UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-38683

GUARDANT HEALTH, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**45-4139254**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

505 Penobscot Dr.
Redwood City, California 94063
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (855) 698-8887

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001	**GH**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated Filer	☐
Non-accelerated Filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $7.6 billion (based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2020 of $81.13 per share).

As of February 19, 2021, the registrant had 100,426,884 shares of common stock, $0.00001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its annual meeting of stockholders to be held in 2021 (the *"*2021 Annual Meeting*"*), to be filed with the Securities and Exchange Commission (the *"*SEC*"*) within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates, are incorporated herein by reference where indicated. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, such proxy statement is not deemed to be filed as part hereof.

GUARDANT HEALTH, INC.
FORM 10-K

For the Fiscal Year Ended December 31, 2020

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections titled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are based on our current expectations, estimates, forecasts and projections about our business, our results of operations, the industry in which we operate and the beliefs and assumptions of our management. Words such as "believe," "may," "will," "estimate," "continue," "anticipate," "would," "could," "should," "intend" and "expect," variations of these words, and similar expressions are intended to identify forward-looking statements. These forward-looking statements are only predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in Part I, Item 1A,"Risk Factors," of this Annual Report on Form 10-K and elsewhere herein, and in other reports we file with the U.S. Securities and Exchange Commission, or the SEC. While forward-looking statements are based on the reasonable expectations of our management at the time that they are made, you should not rely on them. We undertake no obligation to revise or update publicly any forward-looking statements for any reason, whether as a result of new information, future events or otherwise, except as may be required by law.

Each of the terms the "Company," "we," "our," "us" and similar terms used herein refer collectively to Guardant Health, Inc., a Delaware corporation, and its consolidated subsidiaries, unless otherwise stated.

PART I

Item 1. Business

Overview

We are a leading precision oncology company focused on helping conquer cancer globally through use of our proprietary blood-based tests, vast data sets and advanced analytics. We believe that the key to conquering cancer is unprecedented access to its molecular information throughout all stages of the disease, which we intend to enable by a routine blood draw, or liquid biopsy. Our Guardant Health Oncology Platform is designed to leverage our capabilities in technology, clinical development, regulatory and reimbursement to drive commercial adoption, accelerate drug development, improve patient clinical outcomes and lower healthcare costs. In pursuit of our goal to manage cancer across all stages of the disease, we have launched our Guardant360, Guardant360 CDx and GuardantOMNI liquid biopsy-based tests for advanced stage cancer and in February 2021, launched our Guardant Reveal liquid biopsy-based test for residual and recurring cancer to first address the need in Stage II-III colorectal cancer. We are developing tests from our Guardant360 tissue program which aims to address challenges with tissue genotyping products currently available in the market and are also developing tests from our LUNAR program which aims to address the needs of early-stage cancer patients with neoadjuvant and adjuvant treatment selection, cancer survivors with surveillance, and asymptomatic individuals eligible for cancer screening and individuals at a higher risk for developing cancer with early detection. We have also developed our GuardantINFORM platform to further accelerate precision oncology drug development by biopharmaceutical companies by offering them an in-silico research platform to unlock further insights into tumor evolution and treatment resistance across various biomarker-driven cancers.

Therapy selection in advanced stage cancer patients - We are pioneering the clinical comprehensive liquid biopsy market with our tests. Our Guardant360 test is a molecular diagnostic test measuring 74 cancer-related genes, our Guardant360 CDx was the first comprehensive liquid biopsy test approved by the U.S. Food and Drug Administration, or FDA, measuring 55 cancer related genes, and our GuardantOMNI test has a broader 500-gene panel, all of which analyze circulating tumor DNA in blood. Based on SEER Cancer Registry statistics we estimate the total number of metastatic cancer patients in the United States to be approximately 700,000. Our Guardant360 test has been used over 150,000 times by clinicians to help inform which therapy may be effective for advanced stage cancer patients with solid tumors. Our tests are used by biopharmaceutical companies for a range of applications, including identifying target patient populations to accelerate translational science research and clinical trial enrollment, companion diagnostic development, and post-approval commercialization. The increasing diversity of targeted therapies and associated molecular biomarkers has given rise to comprehensive genomic profiling, particularly in tumor types where multiple genomic targets can be found and treated effectively. For example, non-small cell lung cancer, or NSCLC, like other tumors, has multiple effective treatment options targeting different genomic mutations. There are nine targetable genes in NSCLC, which are comprised of alterations across all four genomic variant classes (SNVs, indels, CNVs, and fusions), as well as TMB. Five of these targets are on-label approved biomarkers for FDA-approved therapies. The NCCN treatment guidelines recommended testing for all of the genomic mutations or alterations across different cancer types, which demonstrates the requirement for broader genomic profiling.

Neoadjuvant and adjuvant treatment selection in early-stage cancer patients and surveillance in cancer survivors -We are developing tests from our LUNAR program for neoadjuvant and adjuvant treatment selection in early-stage cancer patients. For early stage solid tumors, neoadjuvant and adjuvant treatment may be given as a first step in care to shrink the tumor or adjuvantly as a secondary treatment after the primary treatment to reduce the risk of recurrence. However, not all early stage cancer patients may benefit from neoadjuvant and adjuvant treatment. For instance, based on data published in 2007 from a randomized study of adjuvant chemotherapy versus observation in patients with colorectal cancer, the use of adjuvant treatment showed significant benefit for a subgroup of the patients who meet certain clinical criteria, but only marginal benefit for the patients who do not meet these criteria. We have developed the Guardant Reveal test for minimal residual disease which can help identify recurrence earlier than traditional modalities in cancer survivors and potentially identify early stage cancer patients who may benefit from adjuvant treatment. Our Guardant Reveal test leverages data and learnings from our tests and is designed to enable clinicians to detect minimal residual disease and to detect cancer recurrence at a stage when intervention may have a higher chance of success. We believe our Guardant Reveal test may also help biopharmaceutical companies identify new drug development opportunities. In return, these relationships could help us establish clinical utility for our tests and create new testing opportunities related to emerging therapies.

Early detection of cancer in asymptomatic individuals eligible for cancer screening - We are developing the LUNAR-2 test to support cancer screening in asymptomatic individuals including who are eligible for colorectal cancer screening based on the 2016 U.S. Preventive Services Task Force, or USPSTF, guidelines for colorectal cancer screening. Recent data reported at the 2019 National Colorectal Cancer Roundtable, shows that amongst this population, approximately 31% are not up to date with the recommended colorectal cancer screening. Therefore, we believe there is a significant unmet need for non-invasive modalities such as our LUNAR-2 assay that, if successfully developed, we believe could increase compliance with the USPSTF guidelines. We are also pursuing further development of our LUNAR-2 test to support screening for additional cancer types in asymptomatic individuals recommended by the USPSTF and cancer types without a reference standard for screening. We believe that developing a blood test for early detection of cancer requires a vast amount of molecular and clinical data across all stages of the disease in order to better understand the biology and clinical relevance of tumor-specific biomarkers in blood. While we believe the benefits of early detection on clinical outcomes are widely known, early detection may also benefit biopharmaceutical companies by identifying a much larger at-risk population who may benefit from early therapeutic intervention or from preventative medicines.

Guardant Health Oncology Platform - We believe our Guardant Health Oncology Platform has developed strengths across five critical layers, each of which facilitates success in the adjacent layers, and together the five layers form a barrier to entry and provide us a competitive advantage and a platform we can efficiently leverage across multiple products. The five layers of our Guardant Health Oncology Platform are as follows:

Technology - Our proprietary Guardant Health digital sequencing technology combines cutting edge capabilities from multiple disciplines including biochemistry, next-generation sequencing, signal processing, bioinformatics, machine learning and process engineering to enable what we believe to be the world's market leading comprehensive liquid biopsy test with a typical turnaround time of less than seven days after we receive the sample

and enable our high performing liquid biopsy tests intended for different market segments. Furthermore, our machine learning capability enables performance improvement as we incorporate additional data.

Clinical utility - We believe that success in the clinical utility layer requires both independent investments in clinical research and strategic relationships with market-leading biopharmaceutical companies. We have invested heavily in clinical studies, including more than 60 clinical outcomes studies demonstrating that overall biomarker detection rates of our non-invasive blood testing were in line with standard of care tissue testing. Our clinical research collaborations have resulted in more than 200 peer-reviewed publications. We also have relationships with over 60 biopharmaceutical customers that have provided rigorous clinical validation of our technology and early insights into test opportunities for emerging therapeutics.

Regulatory approval - We believe our Guardant360 test was the first comprehensive liquid biopsy approved by the New York State Department of Health, or NYSDOH. In addition, based on our review of publicly available records, we believe our facility was the first comprehensive liquid biopsy laboratory to be certified pursuant to the Clinical Laboratory Improvement Amendments of 1988, or CLIA, accredited by the College of American Pathologists, or CAP, and NYSDOH-permitted. Our Guardant360 CDx test was the first comprehensive liquid biopsy test approved by the FDA, to provide tumor mutation profiling for cancer patients with solid tumors and to be used as a companion diagnostic initially in connection with one therapeutic product of a biopharmaceutical customer.

Payer coverage and reimbursement - The analytical and clinical data that we have generated in our efforts to establish clinical utility, combined with the support we have developed with key opinion leaders, or KOLs, in the oncology space have led to positive coverage decisions by a number of commercial payers. Our Guardant360 test is currently covered by Cigna, Priority Health, multiple regional Blue Cross Blue Shield plans as well as the health plans associated with eviCore for NSCLC, which we believe gives us a competitive advantage with these payers with respect to NSCLC patients.

With respect to Medicare, in July 2018, Palmetto GBA, or Palmetto, the Medicare Administrative Contractor, or MAC, responsible for administering Medicare's Molecular Diagnostic Services Program, or MolDx, issued a local coverage determination, or LCD, for our Guardant360 test with respect to NSCLC patients who meet certain clinical criteria, and in May 2020, Noridian Healthcare Solutions, or Noridian, the MAC responsible for adjudicating claims in California, where our laboratory is located, and a participant in MolDx, 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 Medicare's National Coverage Determination for Next Generation Sequencing (90.2) first established in March 2018, or the NGS NCD. Following FDA approval of our Guardant360 CDx test, we believe our Guardant360 CDx test qualifies for Medicare coverage for FDA-approved indications for use. Future actions taken by Medicare, Noridian or Palmetto may change Medicare coverage for our Guardant360 tests.

Commercial adoption - Success in each of the layers above is important for commercial adoption of our tests by clinicians and biopharmaceutical companies. Additionally, for clinicians, endorsement by KOLs, utilization by academic centers and inclusion in national treatment guidelines are important, especially for adoption in the local community setting where 80% of cancer treatment occurs. Our relationships with key stakeholders across the oncology space, clinical data we believe to support use of Guardant360 test ahead of tissue based testing, as well as the inclusion of liquid biopsy as a potential alternative under certain circumstances to tissue biopsy in NCCN guidelines, have helped facilitate the use of our tests by 9,000 oncologists, who have collectively ordered our Guardant360 test over 150,000 times, and over 60 biopharmaceutical companies. We sold 63,254 tests to clinical customers in the year ended December 31, 2020, an increase from 49,926 and 29,238 in the years ended December 31, 2019 and 2018, respectively. We sold 15,983 tests to biopharmaceutical customers in the year ended December 31, 2020, compared to 20,643 and 10,370 in the years ended December 31, 2019 and 2018, respectively.

Our strategy

Our objective is to be the leading provider of precision oncology products for cancer management across all stages of the disease and drive commercial adoption of our products. To achieve this, we intend to:

- **Increase awareness of our products by:**
  - building awareness of liquid biopsy and pioneering a blood-first paradigm for genotyping cancer patients;
  - educating biopharmaceutical companies, KOLs and advocacy groups;

- advocating for inclusion of our tests in treatment guidelines; and
- expanding access to our products globally through direct investment and by leveraging our global network of partners.

- **Expand clinical utility and increase reimbursement for our products by:**
  - working with private and public payers to establish coverage and reimbursement for our tests;
  - investing in clinical evidence directly and through relationships with academia and biopharmaceutical companies to establish expanded indications for use;
  - demonstrating improved clinical utility and health economics from use of our tests to patients, physicians and payers; and
  - pursuing FDA approval of our tests to facilitate reimbursement and global market access.
- **Strengthen our relationships with customers by:**
  - demonstrating the utility of our products in connection with standard of care treatments thereby encouraging clinical adoption;
  - developing and seeking approval of our products as companion diagnostics for targeted therapies and immuno-oncology therapies; and
  - providing earlier insights into emerging clinically relevant biomarkers.
- **Leverage our Guardant Health Oncology Platform to expand our product portfolio by:**
  - using our commercial engine as a force multiplier of returns on research and development investment to generate data and analytical insights to enable development of new products;
  - taking a disciplined and systematic approach to product and market development, by starting with therapy selection and then expanding sequentially towards early cancer detection;
  - utilizing our data, sample biobank and insights into biology of circulating tumor-related biomarkers in blood to develop our new products;
  - building on our regulatory and commercial infrastructure to accelerate new product launches and drive commercial efficiencies; and
  - using our strategic relationships, including our joint venture with SoftBank and partnerships with European cancer centers and research organizations, to drive global commercialization of our products.

Our products and development program

We have launched our Guardant360, Guardant360 CDx, GuardantOMNI and Guardant Reveal tests and are developing additional tests under our Guardant360 tissue and LUNAR program. We believe our product portfolio, once completed, will address the full continuum of care and has utility in both the clinical and biopharmaceutical markets.

Guardant360 CDx test

We believe our Guardant360 CDx test is the market leading comprehensive liquid biopsy test, based on the number of tests ordered. Guardant360 CDx test is a 55 gene FDA approved test that supports treatment selection for advanced stage cancer patients with solid tumors. Additional gene content and immune-oncology biomarkers (e.g. MSI) are reported in a professional services compendium to the FDA approved CDx report. Results are typically delivered within seven days following receipt of sample and delivered by a clinical report.

Guardant360 test

The number of personalized therapy options for advanced cancer patients continues to grow, giving patients who may have cycled through standard of care therapies additional options. Focused on addressing patient care

throughout the diagnostic journey, we launched an updated and expanded version of our laboratory developed test or LDT in 2020 to support new guideline-recommended biomarkers, including our industry leading plasma-based tumor mutational burden or TMB, MSI-High, expanded homologous recombination repair or HRR gene set, and full coverage of neurotrophic receptor tyrosine kinase or *NTRK* fusions. The Guardant360 LDT ensures progressing patients are given the opportunity to be eligible for these new treatment options, without the need to obtain archival tissue or subject the patient to another invasive biopsy. Results are typically delivered, ten days following receipt of sample and delivered by a clinical report.

Guardant360 clinical report

A typical Guardant360 CDx and Guardant360 clinical report contains somatic mutations, immuno-oncology markers detected in patient blood samples, associated treatment options and available clinical trials in the vicinity of the patient's location. Additionally, the report depicts a proprietary visual representation that shows the evolution of somatic mutations in longitudinal blood samples.

Clinical trials and publications

The goal of our clinical development with Guardant360 tests is to support its use for comprehensive genomic profiling across multiple tumor types, including as a preferred alternative to tissue testing to inform first line treatment right after diagnosis and at time of disease progression. We publish peer-reviewed studies in order to influence treatment guidelines, to educate clinicians and other oncology stakeholders about the value proposition of our test and to set the stage for reimbursement with private and public payers. We have over 60 approved, completed or active clinical outcomes studies, more than 200 peer-reviewed publications and more than 400 scientific abstracts. We are proactively pursuing studies to support the use of our Guardant360 tests as a preferred alternative to tissue testing to inform first line treatment right after diagnosis, with the goal to provide evidence that our Guardant360 tests detects genomic alterations at a similar rate compared to standard of care tissue testing in the United States, Europe and Asia. Such a strategy is predicated on the Guardant360 tests' ability to offer accurate, reliable and fast guideline-directed comprehensive genotyping for all adult solid tumors without exposing patients to invasive biopsy procedures' risks, delays or chance of failure.

GuardantConnect

Because metastatic cancer patients often exhaust standard of care treatment options as the disease progresses and guidelines recommend clinical trials for advanced cancer patients, clinical trial matching is an acute need in oncology. At the same time, biopharmaceutical companies need to fill clinical trials that require screening hundreds of thousands of patients. Despite these needs, clinical trial enrollment in oncology has severely lagged, with only 3-6% of cancer patients enrolling in clinical trials. GuardantConnect is our integrated software-based solution designed for our clinical and biopharmaceutical customers, seeking to connect patients tested with the Guardant360 assay with actionable alterations with potentially relevant clinical trials.

GuardantINFORM

In 2020 we launched GuardantINFORM, our real-world evidence platform featuring an extensive clinical-genomic liquid biopsy dataset of advanced cancer patients. The GuardantINFORM platform is intended to help accelerate research and development of the next generation of cancer therapeutics by offering biopharma partners an *in silico* resource that combines de-identified longitudinal clinical information and genomic data collected from the Guardant360 liquid biopsy test. This robust dataset offers real-world insights into anti-cancer therapy use and associated outcomes, and molecular drivers of treatment response and resistance for over 60 advanced cancers including non-small cell lung, breast, colon, and prostate. Applications for the GuardantINFORM platform include targeted drug development, clinical trial optimization and post-marketing studies.

GuardantOMNI Test

Our GuardantOMNI test is built on Guardant Health Digital Sequencing Technology and learnings from our Guardant360 test. The GuardantOMNI test, launched in 2017, has a significantly larger genomic panel footprint than the Guardant360 test and has achieved comparable analytical performance in clinical studies, including for translational science applications in collaboration with several biopharmaceutical companies, including AstraZeneca, Bristol-Myers Squibb, Merck MSD, Merck KGaA of Darmstadt, Germany and Pfizer. It covers 500

genes, including genes associated with homologous recombination repair deficiency and biomarkers for immuno-oncology applications, such as tumor mutational burden and microsatellite instability.

In order to preserve performance characteristics of our Guardant360 test across a broader gene panel, we implemented additional enhancements to the assay efficiency and bioinformatics analysis to improve the sensitivity of our GuardantOMNI test. These enhancements are critical in the context of using the GuardantOMNI test in the retrospective testing of clinical trial samples for translational science applications in collaboration with biopharmaceutical customers, as those samples are often available with only a limited volume of plasma.

Validation data indicates that the GuardantOMNI test exceeds the Guardant360 test's sensitivity for detecting clinically actionable biomarkers. At the same time, broader panel-wide performance of small variants is roughly similar to that of Guardant360 test. The broad genomic footprint of our GuardantOMNI test enables accurate measurement of tumor mutational burden. The GuardantOMNI test received breakthrough device designation from the FDA in December 2018 and is currently being developed, including for use as a potential companion diagnostic, to identify patients who may benefit from immuno-oncology therapeutics, including patients that may more likely respond to immuno-oncology agents based on TMB.

