the insurance landscape, we cannot guarantee future success of, or any payments from, appeals of reimbursement denials by payers. Historic success and payments are not indicative of future success of and payments from such appeals. If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or to achieve and then sustain profitability. Growing understanding of the importance of biomarkers linked with therapy selection, response and early screening is leading to more companies offering services in genomic profiling. The promise of biopsy testing is also leading to more companies attempting to enter the space and compete with us. Over the last year, that has included new and accelerated development programs by a number of potential competitors, and increasing levels of merger and acquisition activity by both existing and new competitors. Currently, our main competition is from diagnostic companies with products and services to profile genes in cancers based on either single- marker or comprehensive genomic profile testing, based on next- generation sequencing in either blood or tissue. This may change over the next few years as a result of new competitors entering through investment and acquisition activity. Our competitors within the liquid biopsy space for therapy selection include Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in 2018; Roche Molecular Systems, Inc., Thermo Fisher Scientific, Inc., Illumina, Inc., Qiagen N. V., Invitae Corporation, Caris Life Science, and Tempus Labs, Inc., and Agilent Technologies, Inc. In addition, NeoGenomics Laboratories, Inc., Natera, Inc., Exact Sciences Corp., and Tempus Labs, Inc., among others, are our competitors in minimal residual disease testing. Additionally, our competitors in the early screening testing space include GRAIL, Inc., Exact Sciences Corp., Freenome Holdings, Inc., Delfi Diagnostics and InterVenn Biosciences. Competitors within the broader genomics profiling space based on tissue include laboratory companies such as Bio- Reference Laboratories, Inc., Laboratory Corporation of America and Quest Diagnostics, Inc., as well as companies such as Caris Biosciences, Tempus Labs, Inc., Foundation Medicine, Inc., Myriad Genetics, Inc., and most if not all of the competitors within the liquid biopsy space for therapy selection, that sell molecular diagnostic tests for cancer to physicians and have or may develop tests that compete with our tests. In addition, we are aware that certain of our customers are also developing their own tests and may decide to enter our market or otherwise stop using our tests. Some of our competitors and potential competitors may have longer operating histories; larger customer bases; greater brand recognition and market penetration; substantially greater financial, technological and research and development resources and selling and marketing capabilities; and more experience dealing with third- party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Increased competition and cost- saving initiatives on the part of governmental entities and other third- party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well- established and well- financed companies. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to product development than we can. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline. In addition to developing kits, certain diagnostic companies also provide next- generation sequencing platforms that could be used for liquid biopsy testing. These include Illumina, Inc., Thermo Fisher Scientific Inc., Pacific Biosciences of California, Inc., Ultima Genomics, Inc., Oxford Nanopore Technologies Limited, and other companies developing next- generation sequencing platforms that are sold directly to biopharmaceutical companies, clinical laboratories and research centers. While many of the applications for these platforms are focused on research and development applications, each of these companies has launched and could continue to commercialize products focused on the clinical oncology market. These tests could include FDA- approved diagnostic kits, which can be sold to the clients who have purchased their platforms. Furthermore, many companies are developing information technology- based tools to support the integration of next- generation sequencing testing into the clinical setting. These companies may also use their own tests or others to develop an integrated system which could limit access for us to certain networks. The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate. Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third- party estimates, including, without limitation, the number of patients with late- stage, solid tumor cancer, the number of individuals who are at a higher risk for developing cancer, and the assumed prices at which we can sell tests for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future



products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell our products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. The precision oncology industry is subject to rapid change, which could make our current products and any future products we may develop, obsolete. Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current and future products obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our platform and develop new products to keep pace with evolving standards of care. If we do not update our product offerings to reflect new scientific knowledge about cancer biology, information about new cancer therapies or relevant clinical studies, our products could become obsolete and sales of our current products and any new products we may develop could decline or fail to grow as expected. We have experienced challenges attracting and retaining qualified personnel due to competitive labor markets and may continue to do so, and may be unable to manage our future growth effectively, all of which could make it difficult to execute our business strategy. Since our inception, we have experienced rapid growth and anticipate further growth in our business operations. Our future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue to increase headcount and to hire more specialized personnel as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, as well as sales and marketing staff, and improve and maintain our technology to properly manage our growth. However, we have experienced challenges attracting and retaining qualified personnel due to competitive labor markets and may continue to do so. In this competitive environment, our business could be adversely impacted by increases in labor costs triggered by regulatory actions regarding wages, scheduling and benefits, ~~and the need to attract and retain high quality employees with the requisite skill sets, and the ongoing effects of the COVID-19 pandemic.~~ In addition, if our new hires perform poorly, if we are unsuccessful in training, managing and integrating these new employees or if we are not successful in developing and retaining our existing employees, our business may be harmed. In addition, we may not be able to maintain the quality or expected turnaround times of our products, or satisfy customer demand as it grows, and our business may be harmed. Our ability to manage our growth properly will also require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain and could be demanding, and failure to complete this in a timely and efficient manner could adversely affect our operations. We may not be able to successfully market, sell or distribute our products, and if we are unable to expand our sales organization to adequately address our customers' needs, our business may be adversely affected. We may not be able to market, sell or distribute our products and tests, and other products we may develop effectively enough to support our planned growth. We currently sell to clinicians in the United States through our own sales organization and to biopharmaceutical companies through our business development team. Each of our target markets is large, distinctive and diverse. As a result, we believe it is necessary for our sales representatives and business development managers to have established oncology-focused expertise. Competition for such employees within the precision oncology industry is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales organization or business development team, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability. Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our products, to increase our sales and to compete effectively will depend, in part, on our ability to manage this potential future growth effectively, without compromising quality. Outside the United States, we established Guardant AMEA for sales of our products throughout Asia, the Middle East and Africa. If the sales and marketing efforts for our products in those regions are not successful, our business would be materially and adversely affected. In other territories, such as Europe, we sell our tests primarily through distributor relationships or direct contracts with hospitals. Locating, qualifying, engaging and maintaining relationships with distribution partners and hospitals with local industry experience and knowledge will be necessary to effectively market and sell our products outside the United States. We may not be successful in finding, attracting and retaining distribution partners or local hospitals, or we may not be able to enter into such arrangements on favorable terms. Sales practices utilized by any such parties that are locally acceptable may not comply with sales practices standards required under U. S. laws that apply to us, which could create additional compliance risk. If our international sales and marketing efforts are not successful, we may not achieve market acceptance for our products outside the United States, which would materially and adversely impact our business. We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or promptly transition to alternative suppliers. We rely on a limited number of suppliers or, in some cases, sole suppliers, including Illumina Inc., or Illumina, for certain sequencers, reagents, blood tubes and other equipment, instruments and materials that we use in our laboratory operations. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing these laboratory equipment, instruments or materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly and adversely affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of the sequencers and as the sole provider of maintenance and repair services for these sequencers. Any disruption in operations of Illumina or other sole or limited suppliers or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations and thus our ability to conduct our business and generate revenue. These limited or sole suppliers could engage in

diverse types of businesses, including selling products or providing services in competition with us, and there can be no assurance that we can continue to receive required equipment, instruments or materials from them. We believe that there are only a limited number of other manufacturers that are capable of supplying and servicing the equipment and materials necessary for our laboratory operations, including sequencers and various associated reagents, and potentially replacing our current suppliers. The use of equipment or materials furnished by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. There can be no assurance that we will be able to secure alternative equipment, reagents and other materials, bring such equipment, reagents and materials online, and revalidate our tests without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, for example, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring or integrating the equipment and reagents we require for our products or in revalidating our products, our business, financial condition, results of operations and reputation could be materially and adversely affected. ~~The COVID-19 global pandemic and the worldwide attempts to contain it have adversely impacted our supply chain and other aspects of our business, as well as our results of operations, and could continue to do so. The global outbreak of coronavirus 2019, or COVID-19, and the various attempts throughout the world to contain it, have created significant volatility, uncertainty and disruption, which has and may continue to impact the global economy, disrupt our supply chain, and create significant volatility and disruption of financial markets. We have experienced significant reduction in access to our customers, including restrictions on our ability to market and distribute our tests and to collect samples. Our partners, vendors, suppliers and customers have similarly had their operations altered or temporarily suspended. Due to impacts and measures resulting from the COVID-19 pandemic, we have experienced and could continue to experience unpredictable reductions in the demand for our tests as healthcare customers divert medical resources and priorities toward the treatment of the virus. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical studies to advance their product development pipelines, for which our tests could be utilized. To the extent the COVID-19 pandemic continues to cause severe disruption, vendors of equipment and reagents for our operations could also reduce productions or even go out of business, resulting in supply constraints for us. For example, movement of supplies has been significantly curtailed worldwide, which has caused supply shortages for certain of our major suppliers. Disruptions caused by the COVID-19 pandemic have adversely affected the quantity and quality of certain sequencers, reagents, blood tubes and other similar materials that are critical to our commercial and research and development programs. We currently have a limited amount of stock of these components. Failure in the future to secure sufficient supply of critical components could materially and adversely affect our ability to manufacture or supply marketed products and product candidates or complete our ongoing research and development programs on the timelines previously established. Our ability to enroll suitable patients in clinical studies has also been negatively impacted and could continue to be adversely affected by the COVID-19 pandemic. The full extent to which the COVID-19 pandemic and the various responses to it impacts our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict, including: the duration and scope of the pandemic; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the adverse effects on our manufacturing operations and supply chain, which may impact our ability to produce and distribute our products, as well as the ability of third parties to fulfill their obligations to us and could increase our expenses; the possibility that third parties on which we rely for certain functions and services, suppliers, distributors, logistics providers, and external business partners, may be adversely impacted by restrictions resulting from COVID-19, which could cause us to experience delays or incur additional costs; the availability, cost to access and effectiveness of COVID-19 tests, vaccines and medicines; the effect on our customers and customer demand for and ability to pay for our tests; restrictions on the ability of our employees and the employees of third parties on which we rely for certain functions and services to work and travel; disruptions related to the distribution of our tests, including impacts on logistics of shipping and receiving blood collection kits; and any stoppages, disruptions or increased costs associated with development, production and marketing of our products. During the COVID-19 pandemic, we may not be able to maintain the same level of customer outreach and service, which could negatively impact our customers' perception of us. We will continue to actively monitor the issues raised by the COVID-19 pandemic and may take further actions that alter our operations, as may be required by federal, state, local or foreign authorities, or that we determine are in the best interests of our employees, customers and stockholders. It is not clear what the potential effects any such alterations or modifications may have on our business, including the effects on our financial results. The COVID-19 pandemic has also led to uncertainties related to our growth, forecast and trends. Our historic results such as revenues, operating margins, net income, cash flows, tests performed, and other financial and operating metrics, may not be indicative of our results for future periods. Any past increases in the number of clinical tests and / or biopharmaceutical tests performed by us may reflect the acceleration of growth that we have experienced but may not see in subsequent periods given the COVID-19 pandemic. Even if government and other restrictions are relaxed, our growth may slow or reverse, including due to a slow recovery. The COVID-19 pandemic and its future developments present uncertainties with respect to our performance, financial condition, volume of business, results of operations, and cash flows. Due to the uncertain scope and duration of the COVID-19 pandemic and uncertain timing of any recovery or normalization, we are currently unable to estimate the resulting impacts on our operations and financial results. In addition to the impacts to our business, the global economy is likely to be significantly weakened as a result of actions taken in response to the COVID-19 pandemic. To the extent that such a weakened global economy impacts customers' ability or willingness to pay for our tests, our business and results of operation could be negatively impacted. As a result, we expect our revenue and results of operations to be adversely affected until testing, treatments and vaccines substantially eliminate the impact of the COVID-19 pandemic. If our existing laboratory facility becomes damaged or inoperable or we are required to~~