Guardant Reveal Test

In the management of early-stage cancer, current tools do not identify all high risk patients who will benefit from adjuvant therapy or detect recurrence early enough when it is most curable. We plan to address this need, first in Stage II-III colorectal cancer, with our Guardant Reveal test launched in February 2021 for residual disease and recurrence monitoring. Guardant Reveal test will enable oncologists to improve the care of early-stage cancer patients by correctly identifying more high-risk patients than clinicopathologic review alone and by detecting recurrent disease months earlier than current standard of care methods like imaging carcinoembryonic antigen tests. We expect the Guardant Reveal test to achieve best in class performance and fast turnaround by simultaneously interrogating both genomic and epigenomic signals from a single blood draw without the need for tissue. Similar to our data development effort for our Guardant360 tests, we are investing very heavily in establishing clinical utility for the use of Guardant Reveal in adjuvant treatment settings. In 2020, we launched three clinical trials in collaboration with key cancer researchers: COBRA, a randomized controlled study, comprising over 1,400 low-risk stage-II colon cancer patients, ACT-3, comprising over 500 stage 3 colorectal cancer patients, and PEGASUS for the de-escalation of therapy, encompassing over 140 high-risk stage-II and stage-III colon cancer patients.

Guardant360 Next-Generation Tissue Program

To complement our liquid biopsy-based products, we are developing a Guardant360 tissue product. Tissue genotyping is currently widely available to physicians and patients. We believe many tissue genotyping products currently available to physicians and patients have experienced long delays in getting results to physicians and high failure rates because of the inability to obtain enough tissue or high-quality DNA for analysis. Such delay or inability to produce results from tissue genotyping can adversely affect providing the right treatment to patients at the right time. We therefore intend our Guardant360 next-generation tissue assay, together with our liquid biopsy-based products, to help address the challenges with tissue genotyping products currently in the market.

LUNAR-2 Program

We believe that there is a critical need to develop products to expand precision oncology to earlier stage cancer settings. Such products would enable clinicians to precisely detect, monitor and select the appropriate intervention at the right times in the disease's evolution, key to significantly improving patient clinical outcomes. In order to systematically address this need, we are developing a test for asymptomatic individuals eligible for cancer screening in line with the USPSTF guidelines and in cancers where a well-established screening paradigm does not yet exist. Our research and development results to date indicate that somatic signatures alone may be insufficient for detection of early stage cancers with high sensitivity. For this reason, we have incorporated epigenomic signatures to enhance the performance of our LUNAR-2 assay in these settings.

Early cancer detection is challenging, especially with respect to clinical specificity. There is a minimal amount of ctDNA in patients with low-disease burden. Additionally, naturally occurring genomic aberrations in blood as well as signals from non-cancer related diseases can add biological noise obfuscating detection of circulating tumor-related biomarkers. We believe we have the unique capability to overcome these challenges by leveraging our:

- *Vast data sets and deep insights:* We have targeted deep sequencing data in combination with low coverage sequencing of whole genome from tens of thousands of cancer patients. This data has enabled discovery of novel epigenomic variations across multiple cancer types. We believe augmenting genomic with epigenomic signatures can enhance the clinical sensitivity and specificity of our tests significantly. Moreover, we developed a database of biological noise sources such as clonal hematopoiesis of indeterminate potential, which enables us to further enhance the sensitivity and specificity of our tests.

- *Extensive blood biobank:* We have a biobank of tens of thousands of cancer samples that we use for discovery and, more importantly, biomarker verification and validation. For example, we are analyzing these samples with whole genome sequencing to identify and confirm tumor associated signatures. Also, we have been collecting additional samples through multiple on-going research collaborations.

Guardant-19 Test

In 2020, we launched our Guardant-19 test and received the FDA's emergency use authorization for use in the detection of the novel coronavirus. Consistent with our belief that earlier cancer detection leads to better outcomes, we believe active surveillance of the novel coronavirus will benefit the health and safety of many essential businesses and communities. Given the significant testing needs for the foreseeable future, we leveraged our expertise to contribute to this need. The Guardant-19 test is being offered to our employees and select partner organizations in our CLIA-certified clinical laboratory.

Commercialization

U.S. clinical commercial efforts

We sell our tests to clinical customers in the United States through our targeted sales organization. Our clinician-focused sales organization in the United States is engaged in sales efforts and promotional activities primarily targeting oncologists and cancer centers. Our sales representatives typically have extensive backgrounds in laboratory testing, therapeutics and oncology. We have supplemented the team with clinical oncology specialists with extensive medical affairs experience for molecular information support in the field.

Our clinical commercial efforts are focused on driving adoption with academic research institutions and with community oncology practices, including through leading physician networks. As we continue to grow our sales organization, we are also expanding our reach to include large community practices, community oncology networks, integrated delivery/ payer-owned systems and government medical facilities that are looking for a reliable partner for comprehensive molecular information testing.

International clinical commercial efforts

We currently offer our tests in countries outside the United States primarily through direct contacts with insurers and hospitals and through distributor relationships.

Currently, all customer samples are shipped globally to our laboratory in Redwood City, California. We are conducting studies in various jurisdictions and have started efforts to secure reimbursement in several countries. As these studies progress and we near commercial opportunities there, we may seek to establish in-country laboratories and direct sales organizations. Specifically, we have already demonstrated the ability to deploy our technology to partner laboratories such as cancer centers, for the development of liquid biopsy assays based on our technology platform. We believe that this capability will be important in accelerating adoption of our platform and the performance of liquid biopsy testing in certain countries.

Together with SoftBank, we formed a joint venture, Guardant Health AMEA, Inc., which we refer to as the Joint Venture. We expect to rely on the Joint Venture to accelerate commercialization of our products in Asia, the Middle East, and Africa. Currently, we and the Joint Venture are primarily focused on expanding our commercial capabilities in Asia. There are estimated to be over 400,000 deaths from solid tumor cancers annually in Japan with a significant portion relating to lung and gastric cancers. We are involved in several nationwide clinical programs that help establish clinical utility of our Guardant360 test in the Japanese population with the first patient tested in

late 2018. In 2021, an affiliate of the Joint Venture submitted an application to the Ministry of Health, Labour and Welfare (MHLW) for regulatory approval of Guardant360 CDx in Japan.

In preparation for wider commercialization in the European Union, we obtained a CE mark for our Guardant360 CDx test performed in Redwood City and also achieved ISO15189 accreditation. In 2020, we signed the first public private partnership agreement with Vall D'Hebron Institute of Oncology, one of Europe's leading cancer research institutions. We expect this partnership will lead to the establishment of liquid biopsy testing services at the partner laboratory, using Guardant Health Digital Sequencing Technology, as well as generation of clinical and economic evidence to support commissioning in other areas of Europe.

Biopharmaceutical commercial efforts

Our business development team is focused on enterprise selling to biopharmaceutical companies in the United States and internationally. Our strategy with each biopharmaceutical customer is to demonstrate the value proposition of the Guardant Health Oncology Platform and expand its utilization across the organization from early stage research through clinical development to commercialization. Given the broad and differentiated utility of our platform, we believe we can support our biopharmaceutical customers across many applications, including:

- discovery of new targets and mechanisms of acquired resistance;
- retrospective sample analysis to rapidly identify biomarkers associated with response and lack of response;
- prospective screening and referral services to accelerate clinical trial enrollment; and
- companion diagnostic development to support the approval and commercialization of therapeutics.

We also expect to be able to capture other commercial opportunities from our genomic data, which can be used in combination with clinical outcomes or claims data for multiple applications, including novel target identification.

Payer coverage and reimbursement

We estimate total lung cancer payer coverage in the United States for our Guardant360 test to be a total of more than 200 million lives, including Medicare beneficiaries and members of several commercial health plans.

Commercial payers

Payment from commercial payers can vary depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payers often reimburse non-participating providers at a lower amount than participating providers or not at all. When we contract with a payer to serve 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. As a result, the potential for more favorable reimbursement associated with becoming a participating provider may be offset by a potential loss of reimbursement for non-covered uses of our tests.

We have provided testing services to patients covered by commercial payers with many cancer types and indications, most of the time as a non-participating provider through 2020. We received reimbursement for tests across the spectrum of these patients, though for amounts that on average were significantly lower than for participating providers. Because we are not contracted with these payers, they determine the amount that they are willing to reimburse us for any of our tests and they can prospectively and retrospectively adjust the amount of reimbursement.

We have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and where commercial payers have determined that the amounts previously paid were too high and sought to recover those perceived excess payments by deducting such amounts from payments owed to us.

Coverage from commercial payers has been focused on NSCLC, which represented approximately 43%, 44% and 46% of our U.S. clinical testing volume in 2020, 2019 and 2018, respectively. Cigna, Priority Health, multiple Blue Cross Blue Shield plans as well as the health plans associated with eviCore adopted policies that cover our Guardant360 test for the majority of NSCLC patients we test. If their policies were to change in the future to cover

additional cancer indications, we anticipate that our total reimbursement would increase. To date, the benefit of increased reimbursement for covered NSCLC Guardant360 testing as a participating provider has been approximately offset by the loss of reimbursement on tests for non-covered indications previously received when we served as a non-participating provider. Therefore, the net result of receiving coverage for a particular indication, including NSCLC, may be little to no change in our average revenue per test for all our patients served by these insurance payers.

In addition to our existing contracted payers, various laboratory benefit managers and evidence review organizations working with commercial payers have endorsed coverage of our Guardant360 test.

We are actively engaged to expand coverage among existing contracted payers and to achieve coverage with the remaining key commercial payers, laboratory benefit managers and evidence review organizations. This includes addressing variable coverage requirements and evidence required, and the need for enhanced guideline support.

As we broaden our coverage amongst contracted payers to include additional tests of ours, we may begin to experience increases in average revenue per test performed; however, we cannot make any assurances that we will be successful in broadening our coverage on a timely basis or at all. Similarly, as we have experienced with our existing contracted payers, we cannot assure that the addition of new contracted payers will increase our average selling price or revenue.

Government payers

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. National coverage determinations are made through an evidence-based process by the Centers for Medicare and Medicaid Services, or CMS, with opportunities for public participation. Medicare's NGS NCD provides coverage for molecular diagnostic tests such as our Guardant360 CDx test, if, among other criteria, such tests are offered within their FDA-approved companion diagnostic labeling.

In September 2018, we began to receive reimbursement from Medicare for claims submitted with respect to Guardant360 clinical 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. 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. On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements under PAMA. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS were required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), 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. As we have begun billing Medicare for our tests, 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 tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are based upon these reported commercial payer rates.

Current Procedural Terminology, or CPT, coding plays a significant role in how our Guardant360 test is reimbursed both from commercial and governmental payers. In addition, Z-Code Identifiers are used by certain payers, including under Medicare's MolDx, to supplement CPT codes for molecular diagnostics tests such as our Guardant360 test. Changes to the codes used to report the Guardant360 test to payers may result in significant changes in its reimbursement. If a coding change were to occur, including as a result of the FDA approval of our Guardant360 test, payments for certain uses of the Guardant360 test could be reduced, put on hold, or eliminated by such payers. Following the FDA approval of our Guardant360 CDx test, a new Z-Code Identifier is expected to be issued, and a new pricing is expected to be established under MolDx for the Guardant360 CDx test. While we expect to continue to submit claims to Medicare for Guardant360 LDT clinical tests performed for such qualifying patients using the existing Z-Code Identifier, Medicare has instructed us to not submit claims to Medicare for Guardant360 CDx clinical tests until the new code is issued for the Guardant360 CDx test and the corresponding pricing is established. A proprietary laboratory analyses, or PLA, code was issued for our Guardant360 CDx test in January 2021 with an effective date in April 2021. Once the PLA code is effective, all Guardant360 CDx services will be billed with this new code. Additionally, based on this new PLA code, we applied to CMS for our Guardant360 CDx

test to become an advanced diagnostic laboratory test, or ADLT. If CMS grants ADLT status to the Guardant360 CDx test, for the first three quarters thereafter, we can only bill Medicare for the test at the lowest available commercial rate at the launch of the test. After the initial three quarters, we can bill Medicare for Guardant360 CDx services at the median rate of claims paid by commercial payers. Changes to the codes used to bill a test to payers may result in significant changes in its reimbursement, which could negatively impact our revenue. As a result of implementing this new coding change for our Guardant360 CDx test, payments for Guardant360 CDx services could be reduced, put on hold, or eliminated by such payers.

State Medicaid programs make individual coverage decisions for diagnostic tests and have taken steps to control the cost, utilization and delivery of healthcare services. We believe that additional state and federal health care reform measures may be adopted in the future, any of which could have a material adverse effect on the clinical laboratory industry and our ability to successfully commercialize our tests. Any of these or other changes could substantially impact our revenues and increase costs. We cannot predict how future healthcare policy changes, if any, will affect our business and financial success.

Other Considerations

Where we are not reimbursed in full or at all, we may elect to appeal the insurer's underpayment or denial of payment or seek payment from the patient. However, insurer appeal and patient collection efforts take a substantial amount of time and resources and are often unsuccessful. 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, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. This variability and unpredictability could increase the risk of future revenue reversal and result in our failing to meet any previously publicly stated guidance we may provide.

Operations

We perform our tests in our clinical laboratory located in Redwood City, California. Our laboratory is an FDA approved (Guardant360 CDx), CAP-accredited, CLIA-certified, NYSDOH-permitted and also licensed in California, Florida, Maryland, Pennsylvania and Rhode Island.

The proprietary validated methods utilize robust semi-automated workflows designed for high throughput sample testing. This methodology allows for rapid scaling of testing volume without impacting performance metrics. Our testing process includes blood collection, laboratory processing, analysis and reporting. All major processing steps utilize quality control to ensure consistent and reproducible results.

Guardant Health Digital Sequencing Technology

Guardant Health Digital Sequencing Technology combines state-of-the-art technology from multiple disciplines and is enabled by robust, high-efficiency biochemistry at the front-end, next-generation sequencing and a machine learning augmented bioinformatics pipeline. The technology, through machine learning, has accrued performance improvements by incorporating learnings generated from the data collected from additional samples.

Supply chain

We utilize industry leading vendors for our supply chain. Most reagents and materials are sourced from a limited number of vendors and would require qualification to transition to a different vendor. To mitigate risk, we employ a multi-month, multi-lot safety stock strategy to ensure an uninterrupted supply of reagent and material to our laboratory. In the event that a latent defect is identified, the lot of material in use is expected to be timely quarantined and changed for a new vendor lot that has been previously qualified for use. The experience with our vendors has provided us confidence in their ability to produce consistent and quality instrumentation, reagents and materials.

In September 2014, we entered into a supply agreement with Illumina, Inc., or Illumina, for Illumina to provide products and services that can be used for certain research and clinical activities, including certain sequencers, reagents, and other consumables for use with the Illumina sequencers, as well as service contracts for the maintenance and repair of the sequencers. The initial term of the supply agreement, as amended, continues until January 2033, and automatically renews for additional one-year terms thereafter unless either we or Illumina

terminate the supply agreement for the other's uncured material breach, bankruptcy or insolvency-related events, or in the event a regulatory authority notifies such party that continued performance under the supply agreement would violate applicable laws or regulations. We may also terminate the supply agreement for convenience upon 90 days' prior written notice.

Competition

Growing understanding of the importance of biomarkers linked with therapy selection and response is leading to more companies offering services in genomic profiling. The promise of liquid biopsy is also leading to more companies attempting to enter the space and compete with us. 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.

Our competitors within the liquid biopsy space 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, and Sysmex Inostics. In addition, GRAIL, Inc., Natera, Inc., Exact Sciences Corp., and Freenome Holdings, Inc. among others, are our competitors in minimal residual disease testing and early screening testing.

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 Foundation Medicine, Inc., Caris Life Science and Myriad Genetics, Inc. 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.

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., 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 our access to certain networks.
The promise of liquid biopsy 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.

We believe key competitive factors affecting our success are the price and performance of our products, evidence of clinical differentiation, support by KOLs, commercial competitiveness, turnaround time and scope and quality of payer contracts. Our Guardant Health Oncology Platform has developed strengths across five layers, which we believe form a barrier to entry and a competitive advantage. However, we cannot assure that we will continue to compete effectively on each of those layers and our competitive landscape may change over the next few years as a result of new competitors entering through investment and acquisition activity.

Intellectual property

Protection of our intellectual property is fundamental to the long-term success of our business. We seek to ensure that investments made into the development of our technology are protected by relying on a combination of patents, trademarks, copyrights, trade secrets (such as know-how), license agreements, confidentiality agreements and procedures, non-disclosure agreements, invention disclosure and assignment agreements and other contractual rights.

Our patent strategy is focused on seeking coverage for our core technology, our digital sequencing platform, and specific follow-on applications and implementations for detecting and monitoring cancer or other diseases by determining genetic variations in patient samples. In addition, we file for patent protection on our on-going research

and development particularly into early-stage cancer detection, including on pattern recognition based, for example, on analyzing our extensive patient blood sample database.

Our patent portfolio includes owned and licensed patents and patent applications, generally falling into three broad categories:

- applications and patents relating to our digital sequencing platform, including claims directed to methods for sequencing cell-free DNA, identifying CNVs, SNVs, indels and fusions in cell-free DNA and techniques for enriching nucleic acid samples;
- applications and patents relating to detecting and monitoring cancer and other diseases by determining genetic variations in biological samples; and
- applications and patents relating to early-stage cancer detection.

Issued U.S. patents and their international counterparts currently in our patent portfolio that relate to various aspects of our technology and products are expected to expire between 2026 and 2037.

Our proprietary technology is also bolstered by our acquisition of, and procurement of licenses to, technologies developed by third parties. While we developed our digital sequencing platform internally, we believe the technologies underlying our licenses from third parties, which typically relate to improvements to next-generation sequencing technologies, are potentially valuable and of possible strategic importance to us or our competitors. Under some of these agreements, we are obligated to pay low single-digit percentage running royalties on net sales where the licensed technology is used in the product or service sold, subject to minimum annual royalties or fees in certain agreements.

Our customers and partners recognize us as being a leader in the liquid biopsy field. Thus, just as patent and trade secret protection is essential to protecting our technology, we believe that it is equally as important for us to protect our brand and identity. We have filed for trademark protection in our name, logo and initial products in the United States.

We intend to pursue additional intellectual property protection to the extent we believe it would advance our business objectives. Despite our efforts to protect our intellectual property rights, they may not be respected in the future or may be invalidated, circumvented or challenged. In addition, laws of various foreign countries where our products are or expected to be sold may not protect our intellectual property rights to the same extent as laws in the United States.

We also rely on trade secrets, including know-how, unpatented technology and other proprietary information, to maintain and strengthen our competitive position. We have determined that certain technologies, such as aspects of our sample preparation methods and some bioinformatic analysis techniques, are better kept as trade secrets. To mitigate the chance of trade secret misappropriation, it is our policy to enter into nondisclosure and confidentiality agreements with parties who have access to our trade secrets, such as our employees, collaborators, outside scientific collaborators, consultants, advisors and other third parties. We also enter into invention disclosure and assignment agreements with our employees and consultants that obligate them to assign to us any inventions they have developed while working for us.

Government regulations

Federal and state laboratory licensing requirements

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of or assessment of health. CLIA requires that a laboratory hold a certificate applicable to the type of laboratory examinations it performs and that it complies with, among other things, standards covering operations, personnel, facilities administration, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. Because we are a CAP accredited laboratory, CMS does not perform this survey and inspection and relies on our CAP survey and inspection. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories

performing less complex tests. In addition, a laboratory that is certified as "high complexity" under CLIA may develop, manufacture, validate and use proprietary tests referred to as laboratory developed tests, or LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to any testing we perform may change over time and any such changes could have a material effect on our business.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. For example, state laws may require that nonresident laboratories, or out-of-state laboratories, maintain an in-state laboratory license to perform tests on samples from patients who reside in that state. As a condition of state licensure, these state laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures or facility requirements or prescribe record maintenance requirements. Because our laboratory is located in the State of California, we are required to and do maintain a California state laboratory license. We maintain a current license with NYSDOH for our laboratory. In addition, our laboratory is licensed in a few states where nonresident laboratories are required to obtain state laboratory licenses under certain circumstances, including Florida, Maryland, Pennsylvania and Rhode Island. Other states may currently have or adopt similar licensure requirements in the future, which may require us to modify, delay or stop its operations in those states.