vacate our existing facility, our ability to perform our tests and pursue our research and development efforts may be jeopardized. We currently derive the majority of our revenue from tests performed at a single laboratory facility located in Redwood City, California. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for our laboratory operations. The inability to perform our tests or to reduce the backlog that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility, to locate and qualify a new facility or enable a third party to practice our proprietary technology, particularly in light of licensure and accreditation requirements. Even if we are able to find a third party with such qualifications to perform our tests, the parties may be unable to agree on commercially reasonable terms. We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facility and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. We are dependent on third parties for the collection of blood samples for our tests. We rely on third-party phlebotomy providers, including physician offices, to collect blood samples for our tests. Our current third-party phlebotomy providers may refuse to continue to collect samples for us in the future, in particular if they have agreements or arrangements with one of our competitors to collect samples for their tests, or if the phlebotomy provider is owned or controlled by a laboratory that offers tests that compete with ours. There has been a trend towards consolidation of independent phlebotomy providers. Independent phlebotomy providers, once acquired by our competitors, may terminate their relationships with us. If our patients are unable to readily access a phlebotomy provider to collect a blood sample for our tests, we may be unable to compete effectively with other laboratories that have greater access to phlebotomy providers and our business, financial condition and results of operations may be harmed. In addition, if third-party phlebotomy providers fail to adequately and properly obtain and collect viable blood samples from patients and to properly package and ship the samples to us, our patients and their physicians may experience problems and delays in receiving test results, which could lead to dissatisfaction with our tests, therefore harming our reputation and adversely affecting our business, financial condition and results of operations. Similarly, our contracts with physician owned phlebotomy providers to collect blood could be scrutinized under federal and state healthcare laws such as the federal Anti-Kickback Statute, or AKS, and the federal law prohibiting physician self-referral, or Stark Law, to the extent these services to us are deemed to provide a financial benefit to or relieve a financial burden for a potential referral source, or are subsequently found not to be for fair market value. If our operations are found to be in violation of any of these laws and regulations, we may be subject to administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs or from coverage of commercial payers, refunding of payments received by us, and curtailment or cessation of our operations, any of which could harm our reputation and adversely affect our business, financial condition and results of operations. We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed. Our business depends on our ability to deliver test results quickly and reliably to our customers. Blood samples are typically received within days from the United States and outside the United States for analysis at our Redwood City, California facility. Disruptions in delivery services to transport samples to that facility, whether due to labor disruptions, bad weather, natural disaster, terrorist acts or threats or for other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner, delay our provision of test results to our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services to transport samples to us on commercially reasonable terms, our operating results may be adversely affected. International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States. We currently have limited international operations, but our business strategy incorporates potentially significant international expansion, including through Guardant AMEA, which we formed to accelerate the commercialization of our products in Asia, the Middle East and Africa. We plan to maintain distributor and partner relationships, to conduct physician and patient association outreach activities, to extend laboratory capabilities and to expand payer relationships, outside of the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us, our distributors, or our local partners to obtain regulatory approvals or certifications for the use of our products in various countries;
- presence of additional third-party patents or other intellectual property rights that may be relevant to our business and may potentially block our expansion;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers, or patient self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to perform our tests locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations, currency controls and cash repatriation restrictions;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, boycotts, curtailment of trade and other business restrictions;
- public health or similar issues, such as epidemics or pandemics, that could cause business disruption for our offices in Japan and Singapore, and make it more difficult to sell our tests in the affected countries or regions, and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act, or FCPA, its books and

records provisions, or its anti-bribery provisions. Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. We could be adversely affected by violations of the FCPA and other anti-bribery laws. We are subject to 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, as a result of our international customers. Our reliance on independent distributors **and third party partner laboratories to market, sell and / or perform** our tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other U.S. companies in the medical device and biopharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including 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, and, as a result, we cannot assure that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, cause us to incur significant costs and expenses, including legal fees, and result in a material adverse effect on our business, prospects, financial condition and results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures. Risks related to our highly regulated industry

We conduct business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition, and harm our business. The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal, state and foreign laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and / or regulatory agencies enforcing those laws and regulations;
- federal, state and foreign health care fraud and abuse laws;
- federal, state and foreign laboratory anti-mark-up laws;
- coverage and reimbursement levels by Medicare, Medicaid, other governmental payers and private insurers;
- restrictions on coverage of and reimbursement for tests;
- federal, state and foreign laws governing laboratory testing, including CLIA, and state licensing laws;
- federal, state and foreign laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including laboratory developed tests, or LDTs;
- federal, state, local and foreign laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations;
- HIPAA, **GDPR, APPI, CCPA, CPRA** and similar state or foreign data privacy and security laws; and
- consumer protection laws.

In particular, the laws and regulations governing the marketing of clinical laboratory tests are complex, and there are often no sufficient regulatory or judicial interpretations of these laws and regulations. For example, some of our clinical laboratory tests are actively regulated by the FDA pursuant to the medical device provisions of the Federal Food, Drug and Cosmetic Act, or FDCA. The FDA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component, part or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. Our clinical laboratory tests are in vitro diagnostic products that are considered by the FDA to be medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, design, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices. If we do not comply with these requirements or fail to adequately comply, our business may be harmed. Certain of our tests are currently marketed as LDTs, and future changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements. We market some of our tests, Guardant360, Guardant360 Response, Guardant360 Tissue Next, **and** Guardant Reveal **and Shield**, as LDTs. LDTs are in vitro diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although LDTs are classified as medical devices and the FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, the FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs. While we believe that we are in material compliance with applicable laws and regulations, we cannot assure that the FDA will agree with us. If there are changes in FDA policy, or if the FDA disagrees that we are marketing our tests as LDTs within the scope of its policy of enforcement discretion, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical studies or take other actions prior to continuing to market our tests. This could significantly increase the costs and expenses of conducting, or otherwise harm, our business. Legislative and administrative proposals proposing to amend the FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our LDTs or to develop and introduce new tests as LDTs. In addition, the FDA and Congress have, for over the past decade, considered a number of proposals to end the FDA's enforcement discretion policy for LDTs and subject LDTs to additional regulatory requirements. Even if the FDA does not modify its policy of enforcement discretion, whether due to changes in FDA policy or legislative action, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements, including the requirement for premarket review and subsequent marketing authorization. We may also be required to conduct clinical studies to support our currently marketed products or



planned product launches. If we are required to conduct such clinical studies delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any currently- marketed tests that we may be required to cease selling or the commercialization of any future tests that we may develop, which could harm our financial prospects. There is no guarantee that the FDA will grant 510 (k) clearance or a premarket approval of our products or that similar foreign authorities or notified bodies will grant premarket approval or certify our products and failure to obtain necessary clearances or approvals or certifications for our products would adversely affect our ability to grow our business. ~~In Before we begin to label and market our products for use as clinical diagnostics in the United States, including as companion diagnostics~~ **event FDA rulemaking of oversight of LDTs were to be formalized**, we may be required to obtain either 510 (k) clearance or a premarket approval, or supplemental premarket approval, or respectively, PMA or PMA supplement, from the FDA, **for some of our LDT products** unless an exemption applies or FDA exercises its enforcement discretion and refrains from enforcing its medical device requirements. For example, the FDA has a policy of refraining from enforcing such requirements with respect to LDTs, which the FDA considers to be a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory. The process of obtaining a PMA is a rigorous, costly, lengthy and uncertain process. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre- clinical, clinical study, manufacturing and labeling data. In the 510 (k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, in order to clear the proposed device for marketing. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support a substantial equivalence determination. In order to sell our products in member states of the EU, our products must comply with the essential requirements of the ~~EU new~~ **In Vitro Diagnostic Regulation Medical Devices Directive ( Directive 98-IVDR) 2017/ 79/EC 746 issued and implemented by the European Union (EU )**, ~~in May 2022. These regulations introduced risk- based classification or for IVDD-IVDs and require notified body involvement for various high complexity devices including next generation sequencing tests such as Guardant360, Guardant360 Response, Guardant360 Tissue Next, and Guardant Reveal~~. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must ~~meet~~ **fulfill** the essential **clinical evidence and post- market performance evidence** requirements ~~laid down in Annex I to the IVDD including the requirement that an in vitro diagnostic medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others~~. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. To demonstrate compliance with the essential requirements we must ~~undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration demonstrate~~ **demonstrate** of conformity of in vitro diagnostic medical devices and their manufacturers with the essential requirements ~~must be based~~, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. ~~The Except for (general) in vitro diagnostic medical devices, where the manufacturer can self- declare the conformity of its products with the essential requirements of the IVDD, a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. The Notified Body would typically audit and examine the product’ s technical file and the manufacturer’ s quality system (notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485: 2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Any delay or failure to obtain necessary regulatory approvals or clearances or certifications would have a material adverse effect on our business, prospects, financial condition and results of operations. The FDA and foreign authorities or notified bodies can delay, limit or deny clearance or approval or certification of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA, similar foreign authorities or notified bodies that our products are safe or effective for their intended uses; • the disagreement of the FDA, similar foreign authorities or notified bodies with the design, conduct or implementation of our clinical studies or the analysis or interpretation of data from our pre- clinical or clinical studies; • serious and unexpected adverse effects experienced by participants in our clinical studies; • the data from our pre- clinical and clinical studies may be insufficient to support clearance or approval, or certification where required; • our inability to demonstrate that the clinical and other benefits of any of our tests outweigh the risks; • an advisory committee, if convened by the FDA, may recommend against approval of our PMA or other application for any of our tests or may recommend that the FDA require, as a condition of approval, additional pre- clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the FDA may still not approve the test; Similar requirements may apply in foreign jurisdictions; • the FDA, similar foreign authorities or notified bodies may identify deficiencies in our marketing application, or certification application and in our manufacturing processes, facilities or analytical methods or those of our third- party contract~~