Failure to comply with CLIA certification and state clinical laboratory licensure requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity.

CLIA and state laws and regulations, operating together, sometimes limit the ability of laboratories to offer consumer-initiated testing (also known as "direct access testing"). CLIA certified laboratories are permitted to perform testing only upon the order of an "authorized person," defined as an individual authorized under state law to order tests or receive test results, or both. Many states do not permit persons other than licensed healthcare providers to order tests. We currently do not offer direct access testing and our CLIA tests may only be ordered by authorized healthcare providers.

Regulatory framework for medical devices in the United States

Pursuant to its authority under the Federal Food, Drug and Cosmetic Act, or the FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostic devices, or IVDs. The FDA regulates, among other things, the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device classification

Under the FDCA, medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's quality system regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.
Class II devices are those that are subject to the General Controls, as well as special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are

subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and special controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. As part of the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. A PMA application must also provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The investigational device exemption (IDE) process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and institutional review board, or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin only after the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Such clinical trials must also comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;

- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports of sponsors of clinical investigations;
- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that our trial designs are unreliable or inadequate to demonstrate safety and efficacy.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. 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 substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous pre-marketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. The *de novo* classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. *De novo* classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in

these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

In addition, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

In September 2019, the FDA finalized 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 intends to develop and maintain a list device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

The PMA process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided and may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.
Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the

PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support changes from the device covered by a PMA and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may 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 or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

In late 2019, we submitted a PMA application to seek the FDA's approval of our Guardant360 CDx test. In August 2020, the FDA approved the PMA application and our Guardant360 CDx test was the first comprehensive liquid biopsy test approved by the FDA to provide tumor mutation profiling for cancer patients with solid tumors.

FDA regulation of laboratory developed tests

Although the FDA regulates medical devices, including IVDs, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDCA and FDA regulations with respect to LDTs, which are a subset of IVDs that are intended for clinical use and are developed, validated and offered within a single laboratory for use only in that laboratory.

Legislative and administrative proposals addressing oversight of LDTs were introduced in recent years and we expect that new legislative and administrative proposals will 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. For example, in 2014 the FDA issued two draft guidance documents proposing a risk-based framework with respect to applying the FDA's oversight over LDTs. The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, we believe the FDA planned to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without
FDA premarket review and oversight. In November 2016, the FDA announced its intention not to finalize the 2014 draft guidance to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution. In January 2017, the FDA issued a discussion paper on possible approaches to LDT regulation.

The FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements.

Research use only or investigational use only devices

Some of our products are currently available for research use only, or RUO, or for investigational use only, or IUO, depending on the proposed application. An RUO device is an IVD that is in the laboratory research phase of development. RUO devices must bear prominent labeling stating: "For Research Use Only. Not for use in diagnostic procedures." An IUO device is an IVD that in the product testing phase of development. An IUO device must bear prominent labeling stating: "For Investigational Use Only. The performance characteristics of this product have not been established." Neither RUO or IUO devices may be used in clinical practice, and such devices cannot be advertised or promoted for clinical or diagnostic purposes. Devices that are intended for RUO or IUO and are properly labeled as RUO or IUO are exempt from compliance with the FDA requirements discussed above, including the approval or clearance and QSR requirements. A device labeled RUO or IUO but intended to be used

diagnostically may be viewed by the FDA as adulterated and misbranded under the FDCA and is subject to FDA enforcement activities. The FDA may consider the totality of the circumstances surrounding distribution and use of an RUO or IUO device, including how the device is marketed, when determining its intended use.

EAP (Expedited Access Program)/Breakthrough Devices Program

The EAP was a voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to premarket submissions. Under the EAP, the FDA worked with device sponsors to try to reduce the time and cost from development to marketing decision without changing the FDA's PMA standard of reasonable assurance of safety and effectiveness or any other standards of valid scientific evidence. Components of the EAP include priority review, more interactive review, senior management involvement, and assignment of a case manager.

Pursuant to the 21st Century Cures Act, the Breakthrough Devices provisions were added to the FDCA. The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. For Breakthrough Devices, the FDA intends to provide interactive and timely communication with the sponsor during device development and throughout the review process. FDA also intends to assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing expectations applicable to the investigational use of a Breakthrough Device. In addition, all submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. The Breakthrough Devices Program superseded the EAP and the previous priority review program for medical device submissions. The FDA has indicated that all participants previously granted EAP designation will have designation as breakthrough devices, and that no separate action will be necessary for sponsors of EAP-designated devices to receive breakthrough device designation for such devices.

In January 2018, we received EAP designation from the FDA for our Guardant360 test. In December 2018, we received breakthrough device designation from the FDA for our GuardantOMNI test.

Companion Diagnostics

For certain of our tests, we are pursuing development as *in vitro* companion diagnostics for use in selecting the patients that may respond to our partners' pharmaceutical products. Companion diagnostics are regulated by the FDA as medical devices. The FDA issued a final guidance document in July 2014 addressing agency policy in relation to *in vitro* companion diagnostic tests. The guidance explains that for some drugs and therapeutic biologics, the use of a companion diagnostic test is essential for the safe and effective use of the product, such as when the use of a product is limited to a specific patient subpopulation that can be identified by using the test. According to the guidance, the FDA generally requires the therapeutic product and the companion diagnostic to be developed and approved or cleared contemporaneously. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and *in vitro* companion diagnostic device on issues related to co-development of the products, and in December 2018, FDA issued a draft guidance describing considerations for the development and labeling of in vitro companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products.

In August 2020, our Guardant360 CDx test was approved by the FDA to be used as a companion diagnostic initially in connection with one therapeutic product of a biopharmaceutical customer.

Pervasive and continuing FDA regulation

After a device enters commercial distribution, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;

- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval of product modifications, or the potential for new 510(k) clearances for certain modifications to 510(k)-cleared devices;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions such as: warning letters, fines, injunctions, consent decrees and civil penalties; unanticipated expenditures, repair, replacement, refunds, recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; the FDA's refusal of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products; the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries; and withdrawing 510(k) clearance or premarket approvals that have already been granted and criminal prosecution.

Foreign regulation of medical devices

Medical devices are subject to extensive regulation, including premarket review and marketing authorization, by similar agencies in other countries. Regulatory requirements and approval processes are similar in approach to that of the United States but are not harmonized. International regulators are independent and not bound by the findings of the FDA and there is a risk that foreign regulators will not accept clinical trial design/results or may require additional data or other information not requested by the FDA.

In the EU, in vitro diagnostic devices can be placed on the market by obtaining a "CE mark," which we have obtained for our Guardant360 CDx test. CE marked products demonstrate conformity with the In Vitro Diagnostic Medical Device Directive (98/79/EC) ("IVDD"), which requirements include:

- *Essential Requirements*. The IVDD specifies "essential requirements" that all medical devices must meet to demonstrate the product is safe and effective under normal conditions of use. The requirements are similar to those adopted by the FDA relating to quality systems and product labeling.
- *Conformity Assessment*. The requirements to obtain a CE mark are risk-based and follow a similar classification system as in the United States. However, unlike the United States, which requires virtually all devices to undergo some level of premarket review by the FDA, the IVDD currently allows manufacturers to bring many devices to market using a process in which the manufacturer self-certifies that the device conforms to the applicable essential requirements.
- *Vigilance*. The IVDD specifies requirements for post-market reporting similar to those adopted by the FDA.

On May 26, 2017, the EU released a new regulatory framework, the In Vitro Diagnostic Medical Device Regulation (2017/746/EU) ("IVDR"), which will replace the IVDD. The IVDR comes into force on May 26, 2022 and imposes

stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Until that time, our Guardant360 CDx test must continue to meet the requirements of IVDD for commercialization in the EU. Additionally, the effective date of the United Kingdom's withdrawal from the EU was January 31, 2020 and so the United Kingdom will not be subject to the IVDR and has instead introduced its own regulatory framework. As a result, there is a new conformity marking solely for the United Kingdom and, as of January 1, 2021, any new products require a U.K. Conformity Assessed, or UKCA, mark, in addition to a CE mark. However, our existing product will be able to rely on the CE mark previously obtained during a transition period that will last until June 30, 2023.

In February 2021, Guardant Health Japan, an affiliate of the Joint Venture with SoftBank, submitted an application, currently under review, to Japan's Ministry of Health, Labour and Welfare ("MHLW") for regulatory approval of Guardant360 CDx. To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval, or "shonin." The Japanese government, through the MHLW, regulates medical devices under the Pharmaceutical Affairs Law ("PAL"). Oversight for medical devices is conducted with participation by the Pharmaceutical and Medical Devices Agency ("PMDA"), a quasi-government organization performing many of the review functions for MHLW. Penalties for a company's noncompliance with PAL can be severe, including revocation or suspension of a company's business license and criminal sanctions. MHLW and PMDA also assess the quality management systems of the manufacturer and product conformity to the requirements of the PAL. We are subject to compliance inspections by these agencies.
We will seek approvals in other countries as may be required in the future.

Federal and state fraud and abuse laws

We are subject to federal fraud and abuse laws such as the federal Anti-Kickback Statute, or AKS, the federal Eliminating Kickbacks in Recovery Act, or EKRA, the federal prohibition against physician self-referral, or Stark Law, and the federal false claims law, or the False Claims Act, or FCA. We are also subject to similar state and foreign fraud and abuse laws.

The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, 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. 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. In addition, the government may assert that a claim including items or services resulting from an AKS violation constitutes a false or fraudulent claim for purposes of the False Claims Act.

The EKRA 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, and EKRA violations result in significant fines and/or up to 10 years in jail, separate and apart from existing AKS regulations.

The Stark Law and similar state laws, including California's Physician Ownership and Referral Act, generally prohibit, among other things, clinical laboratories and other entities from billing a patient or any governmental or commercial payer for any diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has a direct or indirect investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Other federal fraud and abuse laws to which we are subject include but are not limited to the federal civil and criminal false claims laws including the FCA, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government, and 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. Under the FCA, private citizens can bring claims on behalf of the government through qui tam actions. We must also operate within the bounds of the fraud and abuse laws of the states in which we do business which may apply to items or services reimbursed by non-governmental third-party payers, including private insurers.

Efforts to ensure that our business arrangements with third parties comply with applicable laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, 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 the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Privacy and Security

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the U.S. Department of Health and Human Services, or HHS, issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information, or PHI, used or disclosed by covered entities. Covered entities and their business associates are subject to HIPAA and HITECH. Because we are a health care provider that electronically transmits health care information to payers, we are a covered entity under HIPAA. Our subcontractors that create, receive, maintain or transmit or otherwise process PHI on our behalf must also comply with HIPAA as business associates thereunder.

HIPAA and HITECH include the privacy and security rules, breach notification requirements and electronic transaction standards. The privacy rule covers the use and disclosure of PHI by covered entities and business associates. The privacy rule generally prohibits the use or disclosure of PHI except as permitted under the rule. The rule also sets forth individual patient rights, such as the right to access or amend certain records containing his or her PHI, or to request restrictions on the use or disclosure of his or her PHI. The security rule requires covered entities and business associates to safeguard the confidentiality, integrity, and availability of electronically transmitted or stored PHI by implementing administrative, physical and technical safeguards. Under HITECH's breach notification rule, a covered entity must notify individuals, the Secretary of the HHS, and in some circumstances, the media of breaches of unsecured PHI.

If they are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about their privacy practices or an audit by HHS, entities may be subject to significant civil and criminal fines and penalties and/or additional reporting and oversight obligations if such entities are required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

In addition, we may be subject to state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. State laws may be more stringent, broader in scope or offer greater individual rights with respect to PHI than HIPAA. California, for example, has enacted the Confidentiality of Medical Information Act, which sets forth standards in addition to HIPAA and HITECH with which all California health care providers like us must abide. In addition, the California Consumer Privacy Act, or the CCPA, was signed into law on June 28, 2018, and went into effect January 1, 2020. The CCPA contains new disclosure obligations for businesses that collect personal information about California residents and affords those individuals new rights relating to their personal information that may affect our ability to use personal information. The CCPA authorizes private lawsuits to recover statutory damages for certain data breaches. Although the CCPA exempts protected health information regulated by HIPAA and certain data regarding clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we maintain about California residents. The CCPA has substantial penalties for non-compliance and we continue to assess its impact on our business. Complying with these various state laws and regulations, which may differ from state to state, requires significant resources and may complicate our compliance efforts. Penalties for violation of any of these laws and regulations may include sanctions against a laboratory's licensure, as well as civil and/or criminal penalties.

U.S. healthcare reform

In the United States, there have been a number of legislative and regulatory changes at the federal and state levels which seek to reduce healthcare costs and improve the quality of healthcare. For example, 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. The ACA substantially changed the way healthcare is financed by both commercial and government payers and contains a number of provisions expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in federal and state healthcare programs, reimbursement changes and fraud and abuse.

Since its enactment, there have been efforts to repeal all or part of the ACA. For example, the Tax Cuts and Jobs Act, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. On November 10, 2020, the U.S. Supreme Court heard oral arguments in California vs. Texas to determine whether the entire ACA should be unenforceable nationwide or whether it should be unenforceable only to the extent that provisions injure the individual plaintiffs. It is unclear how the Supreme Court decision and efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

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 by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payers to reduce costs while expanding individual healthcare benefits. Changes in healthcare coverage landscape 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 payers, including commercial and government payers.

Employees and Human Capital

As of December 31, 2020, we had 864 full-time employees, of which approximately 853 are in the U.S., with the remainder in Europe and Canada.

We strive to recruit, hire and retain a talented and diverse team of people who align with our values. Our employees are supported with training and development opportunities to pursue their career paths and to ensure compliance with our policies. Our compensation and benefits team strive to develop and implement policies and programs that support our business goals, maintain competitiveness, promote shared fiscal responsibility among our employees, strategically align talent within our organization and reward performance, while also managing the costs of such policies and programs. We provide our employees with competitive fixed and/or variable pay, competitive company equity programs, access to medical, dental and life insurance benefits, disability coverage, 401 (k) program, and numerous well-being benefits. In order to ensure that we are meeting our human capital objectives, we frequently utilize employee engagement surveys to understand the effectiveness of our employee development and compensation programs and where we can improve across the company.

During the COVID-19 pandemic, we commit to safeguard the health of our employees, including their economic health. Steps we have taken include deep cleaning our facilities, providing personal protective equipment to our laboratory and scientific employees, installing plexi-glass, where possible, in our facilities, encouraging hygiene practices advised by health authorities, restricting business travel and site visitors and implementing remote working for all non-essential laboratory related employees. We developed our own proprietary COVID-19 test and make that test available to all Redwood City, California based employees and their dependents at no cost and leverage that testing as a condition for access to our offices. In addition, we have developed special cash compensation and incentive programs to many of our essential employees, in recognition of their outstanding service during the COVID-19 pandemic, and we extended COVID-19 protection pay for employees who were quarantined, sick or needed to provide care for their families. Further, despite the negative impact the COVID-19 pandemic has had on our business, we have not cut salaries or hourly rates for any employees.

Available information

Our website is located at *https://guardanthealth.com*. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including their exhibits, proxy and information statements, and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *http://www.sec.gov.* All statements made in any of our securities

filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors

Set forth below is only a summary of the principal risks associated with our business. You should consider carefully the following discussion of risks, as well as the full discussion of risks included in this Annual Report on Form 10-K.

- 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 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.
- 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.
- 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.
- Our current revenue is primarily generated from sales of our tests and we are highly dependent on them for our success.
- If our products, or our competitors' liquid or tissue biopsy-based products, do not meet the expectations of patients and our customers, our operating results, reputation and business could suffer.
- 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.
- We rely on a limited number of suppliers or sole suppliers for some of our laboratory instruments and materials and may not be able to find replacements or promptly transition to alternative suppliers.
- If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced.
- 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.
- 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 operations and financial condition, and harm our business.
- Certain of our tests are currently marketed as LDTs, and future changes in FDA enforcement discretion for LDTs could subject our product offerings to more significant regulatory requirements.
- 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 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.
- 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 and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.
- Issued patents covering our products could be found invalid or unenforceable if challenged.
- 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.
- Our indebtedness could expose us to risks that could adversely affect our business, financial condition and results of operations or result in dilution to our stockholders.
- The COVID-19 global pandemic and the worldwide attempts to contain it could harm our business and our results of operations have been and could continue to be adversely impacted by the pandemic.

Risk Factors

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, 2020, 2019 and 2018, we incurred net losses of $246.3 million, $67.9 million and $84.3 million, respectively. As of December 31, 2020, we had an accumulated deficit of $606.6 million. 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. 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 products, including our Guardant360, Guardant360 CDx, and GuardantOMNI tests, and our 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 based on our Guardant Health Oncology Platform. 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 by regulatory agencies, including the FDA 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 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 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 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 current outbreak of novel coronavirus (2019-nCoV), boycotts, curtailment of trade and other business restrictions; and
- 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, most of the time as a non-participating provider through 2020. 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, 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 trials;
- 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 of our revenue in the years ended December 31, 2020 and 2019. 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, or our competitors' 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 trials 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 or our competitors' 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 trials, including patient identification, companion diagnostics and retrospective testing. In the years ended December 31, 2020, 2019 and 2018, revenue from our top five biopharmaceutical customers, including their affiliated entities, accounted for 27%, 14% and 36% 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 trial 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 trials, 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 trials, 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 trials 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 trials 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 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. Approximately 37%, 38% and 38% of our U.S. clinical tests were for Medicare beneficiaries in each of the years 2020, 2019 and 2018 respectively. Revenue attributable to Medicare accounted for more than 10% of our total revenue in each of the years ended December 31, 2020 and 2019. 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 and response is leading to more companies offering services in genomic profiling. The promise of liquid biopsy 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 include Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Roche Molecular Systems, Inc., Thermo Fisher Scientific Inc., Illumina, Inc., Qiagen N.V. Invitae Corporation, and Sysmex Inostics. In addition, GRAIL, Inc., Natera Inc., Exact Sciences Corp., and Freenome Holdings, Inc. among others, are developing and/or commercializing tests that are competitive with our LUNAR program for early cancer detection.

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 Foundation Medicine, Inc., Caris Life Sciences, Inc. and Myriad Genetics, Inc., that sell molecular diagnostic tests for cancer to physicians and have or may develop tests which 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. 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 will continue to commercialize products and services 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 Guardant Health Oncology Platform, 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 Guardant Health Oncology 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 trials, 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 may be unable to manage our future growth effectively, 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. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed.

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 the Joint Venture with SoftBank for sales of our products throughout Asia, the Middle East and Africa. We share a measure of control of the Joint Venture, and if its 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 of our precision oncology platform 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.

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 us to operate our Guardant Health Oncology Platform for some period of time. 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.

We are exposed to risks associated with our joint venture with SoftBank, and may not realize the advantages we expect from it.

We have a 50% ownership interest in the Joint Venture, Guardant Health AMEA, Inc., we formed with SoftBank in May 2018 to accelerate the commercialization of our products in Asia, the Middle East and Africa, with a near-term focus on Japan. However, the Joint Venture may not be successful in the timeframe we expect, or at all.

Additionally, SoftBank shares a measure of control over the operations of the Joint Venture. As a result, our investment in our joint venture involves risks that are different from the risks involved in owning facilities and operations independently. These risks include the possibility that our joint venture or SoftBank has economic or business interests or goals that are or become inconsistent with our economic or business interests or goals; is in a position to take action contrary to our instructions, requests, policies or objectives; subjects us to unexpected liabilities; takes actions that reduce our return on investment; or takes actions that harm our reputation or restrict our ability to run our business.

The joint venture agreement between us and SoftBank includes a put-call arrangement with respect to the shares of the Joint Venture held by SoftBank and its affiliates. SoftBank will have a put right to cause us to purchase all shares of the Joint Venture held by SoftBank and its affiliates, and we will have a call right to purchase all such shares in the event of (i) certain material disagreements relating to the Joint Venture or its business that may seriously affect the ability of the Joint Venture to perform its obligations under the joint venture agreement or may otherwise seriously impair the ability of the Joint Venture to conduct its business in an effective matter, other than one relating to the Joint Venture's business plan or to factual matters that may be capable of expert determination; (ii) the effectiveness of our initial public offering, a change in control, the seventh anniversary of the formation of the Joint Venture, or each subsequent anniversary of each of the foregoing events; or (iii) a material breach of the joint venture agreement by the other party that goes unremedied within 20 business days. Unless the shares of the Joint Venture are publicly traded and listed on a nationally recognized stock exchange, the purchase price per share of the Joint Venture in these situations will be determined by a third-party valuation firm on the assumption that the sale is on an arm's-length basis on the date of the put or call notice. The third-party valuation firm may evaluate a range of factors and employ assumptions that are subjective in nature, which may result in the fair value of Softbank's interest in the Joint Venture being determined to be materially different from what has been recorded in our consolidated financial statements, including those included elsewhere in this Annual Report on Form 10-K. We may pay the purchase price for those shares in cash (including in the form of a promissory note), in shares of our common stock, or in a combination thereof. In the event SoftBank exercises its put right, we will choose the form of consideration. In the event we exercise our call right, SoftBank will choose the form of consideration. If we are required or choose to purchase those shares from SoftBank, we could experience significant cash outflow, our other stockholders could see their holdings diluted, and our financial condition and the price of our common stock 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 the Joint Venture with SoftBank, 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, both directly and through our joint venture. 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, our local partners or the Joint Venture with SoftBank to obtain regulatory approvals for the use of our products in various countries;
- additional potentially blocking or relevant third-party patent or other intellectual property rights;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property;
- 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, including the current outbreak of novel coronavirus (2019-nCoV), for which the World Health Organization declared a global emergency on January 30, 2020, that could cause business disruption for the Joint Venture, including the Joint Venture's offices in Japan and Singapore, and make it more difficult to sell our tests in the affected countries or regions, many of which are in the JV Territory, 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 that may order either directly from us or through the Joint Venture with SoftBank. Our reliance on independent distributors to sell 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 and state laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and/or regulatory agencies enforcing those laws and regulations;
- federal and state health care fraud and abuse laws;
- federal and state 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 and state laws governing laboratory testing, including CLIA, and state licensing laws;
- federal and state laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including laboratory developed tests, or LDTs;
- federal, state and local laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar state 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.

The FDA has a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively enforce its regulatory requirements for such tests. However, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. 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 trials 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.

We market some of our other tests as 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.

On July 31, 2014, the FDA notified Congress of its intent to modify, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, FDA issued two draft guidances, entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs),” or the Framework Guidance, and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs).” The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, pursuant to the Framework Guidance, the FDA planned to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. The FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. If such changes to the regulatory framework occur, we could be subject to enforcement of regulatory requirements as a device manufacturer such as registration and listing requirements, medical device reporting requirements and the requirements of the FDA’s Quality System Regulation. Additionally, if the FDA begins to enforce its premarket submission regulations with respect to LDTs, we may be required to obtain premarket clearance or approval for our products we plan to commercialize as LDTs.

There is no guarantee that the FDA will grant 510(k) clearance or a premarket approval of our products and failure to obtain necessary clearances or approvals for our products would adversely affect our ability to grow our business.

Before we begin to label and market our products for use as clinical diagnostics in the United States, including as companion diagnostics, we may be required to obtain either 510(k) clearance or a premarket approval, or supplemental premarket approval, or respectively, PMA or sPMA, from the FDA, 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 trial, 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.

Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, prospects, financial condition and results of operations.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our products are safe or effective for their intended uses;
- the disagreement of the FDA with the design, conduct or implementation of our clinical trials or the analysis or interpretation of data from our pre-clinical studies or clinical trials;
- serious and unexpected adverse effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, 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 trials, 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;
- the FDA may identify deficiencies in our marketing application, and in our manufacturing processes, facilities or analytical methods or those of our third-party contract manufacturers;
- the potential for approval policies or regulations of the FDA to change significantly in a manner rendering our clinical data or regulatory filings insufficient for the clearance or approval; and
- the FDA may audit our clinical trial data and conclude that the data is not sufficiently reliable to support a PMA application.

If we are unable to obtain clearance or approval for any tests for which we plan to seek clearance or approval, 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. If the FDA 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.

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, including our Guardant360 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 non-small cell lung cancer, or 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"), private 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. As we have begun billing Medicare for our tests, 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. 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. We believe that our tests do not meet the current definition of advanced diagnostic laboratory tests, and we will be required to report private payer rates for our tests every three years; but this determination may change. 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. 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. 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. 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 trials may not be predictive of future trial results.

Our ongoing research and development and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting pre-and post-market clinical studies of some of our tests. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the trial eligibility criteria. Clinical studies may need to be conducted in compliance with FDA regulations or the FDA may take enforcement action. We cannot be certain that results from our clinical trials will support our marketing claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and studies. The clinical trial process may fail to demonstrate that our tests are safe and effective for the proposed indicated uses, which could cause us to abandon or delay development of our tests. Any delay or termination of our clinical trials will delay the filing of our marketing applications.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials, and would control only certain aspects of their activities. We would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on 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 trial sponsors, principal investigators and trial sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process.

If there are delays in testing or clearances or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval

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.

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 are currently available for research use only, or RUO, or for investigational use only, or IUO, depending on the proposed application. We make our RUO and IUO products available to a variety of parties, including biopharmaceutical companies and research institutes. Because RUO and IUO 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 IUO 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 governing RUO or IUO 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/IUO Guidance, which highlights the FDA's interpretation that distribution of RUO or IUO 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 IUO status. The RUO/IUO 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 IUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO or IUO 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 IUO products in a manner that is inconsistent with its RUO/IUO Guidance, we may be forced to stop distribution of our RUO/IUO 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 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 Commission, 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, the European Commission, EEA Competent Authorities, or other comparable foreign regulatory agencies, 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 application, 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.

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 or approvals, 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, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA.

Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our current or future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

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 certificate 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 certificate 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 certificate, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

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. In 2014, we obtained CAP accreditation for our Redwood City, California laboratory, 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. Violations are subject to significant civil monetary penalties, plus up to three times the remuneration involved. Violations of the AKS may also result in criminal penalties, including additional fines and imprisonment of up to ten years, and exclusion from Medicare, Medicaid or other governmental healthcare programs;

- 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. Violations of EKRA are subject to significant fines and/or up to 10 years in jail, separate and apart from existing AKS regulations and penalties;

- 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. Sanctions for violating the Stark Law include denial of payment, significant civil monetary penalties (on a per claim basis and additional penalties for a circumvention scheme), and exclusion from the federal health care programs;

- 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. Violations can result in significant civil monetary penalties for each wrongful act;

- 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, certain other health care professionals beginning in 2022, 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;

- 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 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 trials. 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 trials 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, 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 trials in a number of different countries. When we are acting as a vendor in connection with a clinical trial 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 trials, 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-approved therapies and clinical trials 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 trials 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 is expected to be issued, and a new pricing is expected to be established under MolDx for the Guardant360 CDx test. While we expect to continue to submit claims to Medicare for Guardant360 LDT clinical tests performed for such qualifying patients using the existing Z-Code Identifier, Medicare has instructed us to not submit claims to Medicare for Guardant360 CDx clinical tests until the new code is issued for the Guardant360 CDx test and the corresponding pricing is established. This new pricing for Guardant360 CDx

clinical tests could be different from the current pricing for Guardant360 LDT clinical tests which could affect our future revenue. A PLA code was issued for our Guardant360 CDx in January 2021 with an effective date in April 2021. Once the code is effective, all Guardant360 CDx services will be billed with this new code. Additionally, based on this new PLA code, we applied to CMS for our Guardant360 CDx test to become an advanced diagnostic laboratory test, or ADLT. If CMS grants ADLT status to the Guardant360 CDx test, for the first three quarters thereafter, we can only bill Medicare at the lowest available commercial rate at the launch of the test. After the initial three quarters, we can bill Medicare for Guardant360 CDx services at the median rate of claims paid by commercial payers. Changes to the codes used to bill a test to payers may result in significant changes in its reimbursement, which could negatively impact our revenue. As a result of implementing this new coding change for our Guardant360 CDx test, payments for Guardant360 CDx services could be reduced, put on hold, or eliminated by such payers.

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 November 10, 2020, the U.S. Supreme Court heard oral arguments in California vs. Texas to determine whether the entire ACA should be unenforceable nationwide or whether it should be unenforceable only to the extent that provisions injure the individual plaintiffs. It is unclear how the Supreme Court decision, and efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

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 by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, 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.

Our collection, use and disclosure of personally identifiable information, including patient and employee information, is subject to privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information in our possession could result in significant liability or reputational harm.

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, is a major issue in the United States and abroad. 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, including 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. And new privacy legislation may create additional rights for consumers and impose additional requirements on businesses. As these laws and regulations increase in complexity and number, they may change frequently, sometimes conflict and increase our compliance efforts, costs and risks.

HIPAA, as amended by HITECH, establishes a set of national privacy and security standards for the protection of protected health information, or PHI, by health plans, certain healthcare providers and others that submit certain covered transactions electronically, 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 the same requirements.

Penalties for violations of these laws vary. For instance, a single breach incident can result in findings of violations of multiple HIPAA provisions. Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include civil monetary penalties for each provision of HIPAA that is violated and, in certain circumstances, criminal penalties, including imprisonment and/or additional fines. 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, and the California Consumer Privacy Act, which came into effect on January 1, 2020, and creates new data privacy rights for users,. 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.

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, the EU, and elsewhere are often uncertain, contradictory, and in flux. We and our joint ventures 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, EU member countries 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 controllers and processors of personal data of persons within the EU. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The

GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share 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 EU 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, the EU-US Privacy Shield and the Swiss-US Privacy Shield were both invalidated by the Court of Justice of the EU, and the Swiss Commissioner, respectively. Further, the EU Standard Contractual Clauses are the subject of legal challenges in European courts and may face additional challenges in the future, and the absence of successor safeguards for continued data transfer could require us to create duplicative, and potentially expensive, information technology infrastructure and business operations in Europe or limit our ability to collect and use personal information collected in Europe. In addition, the EU Commission has proposed a new ePrivacy Regulation that would address various matters, including provisions specifically aimed at the use of cookies to identify an individual’s online behavior, and any such ePrivacy Regulation may provide for new compliance obligations and significant penalties. 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, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

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.

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 and commercialize products similar or identical to ours, and our ability to successfully commercialize our products 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 protect our intellectual property, 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 recover or restrict use of our intellectual property.

To the extent our intellectual property 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 does not provide adequate

coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time-consuming and expensive.

As is the case with other biotechnology companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we own solely and may own jointly with others or we have licensed and may continue to license from others, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing biotechnology patents is costly, time-consuming and complex, and we may fail to apply for patents on important products, services and 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, enforce and license any 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. 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 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 or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented 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 litigation 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. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

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 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 or commercialize our current or future products.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. 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 might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we 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 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 are commonplace. Grounds for a validity challenge 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 patent protection on our products. 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. For example, we filed separate patent infringement suits against Foundation Medicine, Inc. ("Foundation Medicine") alleging patent infringement related to our digital sequencing technology.

Defendants in such proceedings could counterclaim that the patents covering our product are invalid or unenforceable and could institute legal proceedings to challenge such patents both in court and before patent offices. For example, Foundation Medicine has asserted counterclaims of patent invalidity, unenforceability under the doctrine of inequitable conduct, and non-infringement. Foundation Medicine has also filed petition for post-grant review with the USPTO, challenging the patentability of certain patents asserted by us. If Foundation Medicine were to prevail, we would lose at least part of the patent protection on our products. Such a loss of patent protection could have a material adverse impact on our business. Any assertion of invalidity and/or unenforceability against the patents covering our products, 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.

We are, and we may acquire companies that are, party to various royalty-bearing license agreements that grant us rights to use certain intellectual property, including patents and patent applications, typically in certain specified fields of use. We may need to obtain additional licenses from others to advance our research, development and commercialization activities. 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 and commercialize products 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, seek regulatory approval of, or to market, products identical or similar to ours and we may be required to cease our development and commercialization activities. 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, 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 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 and commercialize the affected product candidates, 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 prevent infringement by third parties, or if the licensed patent or other rights are found to be invalid or unenforceable, our 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 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 or services, including our tests, which could adversely affect our ability to offer products or services, our ability to continue operations and our financial condition.

If we cannot license and maintain rights to use third-party technology on reasonable terms, we may not be able to successfully commercialize our products. Our licensed or acquired technology may lose value or utility or over time.

From time to time, we may identify third-party technology we may need, including to develop or commercialize new products or services. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product, and we may not be able to obtain necessary licenses to such patents or patent applications. If we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable, our business may suffer. In addition, any technology licensed or acquired 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. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products or services. Royalties are a component of cost of products or services and affect the margins on our products or services. 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.

We may not be able to protect or enforce our intellectual property rights adequately throughout the world.

Filing, prosecuting and defending patents on our products and services 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 or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our inventions in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products. Our patents or other intellectual property rights existing outside the United States may not be effective or sufficient to prevent them from competing. 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 in such jurisdictions. Proceedings to enforce our patent 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 on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners 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, consultants 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, consultants 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 commercialize potential products, which could harm 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 or services, we may encounter difficulty in enforcing them against third parties, and if these marks are registered by others, we could infringe such trademarks.

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, 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, consultants 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 against Foundation Medicine, Inc. for infringement over some of our patents 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 product introductions, or interruptions in sale of products or services, as we develop alternative products or services. In addition, if we resort to legal proceedings to enforce our intellectual property rights (as we have against Foundation Medicine, Inc.) 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 or services, such that competitors could copy our products or services. 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 or services, 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 infringement, whether by our competitors or other patent owners, both in the United States and throughout the world

wherever we seek to commercialize our products and services. 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 rights during litigation, our own patents may provide little or no deterrence or protection against patent holding companies or other patent owners who have no relevant product or service revenue. Therefore, our commercial success may depend in part on our non-infringement of the patents or other rights of third parties and on our success in defending ourselves in litigation.

However, our research, development 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 products. As the precision oncology industry expands and more patents are issued, the risk increases that our products or services 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. For example, we have been or are currently involved in legal proceedings against Foundation Medicine related to our patent rights.

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, Inc. filed a lawsuit for patent infringement against us in May 2016, which we settled in July 2018. 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 and services 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 or services in mind and claim that making, having made, using, selling, offering to sell or importing our products or services 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, commercialize and sell certain products or services, and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in product or service introductions while we attempt to develop alternative products or services 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 commercializing products or services, and the prohibition of sale of any of our products or services could materially affect our business and our ability to gain market acceptance for our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition.

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 or services, 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;
- the introduction of new products or product enhancements by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval 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

- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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, or 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, our chief executive officer or our president, 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.

Risks related to COVID-19

The COVID-19 global pandemic and the worldwide attempts to contain it could harm our business and our results of operations have been and could continue to be adversely impacted by such pandemic.

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. In response to government directives and guidelines, health care advisories and employee and customer concerns, we have altered certain aspects of our operations. A number of our employees have had to work remotely from home and those on site have had to follow our social distance guidelines, which could impact their productivity. Travel and visits related to our business have been severely curtailed.

We have also 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 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 trials 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. The COVID-19 pandemic has resulted in, and could continue to cause, increased costs or delays to production and development of our products. Our ability to enroll suitable patients in clinical studies has 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 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 our employees' ability 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.

Making a COVID-19 test available involves a high degree of risk and we may not be successful.

We launched our nasopharyngeal Guardant-19 SARS-CoV-2 test, or Guardant-19 test, and received the FDA's emergency use authorization for use in the detection of the novel coronavirus. The test is being offered to our employees and select partner organizations. We cannot predict the extent to which the Guardant-19 test will be used by third parties. We also cannot guarantee that the test will perform as expected or is free of defects or errors. Additionally, there can be no assurances as to the commercial success of such test. If that test offering is discontinued, we may not be able to utilize the materials we procured as inventory for our Guardant-19 test in our product offerings or at all, and we may suffer a loss.

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 Guardant Health Oncology Platform and 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.

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. Generally, losses incurred will carry forward until such losses expire (for losses generated prior to January 1, 2018) or are used to offset future taxable income, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the IRC, 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 net operating loss, or 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. In addition, the Tax Cuts and Jobs Act of 2017 imposes a reduction to the maximum deduction allowed for NOLs generated in tax years beginning after December 31, 2017, but allow such NOLs to be carried forward indefinitely. These changes may adversely affect our future cash flow.

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations.

We 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.

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, our Chief Executive Officer, and AmirAli Talasaz, our President and Chief Operating Officer and the chairman of our board of directors. 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 Redwood City, 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 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.

We depend on information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications 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. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations. In addition to the aforementioned business systems, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design and the automatic countermeasure operations of our technical systems. These information technology and telecommunications 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. In addition, our third-party provider of billing and collections services for late-stage clinical testing in the United States depends upon technology and telecommunications systems provided by its outside vendors.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. 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. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our reputation, and we may be unable to regain or repair our reputation.

Despite the security and maintenance measures we and our vendors and distributors have in place to help protect against system failures, our systems, and those of our vendors and distributors, remain vulnerable to delays, disruptions, data corruption, programming and/or human errors or other similar events, such as those due to system updates, natural disasters, malicious attacks, accidents, power disruptions, telecommunications failures, acts of terrorism or war, computer viruses, physical or electronic break-ins or similar events. Such incidents may disrupt our operations, result in losses, damage our reputation, and expose us to the risks of litigation and liability (including

regulatory liability); and may have a material adverse effect on our business, results of operations and financial condition.

Cyber-based attacks, security breaches, loss of data and other disruptions in relation to our information systems and computer networks 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.

Cyber-attacks, 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 cyber-attacks, including ransomware, phishing, structured query language injections and distributed denial-of-service attacks. A cyber-attack can also be in the form of unauthorized access or a blocking of authorized access. 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 cyber-attack 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 cyber-attack, our and/or our vendors' remediation efforts may not be successful, and a cyber-attack 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.