manufacturers; • the potential for approval or certification policies or regulations of the FDA or similar foreign authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for the clearance or approval or certification; and • the FDA, similar foreign authorities or notified bodies may audit our clinical study data and conclude that the data is not sufficiently reliable to support a PMA or other applications. If we are unable to obtain clearance or approval or certification for any tests for which we plan to seek clearance or approval or certification, our business may be harmed. Modifications to our FDA- cleared or approved products may require new 510 (k) clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained. For any product approved pursuant to a PMA, we are required to seek supplemental approval for many types of changes to the approved product, for which we will need to determine whether a PMA supplement or other regulatory filing is needed or whether the change may be reported via the PMA Annual Report. Similarly, any modification to a 510 (k)- cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires new 510 (k) clearance or, possibly, approval of a new PMA. The FDA requires us to make this determination in the first instance, but the FDA may review and may not agree with our determination. If the FDA disagrees with our determination and requires us to seek approvals or clearances for modifications to our previously approved or cleared products, for which we concluded that new approvals or clearances are unnecessary, we may be required to cease marketing or distribution of our products or to recall the modified product until we obtain the approval or clearance, and we may be subject to significant regulatory fines or penalties. Similar requirements apply in foreign jurisdictions. For instance, in the EU, we must inform the notified body that carried out the conformity assessment of the devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our in vitro diagnostic medical devices that could affect compliance with the essential requirements ~~laid down in Annex I to IVDD~~ or cause a substantial change to the intended use for which the device has been CE marked. ~~The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the IVDD. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the essential requirements and quality system requirements laid down in the Annexes to the IVDD.~~ If third- party payers, including commercial payers and government healthcare programs, do not provide coverage of, or adequate reimbursement for, our tests, our business and results of operations will be negatively affected. Our revenue and commercial success depend on achieving coverage and reimbursement for our tests from payers, including both commercial and government payers. If payers do not provide coverage of, or do not provide adequate reimbursement for our tests, we may need to seek payment from the patient, which may adversely affect demand for our tests. Coverage determinations by a payer may depend on a number of factors, including but not limited to a payer' s determination that a test is appropriate, medically necessary or cost- effective. If we are unable to provide payers with sufficient evidence of the clinical utility and validity of our test, they may not provide coverage, may provide limited coverage or may terminate coverage, which will adversely affect our revenues and our financial condition. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our tests may decrease as we encounter pricing pressure from our competitors. Each payer makes its own decision as to whether to provide coverage for our tests, whether to enter into a contract with us and the reimbursement rate for a test. Negotiating with payers is time- consuming, and payers often insist on their standard form contracts. There is no guarantee that a payer will provide adequate coverage or reimbursement for our tests or that we can reach an agreement with the payer on reasonable terms without being subject to additional regulatory and compliance risks. In cases where there is no coverage, or we do not have a contracted rate for reimbursement with the payer, the patient is typically responsible for a greater share of the cost of the test, which may result in delay of revenue, increase collection costs or decrease the likelihood of collection. We maintain a financial assistance program, the Guardant Access Program, under which we assess patient financial need and offer provide discounted or no cost tests to certain patients. This may result in scrutiny by payers of our Guardant Access Program, and this could result in recoupment actions or termination of coverage of our tests. Our claims for reimbursement may be denied and we may have to appeal such denials in order to get paid. Such appeals may not result in payment. Payers may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the payers believe the funds were paid in error or determine that our tests were medically unnecessary. If a payer' s audit of our claims results in a negative finding, and we are unable to reverse the finding through appeal, any subsequent recoupment could result in a material adverse effect on our revenue. Additionally, in some cases commercial payers for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was excessive. In these situations, the payer typically notifies us of its decision and then offsets the amount it determines to be overpaid against amounts it owes us on current claims. We do not have a mechanism to dispute these retroactive adjustments, and we cannot predict when, or how often, a payer might engage in these reviews. When we contract with a payer as a participating provider, reimbursements by the payer are generally made pursuant to a negotiated fee schedule and are limited to only covered indications or where prior approval has been obtained. Becoming a participating provider can result in higher reimbursement amounts for covered uses of our test and, potentially, no reimbursement for non-covered uses identified under the payer' s policies or the contract. Although we are a participating provider with some commercial payers, certain other large, national commercial payers, including Anthem, Aetna and Humana, have issued non-coverage policies that consider tissue and liquid CGP testing **which are not FDA approved**, including our Guardant360 **and TissueNext** test, as experimental or investigational. If we are not successful in obtaining coverage from such payers, or if other payers issue similar non- coverage policies, our business and results of operations could be materially and adversely affected. Medicare' s National Coverage Determination, or NCD, for Next Generation Sequencing, or NGS, first established in 2018 and subsequently updated in 2020 states that NGS tests, such as our Guardant360 test, are covered by Medicare nationally, when: (1) performed in a CLIA- certified laboratory, (2) ordered by a treating physician, (3) the patient meets certain clinical and treatment criteria, including having recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, (4) the test is

approved or cleared by the FDA as a companion in vitro diagnostic for an FDA approved or cleared indication for use in that patient's cancer, and (5) results are provided to the treating physician for management of the patient using a report template to specify treatment options. The NGS NCD also states that each Medicare Administrative Contractor, or MAC, may provide local coverage of other next- generation sequencing tests for cancer patients only when the test is performed by a CLIA- certified laboratory, ordered by a treating physician and the patient meets the same clinical and treatment criteria required of nationally covered next- generation sequencing tests under the NGS NCD. An NGS test is not covered by Medicare when cancer patients do not have the above- noted indications for cancer under either national or local coverage criteria. In July 2018, Palmetto GBA, or Palmetto, the MAC responsible for administering Medicare's Molecular Diagnostic Services Program, or MoLDx, issued a local coverage determination, or LCD, for our Guardant360 test for NSCLC patients who meet certain clinical and treatment criteria. Subsequently, in 2018, Noridian Healthcare Solutions, the MAC responsible for adjudicating claims in California, where our laboratory is located, and a participant in MoLDx, finalized its LCD for our Guardant360 test. In September 2018, we began to receive reimbursement from Medicare for claims submitted with respect to Guardant360 clinical tests performed for NSCLC patients. In December 2019, replacing its prior NSCLC patient LCD, Palmetto GBA finalized its expanded LCD for our Guardant360 test that provides limited Medicare coverage for use of the Guardant360 test for qualifying patients diagnosed with solid cancers of non- central nervous system origin. In May 2019, Noridian also issued an expanded draft LCD for our Guardant360 test consistent with the expanded draft LCD issued by Palmetto in March 2019. In May 2020, Noridian issued a coverage article and confirmed limited Medicare coverage for our Guardant360 test for qualifying patients diagnosed with solid tumor cancers of non- central nervous system origin who meet the criteria of the NGS NCD. Noridian also retired the expanded draft LCD issued in May 2019 as being superseded by the coverage article. Future actions taken by Noridian or Palmetto may change Medicare coverage for our Guardant360 test. In March 2020, we began to receive reimbursement from Medicare for claims submitted, with respect to Guardant360 clinical tests performed for qualifying patients diagnosed with solid tumor cancers of non- central nervous system origin other than NSCLC. Under Medicare, payment for laboratory tests like ours is generally made under the Clinical Laboratory Fee Schedule, or CLFS, with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS are generally required to report to CMS, beginning in 2017 and every three years thereafter (or annually for " advanced diagnostic laboratory tests ", or ADLT), commercial payer payment rates and volumes for each test they perform. CMS uses this data to calculate a weighted median payment rate for each test, which is used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We are subject to reporting requirements under PAMA and the Medicare rate for our tests will be calculated in the future based on our private payer rates. For clinical diagnostic laboratory tests furnished on or after January 1, 2018, their Medicare CLFS reimbursement rates are established upon these reported private payer rates. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which delayed by one year the next data reporting period and prevented any reduction in payment amounts from commercial payer rate implementation in 2022. On November 2, 2022, CMS published its final rule for the Medicare Physician Fee Schedule for calendar year (CY) 2023, including changes for clinical laboratories that **take took** effect on January 1, 2023. Changes include updated regulatory definitions to specify the data collection period for the data reporting period of January 1, 2023 through March 31, 2023; revisions to indicate that data reporting is required every 3 years beginning January 2023; and to confirm that for CY 2022, payment may not be reduced by more than 0 % as compared to CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 % as compared to the amount established for the preceding year. On December 29, 2022, Congress passed the Consolidated Appropriations Act, 2023, which prevented any reduction in payment amounts from commercial payer rate implementation for 2023; delayed by one year data reporting requirements for tests other than ADLTs; and extended the three- year period in which payment may not be reduced by more than 15 %, to CYs 2024 through 2026. If we are unable to obtain and maintain favorable reimbursement rates from commercial payers for our tests, this may adversely affect the tests' Medicare reimbursement rates. It is unclear what impact new Medicare pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations or cash flows. Some payers have implemented, or are in the process of implementing, laboratory benefit management programs, often using third- party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence- based guidelines for patient care and lower costs. The impact on laboratories, such as us, of active laboratory benefit management by third parties is unclear, and we expect that it would have a negative impact on our revenue in the short term. Payers may resist reimbursement for our tests in favor of less expensive tests, require pre- authorization for our tests, or impose additional pricing pressure on and substantial administrative burden for reimbursement for our tests. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of payers for our tests. However, we cannot predict whether, under what circumstances, or at what price levels payers will cover and reimburse our tests. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our business and prospects could suffer. Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious, adverse health consequences or death. We may also, on our own initiative, recall a product. The

FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. In the case of our FDA- approved tests, a government- mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products could impair our ability to produce our products in a cost- effective and timely manner, which would have an adverse effect on our reputation, results of operations and financial condition. We may be subject to liability claims, may be required to bear costs or may take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, the FDA could require us to report those actions and take enforcement action for failing to report the recalls when they were conducted. Similar requirements apply in foreign jurisdictions. A future recall announcement could harm our reputation with customers and negatively affect our sales and financial condition. If we initiate a correction or removal for one of our tests, issue a safety alert or undertake a field action or recall to reduce a risk to health imposed by the test, this could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our tests and to negative publicity, including FDA alerts, press releases or administrative or judicial actions. Furthermore, circulation of any such negative publicity could harm our reputation, be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders. Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and studies may not be predictive of future study results. Our ongoing research and development and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad; and by notified bodies in some foreign jurisdictions. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The results of nonclinical and clinical studies of our products conducted to date, and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. The data and results from our clinical studies does not ensure that we will achieve similar results in future clinical studies. Failure can occur at any stage of clinical testing. Clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and nonclinical testing in addition to those we have planned before we are able to seek marketing authorizations or certifications for our products or product candidates. We may experience delays in our clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of such clinical studies. Patient enrollment in clinical studies and completion of patient follow up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available products. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study. In addition, the target enrollment for certain of our clinical studies, including our ECLIPSE study, is based upon our estimates that a given percentage of enrolled patients will have a specified disease or condition, and we cannot be certain that these estimates will prove correct, or that our clinical studies, even if fully enrolled, will produce data sufficient to support the submission of a PMA or other marketing application to the FDA or a comparable regulatory authority. If our clinical studies do not enroll a sufficient number of patients to support submission of a PMA or similar marketing application, or if the number of patients enrolled with the target disease or condition is lower than we estimated, we may be required to enroll additional patients in our clinical studies or conduct additional clinical studies before we are able to seek and / or obtain marketing authorizations for our product candidates, which may result in significant additional expenses for us and could delay or prevent us from bringing our product candidates to market. In addition, we may find it necessary to engage CROs to perform data collection and analysis and other aspects of our clinical studies, which might increase the cost and complexity of our studies. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the studies, and would control only certain aspects of their activities. We would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties would not relieve us of our regulatory responsibilities. We and our third- party contractors are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA, and comparable regulations enforced by foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of study sponsors, principal investigators and study sites. If we or any third- party contractor fails to comply with applicable GCPs, the clinical data generated in clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities or notified bodies may require us to perform additional clinical studies before clearing, or approving our marketing applications or certifying our products. A failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory clearance, approval or certification process. If there are delays in testing or clearances, approvals or certifications as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance, approval, or certification for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, generate revenue or to achieve sustained profitability. Interim, " topline" and preliminary data from our clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies or clinical studies, which is based on a preliminary analysis of then- available data, and the results and related findings and



conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data at time of disclosure. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical and clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, such as the FDA, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Our “research use only” and “investigational use only” products could become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations. In the United States, some of our products, including our GuardantOMNI test, are currently available for research use only, or RUO, or for investigational use only, or IUIO, depending on the proposed application. We make our RUO and IUIO products available to a variety of parties, including biopharmaceutical companies and research institutes. Because RUO and IUIO products are not intended for use in clinical practice and cannot be advertised or promoted for clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled “For Research Use Only. Not for use in diagnostic procedures,” and that IUIO products be labeled “For Investigational Use Only. The performance characteristics of this product have not been established,” such products are not subject to the FDA’s pre- and post-market controls for medical devices. A significant change in the laws or policies governing RUO or IUIO products or how they are enforced may require us to change our business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only,” or the RUO / IUIO Guidance, which highlights the FDA’s interpretation that distribution of RUO or IUIO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as an LDT is in conflict with the RUO or IUIO status. The RUO / IUIO Guidance further articulates the FDA’s position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, is in conflict with RUO or IUIO status. If we engage in any activities that the FDA deems to be in conflict with the RUO or IUIO status held by any of our products so labeled, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO or IUIO products in a manner that is inconsistent with its RUO / IUIO Guidance, we may be forced to stop distribution of our RUO / IUIO tests until we are in compliance, which would reduce our revenue, increase our costs and adversely affect our business, and results of operations. Even if we receive regulatory approval or certification of our products, we will continue to be subject to extensive regulatory oversight. Medical devices are subject to extensive regulation by the FDA in the United States, the MHLW in Japan, the European authorities, EEA competent authorities, and comparable regulatory agencies in other territories where we do business. If any of our products are approved by the FDA, the MHLW, or other comparable foreign regulatory agencies or certified by notified bodies in foreign jurisdictions, we will be required to timely file various reports. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, as a condition of approving a PMA, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data from the post-approval study, become available. Failure to conduct or timely complete post-approval studies in compliance with applicable regulations, update the product labeling, or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business and revenue. The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of medical devices to ensure that their promotional claims made are consistent with the applicable marketing authorizations, that there are adequate and reasonable data to substantiate the claims, and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our promotional claims are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions and we may be required to revise our promotional claims and make other corrections or restitutions. Similar requirements apply in

foreign jurisdictions. The FDA, state and foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions: • adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products; • operating restrictions, partial suspension or total shutdown of production; • customer notifications or repair, replacement or refunds; • refusing our requests for clearances or approvals of new products, new intended uses or modifications to existing products; • withdrawals of current clearances, approvals or certifications, resulting in prohibitions on sales of our products; • refusal to issue certificates needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales of our products and have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our current or future products under development. For example, on February 23, 2022, the FDA issued a proposed rule to amend the Quality System Regulation, or QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization, or ISO, standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose increased costs of compliance, or otherwise negatively affect our business. Additionally, in September 2019, the FDA issued revised final guidance describing an optional “ safety and performance based ” premarket review pathway for manufacturers of “ certain, well- understood device types ” to demonstrate substantial equivalence under the 510 (k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list device types appropriate for the “ safety and performance based ” pathway and continues to develop product- specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices similar to ours, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain marketing authorization or otherwise create competition that may negatively affect our business. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any product candidates or make it more difficult to obtain marketing authorizations for, manufacture, market or distribute any product candidate we are developing. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to seeking marketing authorization, changes to manufacturing methods recalls, replacement or discontinuance of our products or additional record keeping. The FDA’ s and other regulatory authorities’ policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. The EU regulatory landscape concerning medical devices (including in vitro diagnostic medical devices) **is evolving has evolved in recent years**. On April 5, 2017 Regulation (EU) 2017 / 746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98 / 79 / EC and Commission Decision 2010 / 227 / EU, or the IVDR, was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different European markets. ~~The IVDR will become applicable five years after publication (on May 26, 2022). However, on October 14, 2021, the European Commission proposed a “ progressive ” roll- out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. Consequently, if the European Parliament and Council adopt the proposed regulation, the IVDR will fully apply on May 26, 2022 but there will be a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation. These modifications may have an effect on the way we conduct our business in the EU and the EEA.~~ Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies or notified bodies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new medical device products from being developed, authorized or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA, foreign regulatory authorities and notified bodies to review and authorize the sale or certify new products can be affected by a variety of factors, including government budget and funding levels; its ability to hire and retain key personnel and accept the payment of user fees; statutory, regulatory, and policy changes; and other events that may otherwise affect the FDA’ s foreign regulatory authorities’ and notified bodies’ ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for new devices, including in vitro diagnostics to be reviewed and / or authorized or certified for marketing by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the global COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to

monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Other regulatory authorities may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In the EU, notified bodies must be officially designated to certify products and services in accordance with the IVDR. Only a few notified bodies have been designated **to date** so far and the COVID-19 pandemic has significantly slowed down their designation process. Without IVDR designation, notified bodies may not yet start certifying devices in accordance with the new Regulation. As only a few notified bodies have been IVDR-designated they are facing a heavy workload and their review times have lengthened. This situation could impact the way we are conducting or intend to conduct our business in the EU and the EEA. Failure to comply with federal, state and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions. We are subject to the Clinical Laboratory Improvement Amendments, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. Any testing subject to CLIA regulation must be performed in a CLIA certified laboratory. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial payers, for our tests. We have a current CLIA certification to perform our tests at our laboratory in Redwood City, California. To maintain this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time. We are also required to maintain a California clinical laboratory license to perform testing in California. California laboratory laws establish standards for day-to-day operation of our clinical laboratory in Redwood City, California, including the training and skills required of personnel and quality control. In addition, some other states require our California laboratory to be licensed in the state in order to test specimens from those states. In addition to California, our laboratory is licensed in Florida, Maryland, Pennsylvania, Rhode Island and New York. Although we have obtained licenses from states where we believe we are required to be licensed, it is possible that other states we are not aware of currently require out-of-state laboratories to obtain licensure in order to test specimens from the state, and that other states may adopt similar requirements in the future. We may also be subject to regulations in foreign jurisdictions as we seek to expand international utilization of our tests or as such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of specimens necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays. Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA certification and / or state licenses, imposition of a directed plan of action, on-site monitoring, civil monetary penalties, criminal sanctions, inability to receive reimbursement from Medicare, Medicaid and commercial payers, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA certification, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so. In order to test specimens from New York, LDTs must be approved by the New York State Department of Health, or NYSDOH, on a product-by-product basis before they are offered, and our Guardant360 test has been approved by NYSDOH. We will need to seek NYSDOH approval of any future LDTs we develop and want to offer for clinical testing to New York residents, and there can be no assurance that we will be able to obtain such approval. As a result, we are subject to periodic inspection by the NYSDOH and are required to demonstrate ongoing compliance with NYSDOH regulations and standards. To the extent NYSDOH identified any non-compliance and we are unable to implement satisfactory corrective actions to remedy such non-compliance, the State of New York could withdraw approval for our tests. The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. **We have** In 2014, we obtained CAP accreditation for our **laboratories in Redwood City and San Diego, California laboratory, and Japan**, and in order to maintain such accreditation, we are subject to survey for compliance with CAP standards every two years. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations. We are subject to numerous federal and state healthcare statutes and regulations; complying with such laws pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties and a material adverse effect to our business and results of operations. Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations may include, among others: • the AKS, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind (e.g. provision of free or discounted goods, services or items), in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program. The term “remuneration” has been broadly interpreted to include anything of value,

such as phlebotomy kits. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce referrals, purchases or recommendations of covered items or services may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case- by- case basis based on a cumulative review of all its facts and circumstances. Several courts have held that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. Moreover, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the EKRA, which prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory. The EKRA applies to all payers including commercial payers and government payers;
- the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering 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, unless an exception applies;
- federal and state "Anti- Markup" rules, which, among other things, typically prohibit a physician or supplier billing for clinical or diagnostic tests (with certain exceptions) from marking up the price of a purchased test performed by another physician or supplier that does not "share a practice" with the billing physician or supplier;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, biologicals, and kits, medical devices or supplies that require premarket approval by or notification to the FDA, and for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to (i) payments and other transfers of value to physicians (as defined by statute), certain other health care professionals such as physician assistants and nurse practitioners, and teaching hospitals, and (ii) ownership and investment interests in such manufacturers held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties for any payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;
- the federal government may bring a lawsuit under the False Claims Act, or the FCA, against any party whom it believes has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim for payment approved. The federal government and a number of courts have taken the position that claims presented in violation of certain other statutes, including the AKS or the Stark Law, can also be considered a violation of the FCA based on the theory that a provider impliedly certifies compliance with all applicable laws, regulations, and other rules when submitting claims for reimbursement. An FCA violation may provide the basis for the imposition of administrative penalties as well as exclusion from participation in governmental healthcare programs, including Medicare and Medicaid. A number of states including California have enacted laws that are similar to the federal FCA. Private individuals can bring FCA "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in federal healthcare programs. In January 2022, we received a civil investigative demand, or CID, from the United States Attorney for the Northern District of California in connection with an investigation under the False Claims Act. The CID requests information and documents regarding billing government- funded programs for the Company's panel of genetic tests known as Guardant360. We are fully cooperating with the investigation. At this time, we are unable to predict the outcome of this investigation. See "Commitments and Contingencies – Legal Proceedings" in this Annual Report on Form 10- K for more information;
- the HIPAA fraud and abuse provisions, which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private insurers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal and state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, unlawful trade practices, insurance fraud, kickbacks, patient inducement and statutory or common law fraud restrict the provision of products, services or items for free or at reduced charge to government or non- government healthcare program beneficiaries. These laws and regulations relating to the provision of items or services for free are complex and are subject to interpretation by the courts and by government agencies;
- other federal and state fraud and abuse laws, such as state anti- kickback, self- referrals, false claims and anti- markup laws, any of which may extend to services reimbursable by any payer, including private insurers;
- state laws that prohibit other specified practices, such as billing physicians for tests that they order; providing tests at no or discounted cost to induce adoption; waiving co- insurance, co- payments, deductibles or other amounts owed by patients; billing a state healthcare