In the ordinary course of our business, we collect and store sensitive data, including PHI, personally identifiable 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 or integrations with third-party electronic medical records. These applications and data encompass 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.

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 and our information technology infrastructure could be vulnerable to hackers, phishing scams, malware, viruses, security flaws, employee errors, and other malfeasance or inadvertent disruptions. Any breach or interruption of our security measures or information technology infrastructure could compromise our networks, and the information stored there 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 or HITECH, and regulatory penalties. Notice of breaches is required to be made to affected individuals, the Secretary of the Department of Health and Human Services 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. Unauthorized access, loss or dissemination could disrupt our operations (including our ability to perform our analysis, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development, develop intellectual property, collect, process and prepare financial information, provide information about our tests and continue other patient and physician education and outreach efforts, and manage our business) and damage our reputation, any of which could adversely affect our business and financial condition. 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters is located in Redwood City, California, where we lease approximately 163,000 square feet of space in several buildings. These leases currently have expiration dates ranging from 2025 to 2027. Our CLIA-certified laboratory is located in these facilities, where testing for both clinical and biopharmaceutical customers is performed. We also have approximately 286,500 square feet of additional office space under two separate agreements for leases that have not yet commenced. We also maintain leased office spaces in Spring City, Texas and Seattle, Washington. While we believe our existing facilities are adequate to meet our current requirements, we expect to expand our facilities as our operations grow over time. We believe we will be able to obtain such additional space on acceptable and commercially reasonable terms.

Item 3. Legal Proceedings

The information under the caption "***Commitments and Contingencies - Legal Proceedings***" in Note 10 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, concerning certain legal proceedings in which we are involved, is hereby incorporated by reference. The resolution of any such legal proceeding is subject to inherent uncertainty and could have a material adverse effect on our financial condition, cash flows or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market information for common stock

Our common stock is traded on the Nasdaq Global Select Market, or Nasdaq, under the symbol "GH."

Holders of record

As of February 19, 2021, there were 40 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend policy

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any future earnings for the operation and expansion of our business. Accordingly, we do not anticipate declaring or paying dividends in the foreseeable future. The payment of any future dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, including any limitations on payment of dividends, and other factors that the board may deem relevant.

Unregistered sales of equity securities

None.

Purchases of equity securities by the issuer and affiliated purchasers

None.

Securities authorized for issuance under equity compensation plans

The information required by this item with respect to our equity compensation plans is incorporated by reference to our definitive proxy statement relating to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates (the "2021 Proxy Statement").

Stock performance graph

The graph below shows a comparison, from October 4, 2018 (the date our common stock commenced trading on the Nasdaq) through December 31, 2020, of the cumulative total return to stockholders of our common stock relative to the Nasdaq Composite Index ("NBI") and the Nasdaq Biotechnology Index ("IXIC"). The graph assumes that $100 was invested in each of our common stock, the Nasdaq Composite and the Nasdaq Biotechnology at their respective closing prices on October 4, 2018 and assumes reinvestment of gross dividends. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance.

This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Item 6. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with Part II, Item 7, *"Management's Discussion and Analysis of Financial Condition and Results of Operations,"* and the audited consolidated financial statements and related notes included in Part II, Item 8, *"Financial Statements and Supplementary Data,"* of this Annual Report on Form 10-K, including factors that may affect the comparability of such selected information. The consolidated statements of operations data for the years ended December 31, 2020, 2019 and 2018, respectively, and the consolidated balance sheet data as of December 31, 2020 and 2019, respectively, are derived from our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the year ended December 31, 2017 and 2016, and the consolidated balance sheet data as of December 31, 2018, 2017 and 2016, respectively, are derived from our audited consolidated financial statements that is not included in this Annual Report on Form 10-K. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes, and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of our results in any future period.

(in thousands, except per share data)	Year Ended December 31, 2020	2019	2018	2017	2016
Statements of Operations Data:					
Revenue:					
Precision oncology testing [1]	$ 236,324	$ 180,462	$ 78,407	$ 42,088	$ 24,496
Development services and other[1]	50,406	33,913	12,232	7,754	753
Total revenue	286,730	214,375	90,639	49,842	25,249
Costs and operating expenses:					
Cost of precision oncology testing	74,769	62,255	39,846	28,883	22,065
Cost of development services	17,766	8,465	3,364	2,735	59
Research and development expense	149,862	86,292	50,714	25,562	10,859
Sales and marketing expense	106,513	78,335	53,465	32,497	26,192
General and administrative expense	192,770	61,399	36,192	36,777	9,921
Total costs and operating expenses	541,680	296,746	183,581	126,454	69,096
Loss from operations	(254,950)	(82,371)	(92,942)	(76,612)	(43,847)
Interest income	10,171	13,741	5,266	2,234	733
Interest expense	(4,766)	(1,181)	(1,251)	(2,702)	(3,018)
Loss on debt extinguishment	—	—	—	(5,075)	—
Other income (expense), net	3,641	88	4,702	(1,059)	(1)
Loss before provision for income taxes	(245,904)	(69,723)	(84,225)	(83,214)	(46,133)
Provision for (Benefit from) income taxes	379	(1,872)	38	7	6
Net loss	(246,283)	(67,851)	(84,263)	(83,221)	(46,139)
Adjustment of redeemable noncontrolling interest	(7,500)	(7,800)	(800)	—	—
Net loss attributable to Guardant Health, Inc.	$ (253,783)	$ (75,651)	$ (85,063)	$ (83,221)	$ (46,139)
Deemed dividend related to repurchase of Series A convertible preferred stock	—	—	—	(4,716)	—
Deemed dividend related to change in conversion rate of Series D convertible preferred stock	—	—	—	(1,058)	—
Net loss attributable to Guardant Health, Inc. common stockholders	$ (253,783)	$ (75,651)	$ (85,063)	$ (88,995)	$ (46,139)
Net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	$ (2.60)	$ (0.84)	$ (2.80)	$ (7.07)	$ (3.53)
Weighted-average shares used in computing net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	97,504	90,597	30,403	12,582	13,053

(in thousands)	As of December 31, 2020	2019	2018	2017	2016
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 2,041,477	$ 791,585	$ 496,524	$ 294,574	$ 95,256
Working capital [1],[2],[3]	1,821,552	524,624	422,047	223,308	88,813
Total assets [1],[3]	2,271,781	962,535	587,403	342,938	116,565
Total liabilities [3],[4]	916,186	114,542	62,451	34,332	36,869
Redeemable noncontrolling interest	57,100	49,600	41,800	—	—
Total stockholders' equity [1][5]	1,298,495	798,393	483,152	308,606	79,696

(1) Fiscal years 2018, 2017 and 2016 results do not reflect the impact of the adoption of the new revenue accounting standard in fiscal year 2019.

(2) We define working capital as current assets less current liabilities. See our audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K for further details regarding our current assets and current liabilities.

(3) Fiscal years 2018, 2017 and 2016 do not reflect the impact of adoption of the new leasing standard in fiscal year 2019.

(4) Fiscal year 2020 included net carrying amount of our convertible senior notes of $806.3 million.

(5) Fiscal year 2020 included equity portion of convertible senior notes of $330.4 million.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, beliefs, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part I, Item 1A, "Risk Factors," of this Annual Report on Form 10-K.

The following generally compares our results of operations for the years ended December 31, 2020 and 2019. A detailed discussion comparing our results of operations for the years ended December 31, 2019 and 2018 can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2019.

Overview

We are a leading precision oncology company focused on helping conquer cancer globally through use of our proprietary blood-based tests, vast data sets and advanced analytics. We believe that the key to conquering cancer is unprecedented access to its molecular information throughout all stages of the disease, which we intend to enable by a routine blood draw, or liquid biopsy. Our Guardant Health Oncology Platform is designed to leverage our capabilities in technology, clinical development, regulatory and reimbursement to drive commercial adoption, accelerate drug development, improve patient clinical outcomes and lower healthcare costs. In pursuit of our goal to manage cancer across all stages of the disease, we have launched our Guardant360, Guardant360 CDx, and GuardantOMNI liquid biopsy-based tests for advanced stage cancer and our Guardant Reveal liquid biopsy-based tests for residual and recurring cancer to first address the need in Stage II-III colorectal cancer. We are developing tests under our Guardant360 tissue program which aims to address challenges with tissue genotyping products currently available in the market and tests from our LUNAR program which aims to address the needs of early stage cancer patients with neoadjuvant and adjuvant treatment selection, cancer survivors with surveillance, and asymptomatic individuals eligible for cancer screening and individuals at a higher risk for developing cancer with early detection. We have also developed our GuardantINFORM platform to further accelerate precision oncology drug development by biopharmaceutical companies by offering them an in-silico research platform to unlock further insights into tumor evolution and treatment resistance across various biomarker-driven cancers.

We perform our tests in our clinical laboratory located in Redwood City, California. Our laboratory is certified pursuant to the Clinical Laboratory Improvement Amendments of 1988, or CLIA, accredited by the College of American Pathologists, or CAP, permitted by the New York State Department of Health, or NYSDOH, and licensed in California and four other states. In September 2020, we dual-launched our Guardant360 CDx and Guardant360 LDT tests. Our Guardant360 CDx test was the first comprehensive liquid biopsy test approved by the U.S. Food and Drug Administration, or the FDA, to provide tumor mutation profiling for cancer patients with solid tumors and to be used as a companion diagnostic initially in connection with one therapeutic product of a biopharmaceutical customer.

In the United States, we market our tests to clinical customers through our sales organization, which is engaged in sales efforts and promotional activities primarily targeting oncologists and cancer centers. Outside the United States, we market our tests to clinical customers through distributors and direct contracts with healthcare institutions and partnerships with research organizations. We also market our tests to biopharmaceutical customers globally through our business development team, which promotes the broad utility of our tests throughout drug development and commercialization. Additionally, we have established a joint venture with SoftBank to accelerate commercialization of our products including in Asia, the Middle East and Africa.

We generated total revenue of $286.7 million, $214.4 million and $90.6 million for the years ended December 31, 2020, 2019 and 2018, respectively. We also incurred net losses of $246.3 million, $67.9 million and $84.3 million in

the years ended December 31, 2020, 2019 and 2018, respectively. We have funded our operations to date principally from the sale of our common stock, the issuance of convertible senior notes, and revenue from our precision oncology testing and development services and other. In October 2018, we completed our initial public offering, or the IPO, selling 14,375,000 shares of our common stock and raising $249.5 million net of underwriting discounts and commissions and other expenses payable by us. In May 2019, we completed an underwritten public offering of a total of 5,175,000 shares of our common stock, through which we received net proceeds of $349.7 million after deducting underwriting discounts and commissions and offering expenses payable by us. In June 2020, we completed an underwritten public offering of a total of 4,312,500 shares of our common stock, through which we received net proceeds of $354.6 million after deducting underwriting discounts and commissions and offering expenses payable by us. In November 2020, we issued our convertible senior notes with an aggregate principal amount of $1.15 billion. As of December 31, 2020, we had cash, cash equivalents and marketable securities of approximately $2.0 billion.

Factors affecting our performance

We believe there are several important factors that have impacted and that we expect will impact our operating performance and results of operations, including:

- ***Testing volume, pricing and customer mix.*** Our revenue and costs are affected by the volume of testing and mix of customers from period to period. We evaluate both the volume of tests that we perform for patients on behalf of clinicians and the number of tests we perform for biopharmaceutical companies. Our performance depends on our ability to retain and broaden adoption with existing customers, as well as attract new customers. We believe that the test volume we receive from clinicians and biopharmaceutical companies are indicators of growth in each of these customer verticals. Customer mix for our tests has the potential to significantly affect our results of operations, as the average selling price for biopharmaceutical sample testing is currently higher than our average reimbursement for clinical tests because we are not a contracted provider for, or our tests are not covered by clinical patients' insurance for, the majority of the tests that we perform for patients on behalf of clinicians. Approximately 37%, 38% and 38% of our U.S. clinical tests for the years ended December 31, 2020, 2019 and 2018 were for Medicare beneficiaries.

- ***Payer coverage and reimbursement.*** Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payers, including both commercial and government payers. Precision oncology revenue from tests for clinical customers is calculated based on our expected cash collections, using the estimated variable consideration. The variable consideration is estimated based on historical collection patterns as well as the potential for changes in future reimbursement behavior by one or more payers. Estimation of the impact of the potential for changes in reimbursement requires significant judgment and considers payer' past patterns of changes in reimbursement as well as any stated plans to implement changes. Any cash collections over the expected reimbursement period exceeding the estimated variable consideration is recorded in future periods based on actual cash received. Payment from commercial payers can vary depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider". Payers often reimburse non-participating providers, if at all, at a lower amount than participating providers. Because we are not contracted with these payers, they determine the amount that they are willing to reimburse us for any of our tests and they can prospectively and retrospectively adjust the amount of reimbursement, adding to the complexity in estimating the variable consideration. When we contract with a payer to serve 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. As a result, the potential for more favorable reimbursement associated with becoming a participating provider may be offset by a potential loss of reimbursement for non-covered uses of our tests. Current Procedural Terminology, or CPT, coding plays a significant role in how our Guardant360 test is reimbursed both from commercial and governmental 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. Changes to the codes used to report the Guardant360 test to payers may result in significant changes in its reimbursement. If a coding change were to occur, including as a result of the FDA approval of our Guardant360 test, payments for certain uses of the Guardant360 test could be reduced, put on hold, or eliminated by such payers. Cigna, Priority Health, multiple Blue Cross Blue Shield plans as well as the health plans associated with eviCore adopted policies that cover our Guardant360 test for the majority of NSCLC patients we test. If their policies were to change in the future to cover additional cancer indications, we anticipate that our total reimbursement would increase. For the years ended December 31, 2020, 2019 and 2018, approximately 43%, 44% and 46% of our U.S. clinical tests were for

patients tested for NSCLC. In September 2018, we began to receive reimbursements from Medicare for claims submitted with respect to Guardant360 clinical 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. Following the FDA approval of our Guardant360 CDx test, a new Z-Code Identifier is expected to be issued, and a new pricing is expected to be established under MolDx for the Guardant360 CDx test. While we expect to continue to submit claims to Medicare for Guardant360 LDT clinical tests performed for such qualifying patients using the existing Z-Code Identifier, Medicare has instructed us to not submit claims to Medicare for Guardant360 CDx clinical tests until the new code is issued for the Guardant360 CDx test and the corresponding pricing is established. This new pricing for Guardant360 CDx clinical tests could be different from the current pricing for Guardant360 LDT clinical tests which could affect our future revenue. A proprietary laboratory analyses, or PLA code was issued for our Guardant360 CDx in January 2021 with an effective date in April 2021. Once the code is effective, all Guardant360 CDx services will be billed with this new code. Additionally, based on this new PLA code, we applied to CMS for our Guardant360 CDx test to become an advanced diagnostic laboratory test, or ADLT. If CMS grants ADLT status to the Guardant360 CDx test, for the first three quarters thereafter, we can only bill Medicare at the lowest available commercial rate at the launch of the test. After the initial three quarters, we can bill Medicare for Guardant360 CDx services at the median rate of claims paid by commercial payers. Changes to the codes used to bill a test to payers may result in significant changes in its reimbursement, which could negatively impact our revenue. As a result of implementing this new coding change for our Guardant360 CDx test, payments for Guardant360 CDx services could be reduced, put on hold, or eliminated by such payers. 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, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. This variability and unpredictability could increase the risk of future revenue reversal and result in our failing to meet any previously publicly stated guidance we may provide.

- ***Biopharmaceutical customers.*** Our revenue also depends on our ability to attract, maintain and expand relationships with biopharmaceutical customers. As we continue to develop these relationships, we expect to support a growing number of clinical trials globally and continue to have opportunities to offer our platform to such customers for development services, including companion diagnostic development, novel target discovery and validation, as well as clinical trial enrollment. For example, our Guardant360, Guardant360 CDx and GuardantOMNI tests are being developed as companion diagnostics under collaborations with biopharmaceutical companies, including AstraZeneca, Amgen, Janssen Biotech and Radius Health.

- ***Research and development.*** A significant aspect of our business is our investment in research and development, including the development of new products. In particular, we have invested heavily in clinical studies as we believe these studies are critical to gaining physician adoption and driving favorable coverage decisions by payers. With respect to our LUNAR program, we initiated a prospective screening study, which we refer to as the ECLIPSE trial, aiming to recruit approximately 10,000 patients and evaluate the performance of our LUNAR-2 assay in detecting colorectal cancer in average-risk adults. In addition, we are investing very heavily in establishing clinical utility of our Guardant Reveal test in adjuvant treatment settings. In 2020, we launched three trials in collaboration with key cancer researchers: COBRA, a randomized controlled study, comprising over 1,400 low-risk stage-II colon cancer patients, ACT-3, comprising over 500 stage 3 colorectal cancer patients, and PEGASUS for the de-escalation of therapy, encompassing over 140 high-risk stage-II and stage-III colon cancer patients. We have expended considerable resources, and expect to increase such expenditures over the next few years, to support our research and development programs with the goal of fueling further innovation.

- ***International expansion.*** A component of our long-term growth strategy is to expand our commercial footprint internationally, and we expect to increase our sales and marketing expense to execute on this strategy. We currently offer our tests in countries outside the United States primarily through distributor relationships, direct contracts with hospitals or partnerships with research organizations. In May 2018, we formed and capitalized a joint venture, Guardant Health AMEA, Inc., which we refer to as the Joint Venture, with SoftBank, relating to the sale, marketing and distribution of our tests generally outside the Americas and Europe. We expect to rely on the Joint Venture to accelerate commercialization of our products in Asia, the Middle East and Africa.

- ***Sales and marketing expense***. Our financial results have historically, and will likely continue to, fluctuate significantly based upon the impact of our sales and marketing expense, and in particular, our various marketing programs around existing and new product introductions.

- ***General and administrative expense***. Our financial results have historically, and will likely continue to, fluctuate significantly based upon the impact of our general and administrative expense, and in particular, our stock-based compensation expense. Our equity awards, including market-based restricted stock units and performance-based restricted stock units, are intended to retain and incentivize employees to lead us to sustained, long-term superior financial and operational performance.
- ***COVID-19 Global Pandemic***. The global outbreak of coronavirus 2019, or COVID-19, has disrupted, and we expect will continue to disrupt, our operations. To protect the health and well-being of our workforce, partners, vendors and customers, we have provided free COVID-19 testing for employees working on-site, implemented social distance and building entry policies at work, restricted travel and facility visits, and followed California's "shelter in place" public health orders and the guidance from the Centers for Disease Control and Prevention. The COVID-19 global pandemic also has started to negatively affect, and we expect will continue to negatively affect, our revenue and our clinical studies. For example, our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. We launched our Guardant-19 test and received the FDA's emergency use authorization for use in the detection of the novel coronavirus. The test is being offered to our employees and select partner organizations our CLIA-certified clinical laboratory. We cannot predict the extent to which the Guardant-19 test will be used by third parties.

While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. See Part I, Item 1A, *"Risk Factors*" of this Annual Report on Form 10-K for more information.

Non-GAAP Financial Measure

Adjusted Earnings Before Interest, Taxes, Depreciation and Amortization ("Adjusted EBITDA"), a non-GAAP financial measure is a key metric to assess period-to-period comparison in evaluating the performance of our core business by removing the impact of income (expenses) attributable to material non-cash items, specifically stock-based compensation and fair value remeasurements due to the subjectivity, management judgment, and market fluctuations involved around these amounts. We exclude certain other items because we believe that these income (expenses) do not reflect expected future operating expenses. Additionally, certain items are inconsistent in amounts and frequency, making it difficult to perform a meaningful evaluation of our current or past operating performance.