program at a price that is higher than what is charged to other payers; or employing, exercising control over or splitting fees with licensed medical professionals; and • similar foreign laws and regulations in the countries in which we operate or may operate in the future. As a clinical laboratory, our business practices may face additional scrutiny from various government agencies such as the Department of Justice, the U. S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory and the decision to order laboratory tests typically are made or strongly influenced by the physician, with little or no patient input. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an exception. The government has been active in enforcement of these laws against clinical laboratories. Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and from employing or engaging physicians and other medical professionals (generally referred to as the prohibition against the corporate practice of medicine), which could include physician laboratory directors. These laws are designed to prevent interference in the medical decision- making process by anyone who is not a licensed medical professional. For example, California’s Medical Board has indicated that determining the appropriate diagnostic tests for a particular condition and taking responsibility for the ultimate overall care of a patient, including making treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these laws may result in sanctions and civil or criminal penalties. It is possible that governmental authorities may conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for services provided, do not comply with current or future corporate practice of medicine or healthcare fraud and abuse statutes, regulations, agency guidance or case law. The growth and international expansion of our business may increase the potential of violating applicable laws and regulations. The risk is further increased by the fact that many such laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our internal operations and business arrangements with third parties comply with applicable laws and regulations will involve substantial costs. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Any of the foregoing consequences could seriously harm our business and our financial results. To the extent our business operations are found to be in violation of any of these laws or regulations, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the healthcare providers or other parties with whom we interact or may interact in the future, are found not to be in compliance with applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in various healthcare programs, which could also negatively affect our business or revenue. If the validity of an informed consent from patients regarding our test was challenged, we could be forced to stop offering our products or using our resources, our business and results of operations will be negatively affected. We offer our tests to physicians and to biopharmaceutical companies in connection with clinical studies. We have implemented measures to ensure that data and biological samples that we receive have been collected from subjects who have provided appropriate informed consent. We also act as a sponsor of clinical studies in connection with the development of our tests, which are frequently conducted in collaboration with different parties. We seek to receive approval from an ethical review board, or institutional review board, or IRB, or other reviewing bodies for projects that meet the definition of “ human subjects research, ” which includes review and approval of processes for subject informed consent and authorization for use of personal information or waivers thereof. We and our biopharmaceutical partners could conduct clinical studies in a number of different countries. When we are acting as a vendor in connection with a clinical study sponsored by our biopharmaceutical partners, we rely upon them to comply with the requirements to obtain the subject’s informed consent and to comply with applicable laws and regulations. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. Those informed consents could be challenged and prove invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our biopharmaceutical partners, could force us to stop accessing or using data and samples or servicing or conducting clinical studies, which would hinder our product offerings or development. We could also become involved in legal actions, which could consume our management and financial resources. We may be subject to fines, penalties, licensure requirements, or legal liability, if it is determined that through our test reports we are practicing medicine without a license. Our test reports delivered to physicians provide information regarding FDA or foreign regulatory authorities- approved therapies and clinical studies that oncologists may use in making treatment decisions for their patients. We make members of our organization available to discuss the information provided in the reports. Certain state laws prohibit the practice of medicine without a license. Our customer service representatives and medical affairs team provide support to our customers, including assistance in interpreting the test report results. A governmental authority or other parties could allege that the identification of available therapies and clinical studies in our reports and the related customer service we provide constitute the practice of medicine. A state may seek to have us discontinue the inclusion of certain aspects of our test reports or the related services we provide, or subject us to fines, penalties, or licensure requirements. Any determination that we are practicing medicine without a license may result in significant liability to us, and our business and reputation would be harmed. Our billing and claim processing are complex and

time-consuming, and any delay in submitting claims or failure to comply with applicable billing requirements could hinder collection and have an adverse effect on our revenue. Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, such as Medicare, Medicaid, health plans, insurance companies and patients, all of which may have different billing requirements. Several factors make the billing process complex, including: • differences between the list prices for our tests and the reimbursement rates of payers; • compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid, to the extent our tests are covered by such programs; • differences in coverage among payers and the effect of patient co-payments or co-insurance; • differences in information, pre-authorization and other billing requirements among payers; • changes to codes and coding instructions governing our tests; • incorrect or missing billing information; and • the resources required to manage the billing and claim appeals process. These billing complexities and the related uncertainty in obtaining payment for our tests could negatively affect our revenue and cash flow, our ability to achieve profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payers on a timely basis, or if we fail to comply with applicable billing requirements, it could have an adverse effect on our revenue and our business. In addition, the coding procedure used by third-party payers to identify various procedures, including our test, during the billing process is complex, does not adapt well to our tests and may not enable coverage and adequate reimbursement rates. Third-party payers usually require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology, or the CPT code. CPT coding plays a significant role in how our Guardant360 test is reimbursed both from commercial and governmental payers. The CPT code set is maintained by the American Medical Association, or AMA. In cases where there is not a specific CPT code to describe a test, such as Guardant360 test, the test may be billed under an unlisted molecular pathology procedure code or through the use of a combination of single gene CPT codes, depending on the payer. The Protecting Access to Medicare Act, or PAMA authorized the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The AMA has created a new section of CPT codes, Proprietary Laboratory Analyses codes or PLA, to facilitate implementation of this section of PAMA. In addition, CMS maintains the Healthcare Common Procedure Coding System, or HCPCS, and may assign unique level II HCPCS code to tests that are not already described by a unique CPT code. New CPT codes are issued annually and new HCPCS codes are issued as frequently as quarterly. Payers' acceptance of the new code could be delayed, and transition to the new code could result in a decrease in reimbursement for our tests, both of which could potentially reduce revenue from commercial and government payers. In addition, Z-Code Identifiers are used by certain payers, including under Medicare's Molecular Diagnostic Services Program, or MolDX, to supplement CPT codes for molecular diagnostics tests such as our Guardant360 test. Following the FDA approval of our Guardant360 CDx test, a new Z-Code Identifier was issued in August 2020. In January 2021, a proprietary laboratory analyses, or PLA code was issued for our Guardant360 CDx **test** with an effective date in April 2021. Additionally, based on this new PLA code, we applied to the CMS for our Guardant360 CDx test to become an advanced diagnostic laboratory test, or ADLT. In March 2021, CMS approved ADLT status to the Guardant360 CDx test, based on which Medicare paid us at the lowest available commercial rate **per test**, from April 1, 2021 to December 31, 2021. Effective January 1, 2022, Medicare ~~has~~ started to reimburse Guardant360 CDx services at the median rate of claims paid by commercial payers and this rate will ~~apply until December~~ **update annually each year based on the previous year's private payor data submission. In July of 2023** ~~2022~~ **a CPT code was issued for Guardant360**. In March 2022, Palmetto GBA, the Medicare administrative contractor for MolDX, or MAC, responsible for administering Medicare's Molecular Diagnostic Services Program, or MolDX, conveyed coverage for our Guardant360 TissueNext test under the existing local coverage determination. The policy covers our Guardant360 TissueNext test for Medicare fee-for-service patients with advanced solid tumor cancers **a CPT code was issued for TissueNext effective in October of 2022**. In July 2022, Palmetto GBA conveyed coverage for our Guardant Reveal test for fee-for-service Medicare patients in the United States with stage II or III colorectal cancer whose testing is initiated within three months following curative intent therapy, with an effective date of December 2021. **In April 2023 Guardant360 Response received Medicare coverage for tracking patient response to immunotherapy after an initial Guardant therapy selection test. In January, 2024 a CPT code was issued for Guardant360 Response. Effective January 1, 2024, Medicare has increased the reimbursement rate for our Guardant360 LDT test to the same rate as our Guardant360 CDx test.** Due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our tests, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received for a test differs from the revenue recorded for the test. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. Additionally, if coding changes were to occur, payments for certain uses of our tests could be reduced, put on hold, or eliminated. Use of coding for billing our products that does not describe a specific test, requires the claim to be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. Because billing third-party payers for our tests is an unpredictable, challenging, time-consuming and costly process, we may face long collection cycles and the risk that we may never collect at all, either of which could adversely affect our business, results of operations and financial condition, and we may have to increase collection efforts and incur additional costs. Changes in healthcare laws, regulations and policies could increase our costs, decrease our sales and revenues and negatively impact reimbursement for our tests. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA, became law. This law substantially changed the way health care is financed by both commercial payers and government payers, and significantly impacted our industry. The ACA contains a number of provisions expected to impact existing state and federal health care programs or result

in the development of new programs, including those governing enrollments in state and federal health care programs, reimbursement changes and fraud and abuse. Our business and operations could be affected by the ACA, including in ways we cannot currently predict. Since its enactment, there have been efforts to repeal all or part of the ACA. On June 17, 2021 the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U. S. Supreme Court ruling, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, ~~with the exception of a temporary suspension from May 1, 2020 through March 31, 2022~~, unless additional Congressional action is taken. We anticipate there will continue to be proposals by legislators at both the federal and state levels and in foreign jurisdictions, regulators and commercial and government payers to reduce healthcare costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from commercial and government payers. Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our current practices are challenged under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Our collection, use and disclosure of personal information, including patient and employee information, is subject to privacy and security laws and regulations, and our actual or perceived failure to comply with those laws and regulations or to adequately secure the information in our possession could result in significant liability or reputational harm. The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. We collect, process, maintain, retain, evaluate, utilize and distribute large amounts of personal health and financial information and other confidential and sensitive data about our customers and others in the ordinary course of our business. Concerns about and claims challenging our practices with regard to the collection, use, retention, disclosure or security of personally identifiable information or other privacy- related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business. Numerous federal, state and foreign laws and regulations govern collection, dissemination, use and confidentiality of personally identifiable information and protected health information, or PHI, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA; state privacy and confidentiality laws (including state laws requiring disclosure of breaches); federal and state consumer protection and employment laws; and European and other foreign data protection laws. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business. HIPAA establishes a set of national privacy and security standards for the protection of PHI, by health plans, certain healthcare providers that submit certain covered transactions electronically and healthcare clearinghouses, or ‘ ‘ covered entities,’ ’ and their ‘ ‘ business associates,’ ’ which are persons or entities that perform certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. We are a covered entity under HIPAA and therefore must comply with its requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. If we engage a business associate to help us carry out healthcare activities and functions, we must have a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with certain safeguards and other requirements under HIPAA. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and / or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non- compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face additional fines and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer,

or use identifiable health information for commercial advantage, personal gain, or malicious harm. In addition, responding to government investigations regarding alleged violations of these and other laws and regulations, even if ultimately concluded with no findings of violations or no penalties imposed, can consume company resources and impact our business and, if public, harm our reputation. Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Laws in all 50 states require businesses to provide notice to individuals whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, and creating new data privacy and security laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act, or CCPA went into effect on January 1, 2020, and creates certain data privacy rights for California residents. The CCPA increases the privacy and security obligations of entities handling certain personal information, and provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect in January 2023, and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It has also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut, and Utah and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we may have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients, and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as PHI, or personally identifiable information along with increased demands for enhanced data security infrastructure, could greatly increase our costs of providing our services, decrease demand for our services, reduce our revenue and / or subject us to additional risks. Furthermore, the Federal Trade Commission, or the FTC, and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. In addition, the interpretation and application of consumer, health- related, and data protection laws, especially with respect to genetic samples and data, in the United States, European Economic Area, or EEA, and elsewhere are often uncertain, contradictory, and in flux. We operate or may operate in a number of countries outside of the United States whose laws may in some cases be more stringent than the requirements in the United States. For example, EEA member states have specific requirements relating to cross- border transfers of personal data to certain jurisdictions, including to the United States where our laboratory resides. In addition, some countries have stricter consumer notice and / or consent requirements relating to personal data collection, use or sharing, more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, international privacy and data security regulations may become more complex and have greater consequences. For instance, the General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes stringent data protection requirements for the processing of personal data of persons within the EEA. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR imposes strict data protection compliance requirements including: providing detailed disclosures about how personal data is collected and processed; demonstrating that an appropriate legal basis is in place or otherwise exists to justify data processing activities; granting rights for data subjects in regard to their personal data; introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; defining pseudonymized (i. e., key- coded) data; imposing limitations on retention of personal data; maintaining a record of data processing; and complying with the principal of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EEA member states may result in fines of up to € 20, 000, 000 or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Failure to comply with the GDPR and other applicable privacy or data security- related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with client contracts and have an adverse effect on our business, financial condition and results of operations. European data protection law also imposes strict rules on the transfer of personal data out of the EU to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one



jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, in July 2020, the Court of Justice of the EU, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses, or SCCs. In March 2022, the United States and EU announced a new regulatory regime intended to replace the invalidated regulations; however, **In October 2022, this new President Biden signed an executive order to implement the EU- US-U. S. Data Privacy Framework, which serves as a replacement to the Privacy Shield. The European Commission adopted the adequacy decision on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16-10, 2020 2023 have taken a restrictive approach to international data transfers.** As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i. e., fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover. We are also subject to evolving EU privacy laws on cookies and e- marketing. In the EEA, informed consent is required for the placement of a cookie or similar technologies on a user' s device and for direct electronic marketing. The GDPR also imposes conditions on obtaining valid consent, such as a prohibition on pre- checked consents and a requirement to ensure separate consents are sought for each type of cookie or similar technology. Any of these changes to EU data protection law or its interpretation could disrupt and harm our business. We rely on a mixture of safeguards to transfer personal data from our EU business to the U. S., and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators or current challenges to these mechanisms in the European courts. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self- regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or reinterpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products. If so, in addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. Any inability to adequately address data privacy or security- related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results of operations. We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations. Risks related to our intellectual property If we are unable to obtain and maintain sufficient intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop, manufacture and commercialize products, services or technology similar or identical to ours, and our ability to successfully develop, manufacture or commercialize our products, services or technology may be impaired. We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to obtain, maintain and / or protect our intellectual property rights, third parties may be able to compete more effectively against us. In addition, we have incurred and may continue to incur substantial litigation costs in our attempts to enforce or restrict the use of our intellectual property rights against third parties or defend ourselves against third parties claiming that we are infringing upon such third parties' intellectual property rights. To the extent our intellectual property rights offers inadequate protection, or

is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property rights do not provide adequate coverage of our products, services or technology, our competitive position could be adversely affected, as could our business. As is the case with other biotechnology companies, our success depends in large part on our ability to obtain, maintain and protect the intellectual property we own or we have licensed from others. We apply for patents covering our products, services and technologies and uses thereof, as we deem appropriate. However, obtaining, maintaining and enforcing biotechnology patents is costly, time- consuming and complex. We may fail to apply for patents on important products, services or technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain or enforce patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Patent prosecution process can be time- consuming and expensive. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to us by third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We own or license numerous U. S. patents and pending U. S. patent applications, with international counterparts in certain countries. It is possible that our or our licensors' pending patent applications will not result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, services or technologies, may not provide us with any competitive advantages, or may be challenged by third parties and be invalidated or found unenforceable. It is possible that others will design around our current or future patented products, services or technologies. Some of such patent rights are being challenged, including at the United States Patent and Trademark Office, or USPTO, in post- grant proceedings, at the European Patent Office, or EPO, in opposition proceedings, and some of such patent rights may be challenged in the future. We may not be successful in defending any such challenges made against our owned or licensed patents or patent applications. Any successful third- party challenge to such patent rights could result in their unenforceability or invalidity and increased competition to our business. We have challenged and may choose to challenge the patents or patent applications of third parties. The outcome of patent disputes or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business. The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA sequences. In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like our current products and tests, and our future products, are particularly uncertain. Various courts, including the U. S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving legal and administrative standards around the world, including in the United States may adversely affect our ability to obtain patents and may facilitate third- party challenges to any owned or licensed patents. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many foreign jurisdictions do not favor the enforcement of patent rights and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patent rights and other intellectual property rights thereunder. Proceedings to enforce our patent rights and other intellectual property protection in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property rights. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. We may not develop additional proprietary products, services, methods and technologies that are patentable. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy- Smith America Invents Act, or the America Invents Act, enacted in September 16, 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor' s patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution or post- grant proceedings, including post- grant review, inter partes review

and derivation proceedings, to attack the validity of a patent. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence might not be sufficient to invalidate the claim if presented in a district court action. Accordingly, third parties have used and may continue to use the USPTO proceedings to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding our or our licensors' prosecution of patent applications and enforcement or defense of issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Issued patents covering our products, services or technology could be found invalid or unenforceable if challenged. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our owned or licensed patent rights have been, are being or may be challenged at a future point in time in opposition, derivation, re-examination, inter partes review, post- grant review or interference. Any successful third- party challenge to our patent rights in this or any other proceeding could result in the unenforceability or invalidity of such patent rights, which may lead to increased competition to our business, which could harm our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, manufacture or commercialize our current or future products, services or technology. We may not be aware of all third- party intellectual property rights potentially relating to our products, services or technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We, or our licensors, might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and we, or our licensors, might not have been the first to file patent applications for these inventions. To determine the priority of our inventions, we have participated and may continue to participate in interference proceedings, derivation proceedings or other post- grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our or our licensors' patent applications. In addition, changes to the patent laws of the United States allow for various post- grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Our licensors may also license patent rights to others, and we may not be aware of such licenses before they are granted or such licenses may be subject to disputes or uncertainties that affect patent rights licensed by us or could limit our ability to enforce such patent rights. If third parties bring actions against our owned or licensed patent rights, we could experience significant costs and management distraction. In patent litigation in the United States or abroad, defendant counterclaims alleging invalidity or unenforceability of plaintiff' s patents are common. Grounds for a validity challenge for invalidity could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the patent office or made a misleading statement during prosecution. Similar claims may also be raised before patent offices in the United States or abroad, even outside the context of litigation, through mechanisms including re- examination, post- grant review and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patent rights in such a way that they no longer cover our products. The outcome of patent litigation or patent office proceedings following assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the relevant patent that protects our products, service or technology. Such a loss of patent protection could have a material adverse impact on our business. We and some of our licensors have initiated, are currently involved in, and may in the future initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our products, services or technology. Defendants in such proceedings could counterclaim that the patents covering our products, services or technology are invalid or unenforceable and could institute legal proceedings to challenge such patents both in court and before patent offices. Any assertion of invalidity and / or unenforceability against the patents covering our products, services or technology, even if not successful, could be time- consuming and expensive to defend, damage our reputation in the marketplace and the prospects for our business, and divert our management' s attention. We rely on licenses from third parties, and if we lose these licenses then we may be subjected to future litigation. If we cannot license and maintain rights to use third- party intellectual property rights on reasonable terms, we may not be able to successfully develop, manufacture and / or commercialize our products, services or technology. Our licensed intellectual property rights may lose value or utility over time. From time to time, we may identify third- party technology we may need, including those related to develop, manufacture or commercialize new products, services or technology. We may also need to negotiate agreements to in- license patents or other intellectual property rights from third parties before or after introducing a commercial products, service of technology, and we may not be able to obtain necessary licenses to such patents or other intellectual property rights. We are a party to various license agreements, including royalty- bearing agreements, that grant us rights to use and practice certain intellectual property of third parties, including claims included in issued patents, typically in certain specified fields of use. We may need to obtain additional licenses from others to advance our research, development, manufacture and commercialization activities. We may be unable to enter into the necessary license agreements on acceptable terms or at all, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. In return for the use of a third party' s intellectual property rights, we may agree to pay the licensor royalties based on sales of our products, services or technology. Royalties are a component of cost of products, services or technology and affect the margins on our products, services or technology. If we are

unable to negotiate reasonable royalties or if we have to pay royalties on technology that becomes less useful for us or ceases to provide value to us, our profit margin will be reduced and we may suffer losses. Our license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us, including obligations to making payments to our licensors upon achievement of milestones. In spite of our efforts, our licensors have asserted and may in the future assert that we have materially breached our obligations under such license agreements and could therefore seek or threaten to terminate the license agreements. If these licenses are terminated, or if the underlying patent rights fail to provide the intended exclusivity, our ability to develop, manufacture and commercialize products, services and technology covered by these license agreements would be limited or lost, and our competitors or other third parties might have the freedom to develop, produce, manufacture, seek regulatory approval of, or to market, products, services or technology identical or similar to ours and we may be required to cease our development, manufacture and / or commercialization activities in connection with our products, services and / or technology. Our actual or potential licensors could take action with respect to our licensed intellectual property that may decrease the value of such licensed intellectual property. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Moreover, disputes could arise with respect to any aspect of our license agreements, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our products or product candidates, services, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the licensing of patent and other rights controlled by our licensors or developed under our collaborative development relationships to others; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how licensed to us or resulting from the joint creation or use of intellectual property by our licensors, us and / or our partners; • the validity, enforceability or priority of licensed patent rights; and • the amount of royalties and other payments we are obligated to pay under the license agreement. If we do not prevail in such disputes, we may lose the rights under any of such license agreements, the license agreements may not be meaningful for our business and operations, and we may be subject to unnecessary or additional payment obligations. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements could be susceptible to multiple interpretations. The resolution of any such contract interpretation disagreement could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over licensed intellectual property impair our ability to enforce licensed intellectual property against third parties or use it to defend ourselves in litigation, the value of such licensed intellectual property may be diminished. If we fail to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, manufacture and commercialize the affected product, product candidate, service or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. If any of these license agreements is terminated, if the licensor fails to abide by the terms of the license agreement, if the licensor fails to enforce its intellectual property rights licensed to us against third parties that infringe upon such intellectual property rights, or if the licensed patent or other rights are found to be invalid or unenforceable, we may be unable to achieve our business goals and our results of operations and financial condition could be adversely affected. Absent the license agreements, we could infringe patents and other intellectual property rights of the licensors subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products, services or technology, including our tests, which could adversely affect our ability to offer products, services or technology, our ability to continue operations and our financial condition. Any intellectual property rights licensed by us may lose value or utility, including as a result of a change of in the industry, in our business objectives, others' technology, our dispute with the licensor, and other circumstances outside our control. We may not be able to protect or enforce our intellectual property rights adequately throughout the world. Filing, prosecuting and defending patents and other intellectual property rights covering our products, services and technology in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some territories outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries and regions do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling, making or importing products, services or technology by practicing our intellectual property rights. Competitors may practice our intellectual property rights in jurisdictions where we have not obtained patent protection to develop, manufacture, sell or import their own products, services or technology and may also export products, services or technology that infringe upon our intellectual property rights to territories where we have patent protection that do not provide strong intellectual property or enforcement rights as strong as that in the United States. These products, services or technology may compete with our products, services or technology. Our patents or other intellectual property rights existing outside the United States may not be effective or sufficient to prevent third parties from competing with us. Similarly, intellectual property rights may be exhausted in certain situations, and others could import our products sold abroad and compete with us domestically. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries and regions do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents and other intellectual property rights in such jurisdictions. Proceedings to enforce our patent rights and other intellectual property rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our