"Adjusted EBITDA" is defined by us as net loss attributable to Guardant Health, Inc. common stockholders before: (i) interest income, (ii) interest expense, (iii) provision for (benefit from) income taxes, (iv) depreciation and amortization expense, (v) other (income) expense, net, (vi) stock-based compensation expense, (vii) adjustments relating to non-controlling interest and contingent consideration and, (viii) acquisition-related expenses, and other non-recurring items, if applicable in a reporting period.

Our use of Adjusted EBITDA as a non-GAAP financial measure is not intended to be considered in isolation from, as substitute for, or as superior to, the corresponding financial measure prepared in accordance with GAAP and you should not consider it in isolation or substitute for analysis of our results reported under GAAP. There are limitations inherent in non-GAAP financial measures because they exclude charges and credits that are required to be included in a GAAP presentation, and do not present the full measure of our recorded costs against its revenue. In addition, our definition of non-GAAP financial measures may differ from non-GAAP measures used by other companies.

The following table reconciles net loss attributable to Guardant Health, Inc. common stockholders (which is the most directly comparable GAAP operating financial measure) to Adjusted EBITDA.

	Year Ended December 31,	
	2020	2019
Net loss attributable to Guardant Health, Inc. common stockholders	$ (253,783)	$ (75,651)
Adjustments:		
Interest income	(10,171)	(13,741)
Interest expense	4,766	1,181
Other (income) expense, net	(3,641)	(88)
Provision for (benefit from) income taxes	379	(1,872)
Depreciation and amortization	16,065	11,411
Stock-based compensation expense	144,113	16,954
Adjustments relating to noncontrolling interest and contingent consideration	7,380	8,100
Acquisition related expenses [(1)]	9,707	422
Adjusted EBITDA (non-GAAP)	$ (85,185)	$ (53,284)

(1) For the year ended December 31, 2020, acquisition related expenses consist of a dispute settlement expense of $1.2 million and an IPR&D technology write off of $8.5 million incurred during the three months ended March 31, 2020 in connection with a settlement and a license purchase agreement. For the year ended December 31, 2019, acquisition related expenses of $0.4 million primarily include certain diligence, accounting, and legal expenses incurred related to our Bellwether acquisition.

Components of results of operations

Revenue

We derive our revenue from two sources: (i) precision oncology testing and (ii) development services and other.

Precision oncology testing. Precision oncology testing revenue is generated from sales of our Guardant360, Guardant360 CDx and GuardantOMNI tests to clinical and biopharmaceutical customers. In the United States, through December 31, 2020, we generally performed tests as an out-of-network service provider without contracts with health insurance companies. We submit claims for payment for tests performed for patients covered by U.S. private payers. We submit claims to Medicare for reimbursement for Guardant360 clinical testing performed for qualifying patients diagnosed with solid tumor cancers of non-central nervous system origin who meet the criteria of Medicare's National Coverage Determination for Next Generation Sequencing first established in March 2018. Tests for patients covered by Medicare represented approximately 37% and 38% of U.S. tests performed during the year ended December 31, 2020 and 2019. We also provide precision oncology testing to biopharmaceutical customers under contracts for which all recognition criteria are met, and we have recognized revenue on an accrual basis for those services.

Development services and other. Development services and other revenue primarily represents services, other than precision oncology testing, that we provide to biopharmaceutical companies and large medical institutions. It includes companion diagnostic development and regulatory approval services, clinical trial setup, monitoring and maintenance, referrals, liquid biopsy testing development and support, as well as GuardantConnect, GuardantINFORM, Guardant-19, and kits fulfillment related revenues. We collaborate with biopharmaceutical companies in the development and clinical trials of new drugs. As part of these collaborations, we provide services related to regulatory filings to support companion diagnostic device submissions for our liquid biopsy panels. Under these arrangements, we generate revenue from progression of our collaboration efforts, as well as from provision of on-going support. Development services and other revenue can vary over time as different projects start and complete.

Costs and operating expenses

Cost of precision oncology testing. Cost of precision oncology testing generally consists of cost of materials, inventory write-downs, direct labor, including bonus, employee benefits and stock-based compensation; equipment and infrastructure expenses associated with processing liquid biopsy test samples, including sample accessioning, library preparation, sequencing, quality control analyses and shipping charges to transport blood samples; freight; curation of test results for physicians; and license fees due to third parties. Infrastructure expenses include depreciation of laboratory equipment, rent costs, depreciation of leasehold improvements and information technology costs. Costs associated with performing our tests are recorded as the tests are performed regardless of whether revenue was recognized with respect to the tests. Royalties for licensed technology are calculated as a percentage of revenues generated using the associated technology and recorded as expense at the time the related revenue is recognized. One-time royalty payments related to signing of license agreements or other milestones, such as issuance of new patents, are amortized to expense over the expected useful life of the patents. While we do not

believe the technologies underlying these licenses are necessary to permit us to provide our tests, we do believe these technologies are potentially valuable and of possible strategic importance to us or our competitors.

We expect the cost of precision oncology testing to generally increase in line with the increase in the number of tests we perform, but the cost per test to decrease modestly over time due to the efficiencies we may gain as test volume increases, and from automation and other cost reductions.

Cost of development services and other. Cost of development services and other primarily includes costs incurred for the performance of development services requested by our customers comprising of direct labor and material costs including any inventory write-downs. For development of new products, costs incurred before technological feasibility has been achieved are reported as research and development expenses, while costs incurred thereafter are reported as cost of revenue. Cost of development services and other will vary depending on the nature, timing and scope of customer projects.

Research and development expense. Research and development expenses consist of costs incurred to develop technology and include salaries and benefits including stock-based compensation, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, other outside costs and costs to develop our technology capabilities. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical companies before technological feasibility has been achieved. Research and development costs are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. Costs to develop our technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. We expect that our research and development expenses will continue to increase in absolute dollars as we continue to innovate and develop additional products, expand our genomic and medical data management resources and conduct our ongoing and new clinical trials.

Sales and marketing expense. Our sales and marketing expenses are expensed as incurred and include costs associated with our sales organization, including our direct sales force and sales management, client services, marketing and reimbursement, medical affairs, as well as business development personnel who are focused on our biopharmaceutical customers. These expenses consist primarily of salaries, commissions, bonuses, employee benefits, travel expenses and stock-based compensation, as well as marketing, sales incentives, and educational activities and allocated overhead expenses. We expect our sales and marketing expenses to increase in absolute dollars as we expand our sales force, increase our presence within and outside of the United States, and increase our marketing activities to drive further awareness and adoption of our tests.

General and administrative expense. Our general and administrative expenses include costs for our executive, accounting and finance, information technology, legal and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, travel expenses and stock-based compensation, as well as professional services fees such as consulting, audit, tax and legal fees, and general corporate costs and allocated overhead expenses.

We expect that our general and administrative expenses will continue to increase in absolute dollars, primarily due to increased stock-based compensation expense, including resulting from the market-based restricted stock units granted to our Chief Executive Officer and our President and Chief Operating Officer in May 2020, increased headcount and increased costs associated with operating as a growing public company, including expenses related to legal, accounting, information systems, regulatory, maintaining compliance with exchange listing and requirements of the SEC, director and officer insurance premiums and investor relations. These expenses, though expected to increase in absolute dollars, are expected to decrease modestly as a percentage of revenue in the long term, though they may fluctuate as a percentage of revenue from period to period due to the timing and extent of these expenses being incurred.

Interest income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

Interest expense

Interest expense consists primarily of charges relating to amortization/accretion of debt issuance costs and debt discount, interest on finance leases or capital leases and royalty obligations.

Other income (expense), net

Other income (expense), net consists of foreign currency exchange gains and losses, payments due and received in relation to the settlement of a patent dispute, net of credit losses, and the relief fund grant from the Department of Health and Human Services, or HHS, under the U.S. Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. We expect our foreign currency gains and losses to continue to fluctuate in the future due to changes in foreign currency exchange rates.

Provision for (Benefit from) income tax

Income taxes are recorded using an asset and liability approach. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

Our tax positions are subject to income tax audits. We recognize the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. We recognize interest accrued and penalties related to unrecognized tax benefits in its tax provision. We evaluate uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for (benefit from) income taxes includes the effects of any accruals that we believe are appropriate, as well as the related net interest and penalties.

Results of operations

The following table sets forth the significant components of our results of operations for the periods presented.

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Revenue:		
Precision oncology testing	$ 236,324	$ 180,462
Development services and other	50,406	33,913
Total revenue	286,730	214,375
Costs and operating expenses:		
Cost of precision oncology testing[(1)]	74,769	62,255
Cost of development services and other	17,766	8,465
Research and development expense[(1)]	149,862	86,292
Sales and marketing expense[(1)]	106,513	78,335
General and administrative expense[(1)]	192,770	61,399
Total costs and operating expenses	541,680	296,746
Loss from operations	(254,950)	(82,371)
Interest income	10,171	13,741
Interest expense	(4,766)	(1,181)
Other income (expense), net	3,641	88
Loss before provision for income taxes	(245,904)	(69,723)
Provision for (benefit from) income taxes	379	(1,872)
Net loss	$ (246,283)	$ (67,851)

(1) Amounts include stock-based compensation expense as follows:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Cost of precision oncology testing	$ 1,839	$ 863
Research and development expense	10,024	5,907
Sales and marketing expense	9,279	4,716
General and administrative expense	122,971	5,468
Total stock-based compensation expense	$ 144,113	$ 16,954

Comparison of the Years Ended December 31, 2020 and 2019

Revenue

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Precision oncology testing	$ 236,324	$ 180,462	$ 55,862	31 %
Development services	50,406	33,913	16,493	49 %
Total revenue	$ 286,730	$ 214,375	$ 72,355	34 %

Total revenue was $286.7 million for the year ended December 31, 2020 compared to $214.4 million for the year ended December 31, 2019, an increase of $72.4 million, or 34%.

Precision oncology testing revenue increased to $236.3 million for the year ended December 31, 2020 from $180.5 million for the year ended December 31, 2019, an increase of $55.9 million, or 31%. This increase in precision oncology testing revenue was primarily due to an increase in tests performed, an increase in average selling price per test as a result of expanded coverage of our tests for clinical customers. Precision oncology revenue from tests for clinical customers was $171.8 million for the year ended December 31, 2020, up 70% from $101.0 million for the year ended December 31, 2019. This increase in clinical testing revenue was driven primarily by increases in test volume, higher average revenue per test, plus $11.0 million in revenue received from Medicare during the year ended December 31, 2020 for samples processed in 2019 up from $9.4 million in revenue received from Medicare during the year ended December 31, 2019 for samples processed in 2018. Tests for clinical customers increased to 63,254 for year ended December 31, 2020 from 49,926 for the year ended December 31, 2019 mainly due to an increase in the number of physicians ordering Guardant360 clinical tests. 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.

Precision oncology revenue from tests for biopharmaceutical customers was $64.5 million for the year ended December 31, 2020 and $79.5 million for the year ended December 31, 2019. Tests for biopharmaceutical customers decreased to 15,983 for the year ended December 31, 2020 from 20,643 for the year ended December 31, 2019 primarily due to the timing and progression of clinical trials and studies which resulted in fluctuation in the number of samples received for testing. The average selling price of biopharmaceutical tests was $4,037 for the year ended December 31, 2020, up from $3,850 for the year ended December 31, 2019 due to a greater number of such tests being the GuardantOMNI test, which has a higher selling price than the Guardant360 test. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we began receiving fewer samples for testing on a daily average basis from our clinical and biopharmaceutical customers than before the outbreak of the COVID-19 pandemic. Our future sample volumes and precision oncology revenue may be adversely impacted by the COVID-19 pandemic for the affected periods.

Development services and other revenue increased to $50.4 million for the year ended December 31, 2020 from $33.9 million for the year ended December 31, 2019, an increase of $16.5 million, or 49%. This increase in development services and other revenue was primarily due to new collaboration agreements entered in the year ended December 31, 2020 as well as progression of existing collaboration projects from biopharmaceutical customers for companion diagnostic development and regulatory approval services completed during the year ended December 31, 2020. Our development services arrangements with biopharmaceutical customers and development services revenue may continue to be adversely impacted by the COVID-19 pandemic in future periods.

Costs of Revenue and Gross Margin

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Cost of revenue	$ 92,535	$ 70,720	$ 21,815	31 %
Gross profit	$ 194,195	$ 143,655		
Gross margin	68 %	67 %		

Cost of revenue was $92.5 million for the year ended December 31, 2020 compared to $70.7 million for the year ended December 31, 2019, an increase of $21.8 million, or 31%.

Cost of precision oncology testing revenue was $74.8 million for the year ended December 31, 2020 compared to $62.3 million for the year ended December 31, 2019, an increase of $12.5 million, or 20%. This increase in cost of precision oncology testing was attributable to an increase in sample volumes and was primarily due to a $10.9 million increase in production labor and overhead costs, a $3.1 million increase in material costs, and a $1.9 million increase in other costs including costs related to kits, freight and curation of test results for physicians, offset by a $3.3 million decrease in royalties.

Cost of development services and other was $17.8 million for the year ended December 31, 2020 compared to $8.5 million for the year ended December 31, 2019, an increase of $9.3 million, or 110%. This increase in cost of development services and other was primarily due to an increase in labor costs and materials related to companion diagnostic development and regulatory approval service contracts and costs associated with the development of the Guardant-19 product.

Gross margin for the year ended December 31, 2020 was 68% compared to 67% for the year ended December 31, 2019. Gross margin improvement primarily reflects the impact of increased average selling price per test. Our gross margin may continue to be adversely impacted by the COVID-19 pandemic depending on how long the pandemic lasts and the severity of the situation in the coming periods.

Operating Expenses

Research and development expense

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Research and development	$ 149,862	$ 86,292	$ 63,570	74 %

Research and development expenses were $149.9 million for the year ended December 31, 2020 compared to $86.3 million for the year ended December 31, 2019, an increase of $63.6 million, or 74%. This increase in research and development expense was primarily due to an increase of $25.1 million in personnel-related costs for employees in our research and development group, including a $4.1 million increase in stock-based compensation, as we increased our headcount to support continued investment in our technology. The increase is also attributable to an increase of $10.7 million in development consulting fees, an increase of $10.7 million in material costs related to various programs, an increase of $8.5 million relating to in-process research and development (IPR&D) technology expensed in connection with a patent license acquisition that occurred in March 2020, an increase of $5.9 million related to allocated facility and information technology infrastructure costs and an increase of $0.9 million in allocated facilities and information technology infrastructure costs as we increased our headcount to support continued investment in our technology. Our research and development expenses are expected to increase in absolute dollars in coming years as the Company continues to innovate and invest in new product initiatives with a particular focus on LUNAR program.

Sales and marketing expense

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Sales and marketing	$ 106,513	$ 78,335	$ 28,178	36 %

Selling and marketing expenses were $106.5 million for the year ended December 31, 2020 compared to $78.3 million for the year ended December 31, 2019, an increase of $28.2 million, or 36%. This increase was primarily due to an increase of $18.7 million in personnel-related costs, including a $4.6 million increase in stock-based compensation, associated with the expansion of our commercial organization, an increase of $5.3 million related to allocated facilities and information technology infrastructure costs, and an increase of $4.3 million in professional service expenses related to marketing activities. We expect our sales and marketing expenses to increase in absolute dollars as we expand our sales force, increase our presence within and outside of the United States, and increase our marketing activities to drive further awareness and adoption of our tests.

General and administrative expense

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
General and administrative	$ 192,770	$ 61,399	$ 131,371	214 %

General and administrative expenses were $192.8 million for the year ended December 31, 2020 compared to $61.4 million for the year ended December 31, 2019, an increase of $131.4 million, or 214%. This increase was primarily due to an increase of $122.1 million in personnel-related costs, including a $117.5 million increase in stock-based compensation primarily in connection with the issuance of market-based restricted stock units to our Chief Executive Officer and our President and Chief Operating Officer as well as an increase in our headcount, an increase of $4.3 million related to allocated facilities and information technology infrastructure costs, an increase of $1.7 million in office administrative costs, an increase of $1.2 million related to settlement costs in connection with a patent license acquisition that occurred in March 2020, and an increase of $1.2 million in professional service expenses related to outside legal, accounting, consulting and IT services. Our general and administrative expenses may increase in the near term due to increase in stock-based compensation expense associated with increase headcount as well as expense recognition associated with the market-based restricted stock units.

Interest income

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Interest income	$ 10,171	$ 13,741	$ (3,570)	(26)%

Interest income was $10.2 million for the year ended December 31, 2020 compared to $13.7 million for the year ended December 31, 2019, a decrease of $3.6 million, or (26)%. This decrease was primarily due to a significant decrease in interest rate as the U.S. Federal Reserve lowered the risk-free interest rate to nearly zero, offset by a significant increase in cash, cash equivalents and marketable securities related to the receipt of cash proceeds from our follow-on public offering completed in June 2020 and borrowings on our convertible senior notes issued in November 2020.

Interest expense

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Interest expense	$ (4,766)	$ (1,181)	$ (3,585)	304 %

Interest expense was $4.8 million for the year ended December 31, 2020 compared to $1.2 million for the year ended December 31, 2019, an increase of $3.6 million, or 304%. This increase was primarily due to charges related to amortization of debt issuance costs and accretion of debt discount related to our convertible senior notes issued in November 2020, partially offset by the decrease in interest expense due to the settlement of all outstanding royalty obligations in March 2020 related to a patent license agreement we entered into in January 2017.

Other income (expense), net

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Other income (expense), net	$ 3,641	$ 88	$ 3,553	*

* Not meaningful

For the year ended December 31, 2020, other income (expense), net included receipt of $1.8 million received from HHS's relief fund under the CARES Act, and $1.0 million received in connection with settlement of a patent dispute. There was no similar charge or gain for the year ended December 31, 2019.

Other income (expense), net also included foreign currency exchange gains of $0.5 million for the year ended December 31, 2020. Foreign currency exchange gains/losses for the year ended December 31, 2019 was immaterial.

Provision for (benefit from) income taxes

	Year Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Provision for (benefit from) income taxes	$ 379	$ (1,872)	$ 2,251	(120)%

Provision for income taxes was immaterial for the year ended December 31, 2020. Benefit from income taxes of $1.9 million for the year ended December 31, 2019 was primarily due to the release of valuation allowance of $1.6 million associated with nondeductible intangible assets recorded as part of the Bellwether Bio acquisition. Additionally, there was a benefit of $0.4 million for the year ended December 31, 2019 associated with the utilization of tax losses from continuing operations against other comprehensive income gains.

Quarterly results of operations

The following tables set forth our unaudited quarterly consolidated statements of operations data for each of the eight quarters in the 24-month period ended December 31, 2020. The information for each of these quarters has been prepared in accordance with generally accepted accounting principles in the United States of America and on the same basis as our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of our results of operations. This data should be read in conjunction with our audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K. These quarterly operating results are not necessarily indicative of our operating results for the full year or any future period.

	Three Months Ended							
	December 31, 2020	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
	(unaudited) (in thousands)							
Revenue:								
Precision oncology testing	$ 64,703	$ 60,384	$ 50,991	$ 60,246	$ 57,414	$ 52,147	$ 42,064	$ 28,837
Development services	13,613	14,185	15,344	7,264	5,483	8,701	11,911	7,818
Total revenue	78,316	74,569	66,335	67,510	62,897	60,848	53,975	36,655
Costs and operating expenses:								
Cost of precision oncology testing	22,070	16,699	17,809	18,191	20,004	16,578	14,650	11,023
Cost of development services	6,337	4,488	4,626	2,315	1,834	1,936	2,183	2,512
Research and development expense	40,282	36,245	36,319	37,016	25,875	24,569	19,532	16,316
Sales and marketing expense	31,288	25,095	25,015	25,115	22,287	18,802	19,439	17,807
General and administrative expense	69,505	66,294	37,186	19,785	18,859	16,440	13,439	12,661
Total costs and operating expenses	169,482	148,821	120,955	102,422	88,859	78,325	69,243	60,319
Loss from operations	(91,166)	(74,252)	(54,620)	(34,912)	(25,962)	(17,477)	(15,268)	(23,664)
Interest income	1,900	2,313	2,640	3,318	3,871	4,286	3,099	2,485
Interest expense	(4,736)	(8)	(10)	(12)	(321)	(280)	(287)	(293)
Other income (expense), net	1,220	345	2,285	(209)	(187)	179	(51)	147
Loss before provision for income taxes	(92,782)	(71,602)	(49,705)	(31,815)	(22,599)	(13,292)	(12,507)	(21,325)
Provision for(benefit from) income taxes	263	68	34	14	(489)	(202)	(1,207)	26
Net loss	(93,045)	(71,670)	(49,739)	(31,829)	(22,110)	(13,090)	(11,300)	(21,351)
Adjustment of redeemable noncontrolling interest	(700)	(6,000)	(4,900)	4,100	(3,100)	300	(300)	(4,700)
Net loss attributable to Guardant Health, Inc. common stockholders	$ (93,745)	$ (77,670)	$ (54,639)	$ (27,729)	$ (25,210)	$ (12,790)	$ (11,600)	$ (26,051)
Net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	$ (0.94)	$ (0.78)	$ (0.57)	$ (0.29)	$ (0.27)	$ (0.14)	$ (0.13)	$ (0.30)
Weighted-average shares used in computing net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	100,018	99,554	96,011	94,382	93,997	93,303	89,036	85,935

Liquidity and capital resources

We have incurred losses and negative cash flows from operations since our inception, and as of December 31, 2020, we had an accumulated deficit of $606.6 million. We expect to incur additional operating losses in the near future and our operating expenses will increase as we continue to invest in clinical trials and develop new product, expand our sales organization, and increase our marketing efforts to drive market adoption of our tests. As demand for our tests are expected to continue to increase from physicians and biopharmaceutical companies, we anticipate that our capital expenditure requirements could also increase if we require additional laboratory capacity.

We have funded our operations to date principally from the sale of stock, convertible debt and through revenue from precision oncology testing and development services and other. As of December 31, 2020, we had cash and cash equivalents of $833.0 million and marketable securities of $1.2 billion. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to provide liquidity while ensuring capital preservation. Currently, our funds are held in marketable securities consisting of United States treasury securities.

Based on our current business plan, we believe our current cash, cash equivalents and marketable securities and anticipated cash flows from operations, will be sufficient to meet our anticipated cash requirements for more than 12 months from the date of this Annual Report on Form 10-K. We may consider raising additional capital to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons. As revenue from precision oncology testing and development services and other is expected to grow long-term, we expect our accounts receivable and inventory balances to increase. Any increase in accounts receivable and

inventory may not be completely offset by increases in accounts payable and accrued expenses, which could result in greater working capital requirements.

If our available cash, cash equivalents and marketable securities and anticipated cash flows from operations are insufficient to satisfy our liquidity requirements including because of lower demand for our products as a result of lower than currently expected rates of reimbursement from our customers or other risks described in this Annual Report on Form 10-K, we may seek to sell additional common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those 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. Additional capital may not be available to us on reasonable terms, or at all.

Cash flows

The following table summarizes our cash flows for the periods presented:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (103,927)	$ (47,134)
Net cash used in investing activities	(617,086)	(317,570)
Net cash provided by financing activities	1,410,307	367,304

Operating activities

Cash used in operating activities during the year ended December 31, 2020 was $103.9 million, which resulted from a net loss of $246.3 million and net change in our operating assets and liabilities of $47.7 million, partially offset by non-cash charges of $190.0 million. Non-cash charges primarily consisted of $144.1 million of stock-based compensation, $16.1 million of depreciation and amortization, $8.5 million of charge of in-process research and development costs with no alternative future use, $7.2 million of credit loss adjustment and others, $5.6 million of non-cash operating lease costs, and $4.0 million of amortization of premium on investment. The net change in our operating assets and liabilities was primarily the result of a $19.3 million increase in other assets for security deposits relating to new leases we entered into in 2020, a $7.9 million decrease in accounts payable, a $7.5 million increase in inventory due to higher testing volumes, a $6.1 million increase in prepaid expenses and other current assets, a $6.0 million payment of operating lease liabilities net of receipt of tenant improvement allowance, a $5.5 million increase in accounts receivables driven by increased sales to biopharmaceutical customers and a $3.7 million decrease in deferred revenue partially offset by a $9.7 million increase in accrued compensation due to increased personnel.

Cash used in operating activities during the year ended December 31, 2019 was $47.1 million, which resulted from a net loss of $67.9 million and net change in our operating assets and liabilities of $8.3 million, partially offset by non-cash charges of $29.0 million. Non-cash charges primarily consisted of $11.4 million of depreciation and amortization and $17.0 million of stock-based compensation, partially offset by $2.3 million of amortization of discount on investment. The net change in our operating assets and liabilities was primarily the result of a $7.4 million increase in accounts receivable driven by increased sales to biopharmaceutical customers and adoption of ASC 606, a $6.2 million increase in prepaid expenses and other current assets, a $6.0 million increase in inventory to support testing volumes, a $2.9 million increase in other assets for security deposits relating to new leases entered into in 2019 and a $3.9 million decrease in deferred revenue partially offset by a $9.3 million increase in accrued expenses and other current liabilities, a $5.6 million increase in accrued compensation due to increased personnel, a $4.3 million increase in accounts payable and a $1.2 million increase in operating lease liabilities as a result of the adoption of ASC 842.

Investing activities

Cash used in investing activities during the year ended December 31, 2020 was $617.1 million, which resulted primarily from purchases of marketable securities of $1.1 billion, purchases of property and equipment of $36.2 million, and purchases of intangible assets of $17.9 million, partially offset by proceeds from the maturities of marketable securities of $562.5 million.

Cash used in investing activities during the year ended December 31, 2019 was $317.6 million, which resulted primarily from purchases of marketable securities of $614.3 million, purchases of property and equipment of $18.7 million, purchase of business of $7.3 million and purchase of intangible assets of $2.5 million, partially offset by our proceeds from the maturities of marketable securities of $325.3 million.

Financing activities

Cash provided by financing activities during the year ended December 31, 2020 was $1.4 billion which was primarily due to net proceeds of $1.1 billion from borrowings on convertible senior notes, proceeds of $354.6 million from a follow-on offering of our common stock, net of underwriting discounts and commissions and offering expenses payable by us, proceeds of $9.5 million from exercise of stock options and proceeds of $7.1 million from issuances under employee stock purchase plan, partially offset by purchases of note hedges relating to the convertible senior notes of $90.0 million and taxes paid related to net share settlement of restricted stock units of $3.4 million.

Cash provided by financing activities during the year ended December 31, 2019 was $367.3 million which was primarily due to proceeds of $350.4 million from the follow-on offering completed in May 2019, and receipt of proceeds of $11.6 million from issuance of common stock upon exercise of stock options and $6.4 million from issuances under our employee stock purchase plan.

Contractual obligations and commitments

Our contractual commitments will have an impact on our future liquidity. The following table summarizes our contractually committed future obligations as of December 31, 2020:

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(in thousands)				
Operating lease obligations [1] [2]	$ 60,607	$ 9,129	$ 22,203	$ 21,632	$ 7,643

(1) We lease our office and laboratory space in Redwood City, California, and office space in Spring City, Texas and Seattle, Washington under operating leases that expire between January 2021 and November 2027. We also have operating leases for manufacturing and office equipment through March 2023.

(2) Excludes two facility lease agreements entered into in July 2020 that had not yet commenced as of December 31, 2020. The lease terms of these facility leases range from 8-12 years, and one of the lease agreements provides an option to renew the lease term for an additional ten years. As of December 31, 2020, the Company has additional future minimum lease payments relating to these two facility lease agreements amounting to $239.5 million. The Company anticipates to take possession of these facilities within the second fiscal quarter of 2021.

(3) We have patent license agreements with four parties. Under these agreements, we have made one-time and milestone license fee payments that we have capitalized and are amortizing to expense ratably over the useful life of the applicable underlying patent rights. Under some of these agreements, we are obligated to pay low single-digit percentage running royalties on net sales where the patent right(s) are used in the product or service sold, subject to minimum annual royalties or fees in certain agreements.

Off-balance sheet arrangements

As of December 31, 2020, we have not had any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical accounting policies and estimates

We have prepared our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Our preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the consolidated financial statements, as well as revenue and expenses recorded during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition

We derive revenue from the provision of precision oncology testing services provided to our ordering physicians and biopharmaceutical customers, as well as from biopharmaceutical research and development services provided to our biopharmaceutical customers. Precision oncology services include genomic profiling and the delivery of other genomic information derived from our platform. Development services and other include companion diagnostic development, clinical trial set up, monitoring and maintenance, information solutions and laboratory services, and other miscellaneous revenue streams. We currently receive payments from commercial third-party payers, certain hospitals and oncology centers and individual patients, as well as biopharmaceutical companies and research institutes.

Effective January 1, 2019, we began recognizing revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. Revenues are recognized when control of services is transferred to customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those services. ASC 606 provides for a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation.

Precision oncology testing

We recognize revenue from the sale of our precision oncology tests for clinical customers, including certain hospitals, cancer centers, other institutions and patients, at the time results of the test are reported to physicians. Most precision oncology tests requested by clinical customers are sold without a written agreement; however, we determine an implied contract exists with our clinical customers. We identify each sale of our liquid biopsy test to clinical customer as a single performance obligation. With the exception of certain limited contracted arrangements with insurance carriers and other institutions where the transaction price is fixed, a stated contract price does not exist and the transaction price for each implied contract with our clinical customers represents variable consideration. We estimate the variable consideration under the portfolio approach and consider the historical reimbursement data from third-party payers and patients, as well as known current or anticipated reimbursement trends not reflected in the historical data. We monitor the estimated amount to be collected in the portfolio at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the estimate and any subsequent revision contain uncertainty and require the use of judgment in the estimation of the variable consideration and application of the constraint for such variable consideration. We analyze actual cash collections over the expected reimbursement period and compare it with the estimated variable consideration for each portfolio and any difference is recognized as an adjustment to estimated revenue after the expected reimbursement period, subject to assessment of the risk of future revenue reversal.

Revenue from sales of precision oncology tests to biopharmaceutical customers are based on a negotiated price per test or on the basis of an agreement to provide certain testing volume over a defined period. We identify our promise to transfer a series of distinct liquid biopsy tests to biopharmaceutical customers as a single performance obligation. Precision oncology tests to biopharmaceutical customers are generally billed at a fixed price for each test performed. For agreements involving testing volume to be satisfied over a defined period, revenue is recognized over time based on the number of tests performed as the performance obligation is satisfied over time.

Results of our precision oncology services are delivered electronically, and as such there are no shipping or handling fees incurred by us or billed to customers.

Development services and other

We perform development services for our biopharmaceutical customers utilizing our precision oncology information platform. Development services typically represent a single performance obligation as we perform a significant integration service, such as analytical validation and regulatory submissions. The individual promises are not separately identifiable from other promises in the contracts and, therefore, are not distinct. However, under certain contracts, a biopharmaceutical customer may engage us for multiple distinct development services which are both capable of being distinct and separately identifiable from other promises in the contracts and, therefore, distinct performance obligations.

We collaborate with pharmaceutical companies in the development and clinical trials of new drugs. As part of these collaborations, we provide services related to regulatory filings to support companion diagnostic device submissions for our liquid biopsy panels. Under these collaborations, we generate revenue from achievement of milestones, as well as provision of on-going support. These collaboration arrangements include no royalty obligations. For development services performed, we are compensated through a combination of an upfront fee and performance-based non-refundable regulatory and other developmental milestone payments. The transaction price of our

development services contracts typically represents variable consideration. Application of the constraint for variable consideration to milestone payments is an area that requires significant judgment. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be managed to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone. In making this assessment, we consider our historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether achievement of the milestone is dependent on parties other than us. The constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is updated at each reporting period as a revision to the estimated transaction price.

We recognize development services and other revenue over the period in which biopharmaceutical research and development services are provided. Specifically, we recognize revenue using an input method to measure progress, utilizing costs incurred to-date relative to total expected costs as its measure of progress. We also assess the changes to the total expected cost estimates as well as any incremental fees negotiated resulting from changes to the scope of the original contract in determining the revenue recognition at each reporting period. For development of new products or services under these arrangements, costs incurred before technological feasibility is reached are included as research and development expenses in our consolidated statements of operations, while costs incurred thereafter are recorded as cost of development services.

We also have other miscellaneous revenue streams such as relating to GuardantINFORM, Guardant-19 screening in connection with the outbreak of COVID-19, referral fees, maintenance, kits fulfillment related revenues.

Contracts with multiple performance obligations

Contracts with biopharmaceutical customers may include multiple distinct performance obligations, such as provision of precision oncology testing, biopharmaceutical research and development services, and clinical trial enrollment assistance, among others. We evaluate the terms and conditions included within our contracts with biopharmaceutical customers to ensure appropriate revenue recognition, including whether services are considered distinct performance obligations that should be accounted for separately versus together. We first identify material promises, in contrast to immaterial promises or administrative tasks, under the contract and then evaluates whether these promises are both capable of being distinct and distinct within the context of the contract. In assessing whether a promised service is capable of being distinct, we consider whether the customer could benefit from the service either on its own or together with other resources that are readily available to the customer, including factors such as the research, development, and commercialization capabilities of a third party and the availability of the associated expertise in the general marketplace. In assessing whether a promised service is distinct within the context of the contract, we consider whether we provide a significant integration of the services, whether the services significantly modify or customize one another, or whether the services are highly interdependent or interrelated.

For contracts with multiple performance obligations, the transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling price by considering the historical selling price of these performance obligations in similar transactions as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing of other vendors, industry publications and current pricing practices, and expected costs of satisfying each performance obligation plus appropriate margin.

Variable interest entity

We review agreements we enter into with third party entities, pursuant to which we may have a variable interest in the entity, in order to determine if the entity is a variable interest entity, or VIE. If the entity is a VIE, we assess whether or not we are the primary beneficiary of that entity. In determining whether we are the primary beneficiary of an entity, we apply a qualitative approach that determines whether we have both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If we determine we are the primary beneficiary of a VIE, we consolidate the statements of operations and financial condition of the VIE into our consolidated financial statements. Accounting for the consolidation is based on our determination if the VIE meets the definition of a business or and asset. Assets, liabilities and noncontrolling interests, excluding goodwill, of VIEs that are not determined to be businesses are recorded at fair value in our financial statements upon consolidation. Assets and liabilities that we have transferred to a VIE, after, or shortly before the date we became the primary beneficiary are recorded at the same amount at which the assets and liabilities would have been measured if they had not been transferred. Our determination about whether we should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event.

In May 2018, we and an affiliate of SoftBank formed and capitalized the Joint Venture for the sale, marketing and distribution of our tests in the JV Territory. We expect to rely on the Joint Venture to accelerate commercialization of our products in Asia, the Middle East and Africa. The Joint Venture is deemed to be a VIE and we are identified as the primary beneficiary of the VIE. Consequently, we have consolidated the financial position, results of operations and cash flows of the Joint Venture in our financial statements and all intercompany balances have been eliminated in consolidation.

The joint venture agreement also includes a put-call arrangement with respect to the shares of the Joint Venture held by SoftBank and its affiliates. SoftBank will have a put right to cause us to purchase all shares of the Joint Venture held by SoftBank and its affiliates, and we will have a call right to purchase all such shares in the event of (i) certain material disagreement relating to the Joint Venture or its business that may seriously affect the ability of the Joint Venture to perform its obligations under the joint venture agreement or may otherwise seriously impair the ability of the Joint Venture to conduct its business in an effective matter, other than one relating to the Joint Venture's business plan or to factual matters that may be capable of expert determination; (ii) the effectiveness of our initial public offering, a change in control, the seventh anniversary of the formation of the Joint Venture, or each subsequent anniversary of each of the foregoing events; or (iii) a material breach of the joint venture agreement by the other party that goes unremedied within 20 business days. Unless the shares of the Joint Venture are publicly traded and listed on a nationally recognized stock exchange, the purchase price per share of the Joint Venture in these situations will be determined by a third-party valuation firm on the assumption that the sale is on an arm's-length basis on the date of the put or call notice. The third-party valuation firm may evaluate a range of factors and employ assumptions that are subjective in nature, which could result in the fair value of SoftBank's interest in the Joint Venture being determined to be materially different from what has been recorded in our consolidated financial statements, including those included elsewhere in this Annual Report on Form 10-K.

In the event we exercise our call right, the fair value of the Joint Venture will be deemed to be no less than an amount that yields a 20% internal rate of return on each tranche of capital invested by SoftBank and its affiliates in the Joint Venture, taking into account all proceeds received by SoftBank and its affiliates arising from their shares through such date.

In the event SoftBank exercises its put right and the fair value of the Joint Venture is determined to be greater than 40% of our fair value, we will only be required to purchase the number of shares of the Joint Venture held by SoftBank and its affiliates having an aggregate value equal to the product of 40% of our fair value and the pro rata portion of the outstanding shares of the Joint Venture held by SoftBank and its affiliates.

We may pay the purchase price for the shares of the Joint Venture in cash, in shares of our common stock, or in a combination thereof. In the event we exercise the call right, SoftBank will choose the form of consideration. In the event SoftBank exercises the put right, we will choose the form of consideration. The noncontrolling interest held by SoftBank contains embedded put-call redemption features that are not solely within our control and has been classified outside of permanent equity in our consolidated balance sheets. The put-call feature embedded in the redeemable noncontrolling interest do not currently require bifurcation as it does not meet the definition of a derivative and is considered to be clearly and closely related to the redeemable noncontrolling interest. The noncontrolling interest is considered probable of becoming redeemable as SoftBank has the option to exercise its put right to sell its equity ownership in the Joint Venture to us on or after the seventh anniversary of the formation of the Joint Venture, on each subsequent anniversary of the IPO and under certain other circumstances. We elected to recognize the change in redemption value immediately as they occur as if the put-call redemption feature were exercisable at the end of the reporting period.

Stock-based compensation

After the adoption of Accounting Standards Update 2018-07, *Compensation—Stock Compensation (Topic 718):* Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019, we measure stock-based compensation expense for stock options granted to our employees, directors, and nonemployee consultants on the date of grant and recognize the corresponding compensation expense of those awards over the period that the related services are rendered, which is generally the vesting period of the respective award. Compensation expense for stock options with performance metrics is calculated based upon expected achievement of the metrics specified in the grant.