business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed. In addition to pursuing patents covering our products, services and technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality and non-disclosure agreements with those that have access to our confidential and proprietary information including employees, independent contractors, academic institutions, corporate partners and our advisers, and invention assignment agreements with our employees and independent contractors, and when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized use or disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction. Monitoring unauthorized use or disclosure is difficult, and we do not know whether the steps we have taken to prevent such use or disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. We also seek to preserve the integrity and confidentiality of our proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed trade secrets of their former employers. We have employed or engaged and expect to employ or engage individuals who were previously employed at or associated with universities or other companies, including our competitors or potential competitors. Although we try to ensure that our employees and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we lose, in addition to paying monetary damages, we may be deprived of valuable intellectual property and face increased competition. A loss of key research personnel or work product could hamper or prevent our ability to develop, manufacture and / or commercialize products, services or technology, which could materially adversely affect our business. Even if we are successful in defending against these claims, litigation could result in damage to our reputation and substantial costs and be a distraction to management and affected individuals. We may not be able to protect and enforce our trademarks and we could infringe others' trademarks. We have not yet registered trademarks in all of our potential markets, although we have registered Guardant Health, Guardant360 and GuardantOMNI in the United States. If we apply to register additional trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not timely register and enforce marks used in connection with our products, services or technology, we may encounter difficulty in enforcing them against third parties, and if these marks are registered by others, we could infringe such trademarks and may have to defend ourselves to continue the use of our trademarks, which may be time consuming and costly, and we may be unsuccessful. We may be subject to claims challenging the inventorship or ownership of our owned or licensed intellectual property. We or our licensors may be subject to claims that former employees, independent contractors, collaborators or other third parties have an interest in or right to our owned or licensed patents, trade secrets or other intellectual property. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, independent contractors or others who are involved in developing such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending against any such claims, we may lose exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in damage to our reputation and substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We are and may continue to be involved in litigation and other legal proceedings related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition. We have been, are currently in, and may also in the future be, involved with litigation or USPTO actions with various third parties. We expect that the number of such claims may increase as the number of our products or services grows, and the level of competition in our industry segments increases. Any infringement claim, regardless of its validity, could harm our business by, among other things, resulting in time-consuming and costly litigation, diverting management's time and attention from the development of our business, or requiring the payment of monetary damages (including treble damages, attorneys' fees, costs



and expenses if we are found to have willfully infringed) and ongoing royalties. Litigation may be necessary for us to enforce our intellectual property and proprietary rights or to determine the scope, coverage and validity of the intellectual property and proprietary rights of others. We are currently engaged in lawsuits and in proceedings before the USPTO in relation to certain such patents. The outcome of such lawsuits, as well as any other litigation or proceeding, is inherently uncertain and might not be favorable to us. Further, we could encounter delays in introductions or interruptions in the development, manufacture or sale of products, services or technologies, as we develop alternative products, services or technologies. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. If we do not prevail in such legal proceedings, we may be required to pay damages, and we may lose significant intellectual property protection for our products, services or technologies, such that competitors could copy our products, services or technologies. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition. As we move into new markets and applications for our products, services or technologies, incumbent participants in such markets may assert their patents and other intellectual property or proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. As our business matures and our public profile grows, we may also be subject to an increased number of allegations of patent or other intellectual property infringement, whether by our competitors or other third parties, both in the United States and throughout the world wherever we seek to manufacture, commercialize or import our products, services or technologies. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In addition, while we can assert our own patents or other intellectual property rights during litigation, our own patents or other intellectual property rights may provide little or no deterrence or protection against third parties. Therefore, our commercial success may depend in part on our non-infringement of the patents or other intellectual property rights of third parties and on our success in defending ourselves in litigation. However, our research, development, manufacture and commercialization activities are currently and may in the future be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other patent challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the USPTO, and corresponding proceedings before foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing, manufacturing and / or commercializing products, services or technologies. As the precision oncology industry expands and more patents are issued, the risk increases that our products, services or technologies may be subject to claims of infringement of the patent rights of third parties. Numerous significant intellectual property issues have been litigated, are being litigated and will likely continue to be litigated, between existing and new participants in our existing and targeted markets, and our competitors have asserted and may in the future assert that our products or services infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets, and we may enforce our owned or licensed intellectual property rights against our competitors and other parties. Third parties have asserted and may in the future assert that we are employing their proprietary technology or trade secrets without authorization. For instance, **Foundation Medicine-TwinStrand Biosciences, Inc. and the University of Washington** filed a lawsuit for patent infringement against us in **May-August 2016-2021**, which **we settled and a jury verdict was entered against us** in **July 2018-November 2023**. We are also aware of issued U. S. patents and patent applications with claims related to our products and services, and there may be other related third-party patents or patent applications of which we are not aware. By interacting with us, our licensors may learn more about our business or technology and could assert additional patent rights against us, such as patent rights that are not currently licensed to us or patent rights that may be obtained by any such licensors in the future, which may occur if such patent rights are not available for licensing or if they are not offered on acceptable or commercially reasonable terms. Because patent applications can take many years to issue and are not publicly available until a certain period of time passes from filing, there may be currently pending patent applications which may later result in issued patents that our current or future products, services or technologies may infringe. In addition, similar to what other companies in our industry have experienced, we expect our competitors and others may develop or obtain patents with our products, services or technologies in mind and claim that making, having made, using, selling, offering to sell or importing our products, services or technologies infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can, for example, because they have substantially greater resources. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, manufacture, commercialize, sell and import certain products, services or technologies, and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from developing, manufacturing, commercializing, selling and importing certain products, services or technologies. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in product, service or technologies introductions while we attempt to develop alternative products, services or technologies to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from developing, manufacturing or commercializing products, services or technologies and the prohibition of developing, manufacturing or commercializing of any of our products, services or technologies could materially affect our business and our ability to gain market acceptance for our products, services or technologies. Furthermore, because of the

substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In addition, our agreements with some of our customers, suppliers, vendors or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition. Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non- compliance can result in abandonment or forfeiture of the patent or patent application and thus loss of patent rights in the relevant jurisdiction. Such an event would allow our competitors to enter the unprotected market and have a material adverse effect on our business. Patent terms may be inadequate to protect our competitive position for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or services are obtained, once the patent life has expired, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of our new products, services or technologies, patents protecting them might expire before or shortly after they are commercialized. As a result, our owned and licensed patent portfolio may not provide us with a sufficient exclusivity period to exclude others from commercializing products or services similar or identical to ours.

Risks related to our common stock and indebtedness The price of our common stock has fluctuated substantially and may do so in the future, and you may not be able to resell shares of our common stock at or above the price at which you purchased them. The market price of our common stock has been volatile and may fluctuate substantially in the future due to many factors, including:

- volume and customer mix for our precision oncology testing;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- product liability claims or other litigation;
- quarterly or annual variations in our results of operations or those of others in our industry;
- media exposure of our products or of those of others in our industry;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in earnings estimates or recommendations by securities analysts; and

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell their shares, could result in a decrease in the market price of our common stock. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management' s attention and resources from our business. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, future debt or other agreements we may enter into may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Our indebtedness could expose us to risks that could adversely affect our business, financial condition and results of operations. In 2020, we sold \$ 1, 150, 000, 000 aggregate principal amount of 0 % convertible senior notes due 2027, or the 2027 Notes. We may also incur additional indebtedness to meet future needs. Our indebtedness could have significant negative consequences for our security holders, business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- in the event interest accrues on the 2027 Notes or additional indebtedness, requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders if we issue shares of our common stock upon conversion of the Notes or additional indebtedness; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under the 2027 Notes or any additional indebtedness that we may incur. In addition, the 2027 Notes contain, and any future indebtedness that we may incur may contain, financial and other

restrictive covenants that limit our ability to operate our business, raise capital or make payments under our indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that indebtedness becoming immediately payable in full. The conditional conversion features of the 2027 Notes, if triggered, may adversely affect our financial condition. Conversion of the 2027 Notes, to the extent the 2027 Notes are not redeemed or repurchased, will dilute the ownership interest of existing stockholders, and even if anticipated, may otherwise depress the price of our common stock. In the event the conditional conversion feature of the 2027 Notes is triggered, holders of the 2027 Notes will be entitled to convert their 2027 Notes into shares of our common stock upon the occurrence of certain events. If one or more holders of the 2027 Notes elect to convert their 2027 Notes, unless we satisfy our conversion obligation by delivering only shares of our common stock, we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our financial condition. In the event the conditional conversion feature of the 2027 Notes is triggered, the conversion of some or all of the 2027 Notes will dilute the ownership interests of our existing stockholders to the extent we deliver shares of our common stock upon such conversion. The 2027 Notes may become in the future convertible at the option of the holders of the 2027 Notes prior to August 15, 2027 under certain circumstances as provided in the indenture governing the 2027 Notes. Any sales in the public market of shares of our common stock issuable upon such conversion could adversely affect the price of our common stock. In addition, the existence of the 2027 Notes may encourage short selling by market participants because the conversion of the 2027 Notes could be used to satisfy short positions, and even anticipated conversion of the 2027 Notes into shares of our common stock could depress the price of our common stock. The convertible note hedge may affect the value of the 2027 Notes and our common stock. In connection with the sale of the 2027 Notes, we entered into convertible note hedge, the 2027 Note Hedge, transactions with certain financial institutions, or option counterparties. The 2027 Note Hedge transactions are expected generally to reduce the potential dilution upon any conversion of the 2027 Notes and / or offset any cash payments we are required to make in excess of the principal amount of converted 2027 Notes. The option counterparties and / or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock in secondary market transactions prior to the maturity of the 2027 Notes (and are likely to do so during any observation period related to a conversion of the Notes, or following any repurchase of the 2027 Notes by us on any fundamental change repurchase date (as provided in the indenture governing the 2027 Notes) or otherwise). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2027 Notes, which could affect note holders' ability to convert the 2027 Notes and, to the extent the activity occurs during any observation period related to a conversion of the 2027 Notes, it could affect the amount and value of the consideration that note holders will receive upon conversion of the 2027 Notes. The potential effect, if any, of these transactions and activities on the market price of our common stock or the 2027 Notes will depend in part on market conditions and cannot be ascertained at this time. Any of these activities could adversely affect the value of our common stock and the value of the 2027 Notes (and as a result, the value of the consideration, the amount of cash and / or the number of shares, if any, that note holders would receive upon the conversion of the 2027 Notes) and, under certain circumstances, the ability of the note holders to convert the 2027 Notes. We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the 2027 Notes or our common stock. In addition, we do not make any representation that the option counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice. We are subject to counterparty risk with respect to the 2027 Note Hedge transactions. The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the 2027 Note Hedge transactions. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with that option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties. Provisions in our corporate charter documents and under Delaware law could make a change in control of us more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may make it more difficult for our stockholders to replace current members of our board of directors or add new members thereto. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempts by our stockholders to change our management team. Among others, these provisions include that: • our board of directors has the exclusive right to expand its size and to elect directors to fill a vacancy created by the expansion of the board or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three- year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • a special meeting of stockholders may be called only by our board of directors, its chairman, or our co- chief executive officers, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; • our amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which

limits the ability of minority stockholders to elect their director candidates; • our board of directors may alter our bylaws without obtaining stockholder approval; • approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors is required to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors; • stockholders must provide advance notice and additional disclosures in order to nominate candidates for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and • our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law by Delaware courts, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits brought against us and our directors and officers by our stockholders. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. However, a Delaware court held that such an exclusive forum provision relating to federal courts was unenforceable under Delaware law, and unless and until the Delaware court decision is reversed on appeal or otherwise abrogated, we do not intend to enforce such a provision in the event of a complaint asserting a cause of action arising under the Securities Act against us or any of our directors, officers, employees or agents.

**General Risk Factors** We may acquire businesses, form joint ventures or make investments in companies or technologies that could negatively affect our operating results, distract management's attention from other business concerns, dilute our stockholders' ownership, and significantly increase our debt, costs, expenses, liabilities and risks. We have made acquisitions of businesses, technologies and assets and may pursue additional acquisitions in the future. We also may pursue strategic alliances and additional joint ventures that leverage our industry experience to expand our product offerings or distribution. We have limited experience with acquisitions and forming strategic partnerships. We compete for those opportunities with others including our competitors, some of which have greater financial or operational resources than we do. We may not be able to identify suitable acquisition candidates or strategic partners, we may have inadequate access to information or insufficient time to complete due diligence, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Difficulties in assimilating acquired businesses include redeployment or loss of key employees and their severance, combination of teams and processes in various functional areas, reorganization or closures of facilities, relocation or disposition of excess equipment, and increased litigation, regulatory and compliance risks, any of which could be expensive and time consuming and adversely affect us. Integration of an acquired business also may disrupt our ongoing operations and require management resources that we would otherwise focus on developing our existing business. In addition, any acquisition could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We may also experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture. To finance any acquisitions, joint ventures or investments, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. We may need to raise additional capital to fund our existing operations, develop our platform, commercialize new products or expand our operations. We may consider raising additional capital in the future to expand our business, to meet existing obligations, to pursue acquisitions or strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our current products and tests, and address competitive developments;
- fund development and marketing efforts of our products under development or any other future products we may develop;
- expand our technologies into other types of cancer management and detection products;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

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

- our ability to achieve revenue

growth; • our rate of progress in establishing payer coverage and reimbursement arrangements with domestic and international commercial payers and government payers; • the cost of expanding our laboratory operations and product offerings, including our sales and marketing efforts; • our rate of progress in, and costs of our sales and marketing activities associated with, establishing adoption of and reimbursement for our current products, including our tests; • our rate of progress in, and costs of our research and development activities associated with, products in research and early development; • the effect of competing technological and market developments; • costs related to our international expansion; and • the potential costs of and delays in product development as a result of any existing or new regulatory oversight applicable to our products. We may seek to sell equity or convertible securities, enter into a credit facility or another form of third- party funding, or seek other debt financing. The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity or convertible securities, dilution to our stockholders could result. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products or grant licenses on terms that are not favorable to us. These alternatives of raising additional capital may not be available to us on acceptable or commercially reasonable terms, if at all, or in amounts sufficient to meet our needs. The failure to obtain any required future financing may require us to reduce or curtail existing operations and could contribute to negative market perceptions about us or our securities. As a result of adverse geopolitical and macroeconomic developments, including economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions and there has been increasing uncertainty about economic stability. If the equity and credit markets remain depressed or further deteriorate as a result of this global uncertainty, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred net losses since our inception and we may never achieve or sustain profitability. Under the Tax Cuts and Jobs Act, federal net operating loss, or NOL, carryforwards we generated in tax years through December 31, 2017 may be carried forward for 20 years and may fully offset taxable income in the year utilized, and federal NOLs we generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80 % of our taxable income annually. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation’s ability to use its pre- change NOL carryforwards and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. We have not completed a study to assess whether an ownership change for purposes of Section 382 or 383 has occurred, or whether there have been multiple ownership changes since our inception. For purposes of Section 382 or 383, we may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre- change NOL carryforwards to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. Therefore, if we attain profitability, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. Changes in tax laws or regulations could harm our financial condition and results of operations. Changes in tax laws or regulations, or changes in interpretations of existing laws and regulations, could materially affect our financial condition and results of operations. For example, the Biden administration and members of Congress have proposed, and future U. S. presidential administrations may propose, various U. S. federal tax law changes, which if enacted could have a material impact on our business operations and financial performance. In addition, many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws, including as a result of the base erosion and profit shifting, or BEPS, project that is being led by the Organization for Economic Co- operation and Development, or OECD, and other initiatives led by the OECD or the European Commission. Due to the expanding scale of our international business activities, these types of changes to the taxation of our activities could increase the amount of taxes imposed on our business. Any of these outcomes could harm our financial position and results of operations. **The requirements we expect to incur significant additional costs as a result of being a public company have and may continue to strain our resources**, which may adversely affect our business, financial condition and results of operations. We **have incurred, and expect to incur**, costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, as well as the rules of Nasdaq. These rules and regulations, including those applicable to a large accelerated filer such as us, significantly increase our accounting, legal and financial compliance costs and make some activities more time- consuming. These rules and regulations also make it more expensive for us to maintain directors’ and officers’ liability insurance. Accordingly, increases in costs incurred as a result of being a publicly traded company may adversely affect our business, financial condition and results of operations. **In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.**



**For example, pursuant to SEC rules, we are required to make certain cybersecurity disclosures, including related to material cybersecurity incidents and the reasonably likely impact of such an incident. Determining whether a cybersecurity incident is reportable may not be straightforward and any such disclosures could be costly and lead to negative publicity, loss of customer confidence, diversion of management's attention, and government investigations.**

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. In connection with adopting and implementing a new revenue recognition standard, FASB ASC Topic 606, Revenue from Contracts with Customers, management has made and will continue to make judgments and assumptions based on our interpretation of the new standard. The new revenue recognition standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. We also adopted a new lease accounting standard, FASB ASC Topic 842, Leases, which involved significant judgment and assumptions, including the estimation of incremental borrowing rate used to discount our lease liabilities and the assessment of risks associated with the specific economic environment of our leased assets. It is possible that interpretation, industry practice and guidance may evolve as we work toward implementing these new accounting standards. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of analysts and investors, resulting in a decline in the market price of our common stock. The loss of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians, sales representatives and business development managers could adversely affect our business. Our success depends on the skills, experience and performance of key members of our senior management team, including Helmy Eltoukhy and AmirAli Talasaz, our Co- Chief Executive Officers. The individual and collective efforts of these employees will be important as we continue to develop our platform and additional products, and as we expand our commercial activities. The loss or incapacity of existing members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers signed offer letters when first joining our company, but do not have employment agreements, and we cannot guarantee their retention for any period of time. We do not maintain "key person" insurance on any of our employees. Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our headquarters in Palo Alto, California. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, we may have difficulties locating, recruiting or retaining qualified sales representatives and business development managers. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time. If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us and, as a result, the value of our common stock. As a result of becoming--- being a public company, we are required, under Section 404 of the Sarbanes- Oxley Act, to furnish annual reports by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis. If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including: • faulty human judgment and simple errors, omissions or mistakes; • fraudulent action of an individual or collusion of two or more people; • inappropriate management override of procedures; and • the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control. Pursuant to the Sarbanes- Oxley Act and the rules and regulations promulgated by the SEC, we are required to furnish in this Annual Report on Form 10- K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we believe our internal control over financial reporting is currently effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and would increase our costs of doing business. In addition, under the federal securities laws, our auditors are required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of

our financial reports, which could cause the price of our common stock to decline. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated, communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, CMS and non- U. S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations, lawsuits or other actions stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or from coverage of commercial payers, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with the law and curtailment or restructuring of our operations, which could have a significantly adverse impact on our business. Whether or not we are successful in defending against such actions, we could incur substantial costs and expenses, including legal fees, and divert the attention of management from the operation of our business. If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources. The marketing, sale and use of our products could lead to the filing of product liability claims were someone to allege that our products identified inaccurate or incomplete information regarding the genomic alterations of the tumor or malignancy analyzed, reported inaccurate or incomplete information concerning the available therapies for a certain type of cancer, or otherwise failed to perform as designed. We may also be subject to professional liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time- consuming for us to defend. We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could damage our reputation or cause current clinical customers to terminate existing agreements with us and potential clinical customers to seek other partners, any of which could adversely impact our results of operations. Cyberattacks, security breaches, loss of data and other disruptions in relation to our information technology systems, as well as those of our third- party service providers, could compromise sensitive information related to our business, prevent us from accessing it and expose us to substantial liability, which could adversely affect our business and reputation. In the ordinary course of our business, we collect and store sensitive data, including PHI and other personal information, credit card and other financial information, intellectual property and proprietary business information owned or controlled by us or other parties such as customers and payers. We manage and maintain our applications and data utilizing a combination of on- site systems and cloud- based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. We also communicate sensitive data, including patient data, through phone, Internet, facsimile, multiple third- party vendors and their subcontractors. We depend on information technology systems for significant elements of our operations, including our laboratory information management system, our computational biology system, our knowledge management system, our customer reporting and our GuardantConnect software platform. Our information technology systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. Our information technology systems store a wide variety of information critical to our business, including research and development information, patient data, commercial information and business and financial information. We face a number of risks related to protecting this critical information, including loss of access, inappropriate use or disclosure, unauthorized access, inappropriate modification and our being unable to adequately monitor, audit or modify our controls over such critical information. This risk extends to the third- party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. Cyberattacks, security breaches,

computer viruses, malware and other incidents could cause misappropriation, loss or other unauthorized disclosure of confidential data, materials or information, including those concerning our customers and employees. Increasingly complex methods have been used in cyberattacks, including ransomware, phishing, structured query language injections, social engineering schemes, and distributed denial-of-service attacks. A cyberattack can also be in the form of unauthorized access or a blocking of authorized access. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer ~~hackers~~ **attackers**, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Our information technology systems and those of our third-party providers, strategic partners and other contractors, subcontractors or consultants are also vulnerable to attack and damage or interruption from telecommunications or network failures, natural disasters, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. As a result of the ~~COVID-19 pandemic~~, and continued hybrid working environment, we and our third party service providers and partners may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We can provide no assurance that we or our vendors will be able to detect, prevent or contain the effects of such attacks or other information security risks or threats in the future. The costs of attempting to protect against the foregoing risks and the costs of responding to a cyberattack are significant. Large scale data breaches at other entities increase the challenge we and our vendors face in maintaining the security of our information technology systems and of our customers' sensitive information. Following a cyberattack, our and / or our vendors' remediation efforts may not be successful, and a cyberattack could result in interruptions, delays or cessation of service, and loss of existing or potential customers. In addition, breaches of our and / or our vendors' security measures and the unauthorized dissemination of sensitive personal information or proprietary information or confidential information about us, our customers or other third-parties, could expose our customers' private information and our customers to the risk of financial or medical identity theft, or expose us or other third parties to a risk of loss or misuse of this information, and result in investigations, regulatory enforcement actions, material fines and penalties, loss of customers, litigation or other actions which could have a material adverse effect on our business, prospects, reputation, results of operations and financial condition. In addition, if we fail to adhere to our privacy policy and other published statements or applicable laws concerning our processing, use, transmission and disclosure of protected information, or if our statements or practices are found to be deceptive or misrepresentative, we could face regulatory actions, fines and other liability. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use, modification or disclosure, no security measures can be perfect. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. For example, in the past year, we identified security incidents involving an unauthorized actor obtaining access to our email system and sending phishing messages. Despite the precautionary measures we have taken in response to such incidents and to prevent other unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from performing our comprehensive genomic analysis, preparing and providing reports to pathologists and oncologists, billing payers, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur, the information stored on our information technology systems could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings, and liability under federal, state or foreign laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Notice of breaches is required to be made to affected individuals, the Secretary of the HHS or other state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures and an enterprise security program to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect all data from breach. We continue to prioritize security and the development of practices and controls to protect our systems. As cyber threats evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities, and these efforts may not be successful. We have contingency plans and insurance coverage for certain potential claims, liabilities, and costs relating to security incidents that may arise from our business or operations; however, the coverage may not be sufficient to cover all claims, liabilities, and costs arising from the incidents, including fines and penalties. It could be difficult to predict the ultimate resolution of any such incidents or to estimate the amounts or ranges of potential loss, if any, that could result therefrom. If we cannot successfully resolve a security incident or contain any potential loss, it could materially impact our ability to operate our business as well as our results of operations and financial position. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. 78 **75**