We estimate the fair value of stock options granted under the 2012 Stock Plan, the 2018 Incentive Award Plan, and under the Guardant Health AMEA, Inc.'s 2020 Equity Incentive Plan for the Joint Venture, and stock purchase rights granted under our 2018 Employee Stock Purchase Plan on the grant date using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of assumptions regarding a number of variables

that are complex, subjective and generally require significant judgment to determine. The assumptions used to calculate the fair value of our stock options were:

Fair Value of Common Stock

The fair value of our common stock is determined by the closing price, on the date of grant, of its common stock, which is traded on the Nasdaq Global Select Market. The board of directors of the Joint Venture has determined the fair value of common stock of the Joint Venture. The grant date fair value of the Joint Venture's common stock was determined using valuation methodologies which utilizes certain assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability. In determining the fair value of the Joint Venture's common stock, the methodologies used to estimate the enterprise value of the Joint Venture were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Expected term

Our expected term represents the period that our stock options are expected to be outstanding. After the adoption of Accounting Standards Update 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* on January 1, 2019, the expected term of stock options issued to employees, directors and nonemployee consultants is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term), as we do not have sufficient historical data to use any other method to estimate expected term.

Expected volatility

Prior to the commencement of trading of our common stock on the Nasdaq Global Select Market on October 4, 2018 in connection with the IPO, there was no active trading market for our common stock. Due to limited historical data for the trading of our common stock, expected volatility is estimated based on the average volatility for comparable publicly traded peer group companies in the same industry plus our expected volatility for the available periods. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.

The Joint Venture derived the expected volatility from the average historical volatility over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends as the Joint Venture does not have any trading history for its common stock. The Joint Venture will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-free interest rate

The risk-free interest rate is based on the U.S. treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.

Expected dividend yield

We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

Black-Scholes assumptions

The weighted-average assumptions used in our Black-Scholes option-pricing model, including the Joint Venture, were as follows for stock option granted to our employees, directors and nonemployees for the periods presented:

	Year Ended December 31,		
	2020	**2019**	**2018**
Expected term (in years)	5.50 – 6.10	5.50 – 6.22	5.01 – 6.51
Expected volatility	63.6% – 73.3%	63.2% – 68.7%	68.7% – 78.8%
Risk-free interest rate	0.3% – 1.6%	1.6% – 2.7%	2.5% – 3.0%
Expected dividend yield	—%	—%	—%

For market-based restricted stock units, we derive the requisite service period using the Monte Carlo simulation model. The estimated fair value of the market-based restricted stock units was determined using a Monte Carlo simulation model which requires the use of assumptions regarding a number of variables that are complex,

subjective and generally require significant judgment to determine. Stock-based compensation expense will be recorded regardless of achieving the market conditions or not. If the related market condition is achieved earlier than its expected derived service period, the stock-based compensation expense will be recognized as a cumulative catch-up expense from the grant date to that point in time in achieving the share price goal.

The assumptions used to calculate the fair value of our market-based restricted stock units were as follows:

Fair Value of Common Stock

The fair value of our common stock is determined by the closing price, on the date of grant, of its common stock, which is traded on the Nasdaq Global Select Market.

Expected Volatility

Due to limited historical data for the trading of our common stock, expected volatility is estimated based on the average volatility for comparable publicly traded peer group companies and implied volatility of publicly traded options in the same industry plus our expected volatility for the available periods. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.

Expected Term

The expected term represents the derived service period for the respective tranches which has been estimated using the Monte Carlo simulation model.

Risk-Free Interest Rate

The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the market-based restricted stock units.

Risky Rate

The risky rate represents our cost of equity.

Expected Dividend Yield

We do not anticipate paying any dividends in the foreseeable future and, therefore, uses an expected dividend yield of zero.

Discount for Lack of Marketability

The discount for lack of marketability represents the discount applied for post vest term restrictions and has been derived using the Monte Carlo simulation model.

The following assumptions were used to calculate the stock-based compensation for market-based restricted stock units: a weighted-average expected term of 0.83 – 2.07 years; expected volatility of 65.5%; a risk-free interest rate of 0.53%; a zero dividend yield; a risky rate (cost of equity) of 16%; and a discount for post-vesting restrictions of 10.4% – 14.5%.

We recognize stock-based compensation expense net of forfeitures as they occur.

We will continue to use judgment in evaluating the assumptions related to our stock-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may have refinements to our estimates, which could materially impact our future stock-based compensation expense.

Convertible Senior Notes

In accounting for the issuance of the convertible senior notes, we separate the notes into liability and equity components. The carrying amount of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated convertible feature, using a discounted cash flow model with a risk adjusted yield. The carrying amount of the equity component representing the conversion option is determined by deducting the fair value of the liability component from the par value of the notes as a whole. This difference represents a debt discount that is amortized to interest expense using the effective interest method over the term of the notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. In accounting for the transaction costs related to the issuance of the notes, we allocated the total amount incurred to the liability and equity components based on their relative fair values. Transaction costs attributable to the liability component are netted with the liability component and amortized to interest expense using the effective interest

method over the term of the notes. Transaction costs attributable to the equity component are netted with the equity component of the notes in additional paid-in capital in the consolidated balance sheets.

Recent accounting pronouncements

See Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest rate risk

We are exposed to market risk for changes in interest rates related primarily to our cash and cash equivalents, marketable securities and our indebtedness. As of December 31, 2020, we had cash and cash equivalents of $833.0 million held primarily in cash deposits and money market funds. Our marketable securities are held in U.S. government debt securities, U.S. government agency bonds and corporate bonds. As of December 31, 2020, we had short-term marketable securities of $961.9 million and long-term marketable securities of $246.6 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. As of December 31, 2020, a hypothetical 100 basis point increase in interest rates would have resulted in an approximate $8.1 million decline of the fair value of our available-for-sale securities and a hypothetical 100 basis point decrease in interest rates would have resulted in an approximate $1.0 million increase of the fair value of our available-for-sale securities. This estimate is based on a sensitivity model that measures market value changes when changes in interest rates occur.

Foreign currency risk

The majority of our revenue is generated in the United States. Through December 31, 2020, we have generated an insignificant amount of revenues denominated in foreign currencies. As we expand our presence in the international market, our results of operations and cash flows are expected to increasingly be subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. As of December 31, 2020, the effect of a hypothetical 10% change in foreign currency exchange rates would not be material to our financial condition or results of operations. To date, we have not entered into any hedging arrangements with respect to foreign currency risk. As our international operations grow, we will continue to reassess our approach to manage our risk relating to fluctuations in currency rates.

Item 8. Financial Statements and Supplementary Data

Guardant Health, Inc.

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As of December 31, 2020 and 2019, and

For the Years Ended December 31, 2020, 2019 and 2018

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The supplementary financial information required by this Item 8 is included in Part II, Item 7 under the caption "*Quarterly Results of Operations*", which is incorporated herein by reference.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Guardant Health, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Guardant Health, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, redeemable noncontrolling interest and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Precision Oncology Revenue (testing services provided to ordering physicians)

Description of the Matter	For the year ended December 31, 2020, revenue recognized from Precision Oncology was $236.3 million. As described in Note 2 to the consolidated financial statements, the Company recognizes revenue from the performance of precision oncology tests for clinical customers upon delivery of test results to the ordering physician. As most precision oncology tests requested by customers are sold based on a physician requisition form without further written terms and conditions, the Company determined an implied contract exists with its patients and estimates variable consideration to be received for these services. Management estimates variable consideration based on historical payment data from third-party payers and patients adjusted for known and forecasted changes in payment patterns and subject to a constraint such that revenue recognized is not expected to be reversed. Auditing the Company's estimate of total consideration expected to be received for the precision oncology tests is complex and requires significant judgement to evaluate management's estimate of payments to be received for the tests. This estimate is affected by assumptions on coverage of the tests for the patient and experience with collection from third-party payors.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls that address the risks of material misstatement relating to the measurement of precision oncology revenues based upon estimating variable consideration. This included testing controls relating to management's review of the significant assumptions described above and inputs used in the determination of the estimated amount that would be collected for tests performed during the period. We also tested controls over the current and historical data used by management in determining this estimate of variable consideration, subject to a constraint, including the completeness and accuracy of the data. Our audit procedures over the Company's precision oncology revenue included, among others, assessing assumptions and inputs described above, testing the completeness and accuracy of the underlying data used by the Company in its analysis, including the constraint applied. We agreed the terms and conditions of the type of test (i.e. lung, non-lung, etc.) to be performed to the requisition forms submitted by the physician. We compared the significant assumptions and inputs used by management to the Company's third-party payor collection trends and other relevant factors. This included testing inputs to the calculation by comparing historical information to source documents and evaluating the historical accuracy of management's estimates by comparing such estimates to actual results.

Valuation of Redeemable Non-Controlling Interest

Description of the Matter	As described in Note 3 to the consolidated financial statements, in May 2018, the Company entered into an agreement with an entity affiliated with SoftBank, a related party, to establish a Joint Venture to distribute the Company's tests in certain markets outside the United States. The Company is consolidating the Joint Venture and as part of the accounting for the redeemable noncontrolling interest ("NCI") held by Softbank, the Company is carrying the NCI at its fair value as the agreement has a put feature which contractually allows Softbank to return the NCI interest back to the Company. The fair value of the NCI was determined using two valuation models, the income approach and the market approach. Determining the fair value of the NCI requires judgment and the use of significant estimates and assumptions, such as, a discount rate and an exit multiple rate. The discount rate is applied to calculate the present value the expected future cash flows of the Joint Venture. The selection of exit multiple rate is used in establishing the value of an exit event (i.e. sale or initial public offering) of the Joint Venture. These significant estimates and assumptions are forward looking and could be affected by future economic and market conditions. At December 31, 2020, the Company's non-controlling interest was $57.1 million.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls over the fair value estimation of the NCI. We tested controls over the selection and application of the valuation models and the underlying significant estimates and assumptions noted above. To test the estimated fair value of the NCI, our audit procedures included, among others, involvement of our valuation specialist to assist us in the evaluation of the Company's valuation methodology and testing of the significant estimates and assumptions. For example, we compared the discount rate to industry trends and market conditions and the exit multiple rate to the comparable public companies. We also compared the revenue forecast to evidence of approval by the Joint Venture board of directors.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

Redwood City, California
February 25, 2021

Guardant Health, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	As of December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 832,977	$ 143,228
Short-term marketable securities	961,903	379,574
Accounts receivable, net	53,299	47,986
Inventory	22,716	15,181
Prepaid expenses and other current assets, net	17,466	11,389
Total current assets	1,888,361	597,358
Long-term marketable securities	246,597	268,783
Property and equipment, net	62,782	43,668
Right-of-use assets	37,343	29,140
Intangible assets, net	16,155	8,524
Goodwill	3,290	3,290
Capitalized license fees	45	6,890
Other assets, net	17,208	4,882
Total Assets[1]	$ 2,271,781	$ 962,535
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,340	$ 16,197
Accrued compensation	28,280	18,557
Accrued expenses	22,639	25,703
Deferred revenue	8,550	12,277
Total current liabilities	66,809	72,734
Convertible senior notes, net	806,292	—
Long-term operating lease liabilities	41,565	33,256
Obligation related to royalty	—	6,880
Other long-term liabilities	1,520	1,672
Total Liabilities[1]	916,186	114,542
Commitments and contingencies (Note 10)		

	As of December 31,	
	2020	2019
Redeemable noncontrolling interest	57,100	49,600
Stockholders' equity:		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, par value of $0.00001 per share; 350,000,000 shares authorized as of December 31, 2020 and 2019; 100,213,985 and 94,261,414 shares issued and outstanding as of December 31, 2020 and 2019, respectively	1	1
Additional paid-in capital	1,902,389	1,150,090
Accumulated other comprehensive income	2,697	1,111
Accumulated deficit	(606,592)	(352,809)
Total Stockholders' Equity	1,298,495	798,393
Total Liabilities, Redeemable Noncontrolling Interest and Stockholders' Equity	$ 2,271,781	$ 962,535

(1) As of December 31, 2020 and 2019, this balance includes $35.0 million and $45.1 million of assets, respectively, that can be used only to settle obligations of the consolidated variable interest entity ("VIE") and VIE's subsidiaries, and $4.9 million and $5.7 million of liabilities of the consolidated VIE and VIE's subsidiaries, respectively, for which their creditors do not have recourse to the general credit of the Company. See Note 3, Investment in Joint Venture.

The accompanying notes are an integral part of these consolidated financial statements.

Guardant Health, Inc.

Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,		
	2020	**2019**	**2018**
Revenue:			
Precision oncology testing [1]	$ 236,324	$ 180,462	$ 78,407
Development services and other [1]	50,406	33,913	12,232
Total revenue	286,730	214,375	90,639
Costs and operating expenses:			
Cost of precision oncology testing	74,769	62,255	39,846
Cost of development services and other	17,766	8,465	3,364
Research and development expense	149,862	86,292	50,714
Sales and marketing expense	106,513	78,335	53,465
General and administrative expense	192,770	61,399	36,192
Total costs and operating expenses	541,680	296,746	183,581
Loss from operations	(254,950)	(82,371)	(92,942)
Interest income	10,171	13,741	5,266
Interest expense	(4,766)	(1,181)	(1,251)
Other income	3,641	88	4,702
Loss before provision for income taxes	(245,904)	(69,723)	(84,225)
Provision for (benefit from) income taxes	379	(1,872)	38
Net loss	(246,283)	(67,851)	(84,263)
Adjustment of redeemable noncontrolling interest	(7,500)	(7,800)	(800)
Net loss attributable to Guardant Health, Inc. common stockholders	$ (253,783)	$ (75,651)	$ (85,063)
Net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	$ (2.60)	$ (0.84)	$ (2.80)
Weighted-average shares used in computing net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	97,504	90,597	30,403

[1] Fiscal year 2018 results do not reflect the impact of the adoption of the new revenue accounting standard in fiscal year 2019.

The accompanying notes are an integral part of these consolidated financial statements.

Guardant Health, Inc.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Net loss	$ (246,283)	$ (67,851)	$ (84,263)
Other comprehensive income (loss), net of tax impact:			
Unrealized gain on available-for-sale securities	1,131	1,110	449
Foreign currency translation adjustments	455	84	—
Other comprehensive income	1,586	1194	449
Comprehensive loss	$ (244,697)	$ (66,657)	$ (83,814)
Comprehensive loss attributable to redeemable noncontrolling interest	(7,500)	(7,800)	(800)
Comprehensive loss attributable to Guardant Health, Inc.	$ (252,197)	$ (74,457)	$ (84,614)

The accompanying notes are an integral part of these consolidated financial statements.

Guardant Health, Inc.
Consolidated Statements of Redeemable Noncontrolling Interest and Stockholders' Equity
(in thousands, except share data)

	Redeemable Noncontrolling Interest	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
		Shares	Amount	Shares	Amount				
Balance as of January 1, 2018	$ —	78,627,369	$ 499,974	11,896,882	$ —	$ 4,900	$ (532)	$ (195,736)	$ 308,606
Conversion of convertible preferred stock to common stock upon initial public offering	—	(78,627,369)	(499,974)	58,264,577	1	499,973	—	—	—
Issuance of common stock upon initial public offering, net of offering costs of $4,475	—	—	—	14,375,000	—	249,531	—	—	249,531
Issuance of common stock upon exercise of stock options	—	—	—	963,119	—	2,905	—	—	2,905
Issuance of common stock upon early exercise of stock options	—	—	—	44,268	—	—	—	—	—
Issuance of common stock upon exercise of warrants	—	—	—	320,289	—	45	—	—	45
Repurchase of common stock	—	—	—	(31,681)	—	(172)	—	—	(172)
Stock-based compensation	—	—	—	—	—	6,851	—	—	6,851
Issuance of equity interests in redeemable noncontrolling interest	41,000	—	—	—	—	—	—	—	—
Adjustment of redeemable noncontrolling interest	800	—	—	—	—	—	—	(800)	(800)
Other comprehensive gain, net of tax impact	—	—	—	—	—	—	449	—	449
Net loss	—	—	—	—	—	—	—	(84,263)	(84,263)
Balance as of December 31, 2018	41,800	—	—	85,832,454	1	764,033	(83)	(280,799)	483,152
Cumulative effect adjustment for Topic 606 adoption	—	—	—	—	—	—	—	4,907	4,907
Cumulative effect adjustment for ASU 2018-07 adoption	—	—	—	—	—	1,266	—	(1,266)	—
Issuance of common stock upon follow-on offering, net of offering costs of $723	—	—	—	5,175,000	—	349,709	—	—	349,709
Issuance of common stock upon exercise of stock options	—	—	—	2,999,419	—	11,638	—	—	11,638
Vesting of restricted stock units	—	—	—	22,208	—	—	—	—	—
Vesting of common stock exercised early	—	—	—	—	—	95	—	—	95
Common stock issued under employee stock purchase plan	—	—	—	232,333	—	6,395	—	—	6,395
Stock-based compensation	—	—	—	—	—	16,954	—	—	16,954
Adjustment of redeemable noncontrolling interest	7,800	—	—	—	—	—	—	(7,800)	(7,800)
Other comprehensive gain, net of tax impact	—	—	—	—	—	—	1,194	—	1,194
Net loss	—	—	—	—	—	—	—	(67,851)	(67,851)
Balance as of December 31, 2019	49,600	—	—	94,261,414	1	1,150,090	1,111	(352,809)	798,393
Issuance of common stock upon follow-on offering, net of offering costs of $1,130	—	—	—	4,312,500	—	354,600	—	—	354,600
Equity component of convertible senior notes, net	—	—	—	—	—	330,403	—	—	330,403
Purchase of convertible senior note hedges	—	—	—	—	—	(90,045)	—	—	(90,045)
Issuance of common stock upon exercise of stock options	—	—	—	1,446,843	—	9,528	—	—	9,528
Vesting of restricted stock units	—	—	—	97,188	—	—	—	—	—
Vesting of common stock exercised early	—	—	—	—	—	52	—	—	52
Common stock issued under employee stock purchase plan	—	—	—	96,040	—	7,095	—	—	7,095
Taxes paid related to net share settlement of restricted stock units	—	—	—	—	—	(3,447)	—	—	(3,447)
Stock-based compensation	—	—	—	—	—	144,113	—	—	144,113
Adjustment of redeemable noncontrolling interest	7,500	—	—	—	—	—	—	(7,500)	(7,500)
Other comprehensive gain, net of tax impact	—	—	—	—	—	—	1,586	—	1,586
Net loss	—	—	—	—	—	—	—	(246,283)	(246,283)
Balance as of December 31, 2020	$ 57,100	—	$ —	100,213,985	$ 1	$ 1,902,389	$ 2,697	$ (606,592)	$ 1,298,495

The accompanying notes are an integral part of these consolidated financial statements.

Guardant Health, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
OPERATING ACTIVITIES:			
Net loss	$ (246,283)	$ (67,851)	$ (84,263)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	16,065	11,411	7,136
Non-cash operating lease costs	5,567	4,409	—
Charge of in-process research and development costs with no alternative future use	8,500	—	—
Unrealized translation gains on obligation related to royalty	—	(147)	(357)
Re-valuation of contingent consideration	(120)	300	—
Non-cash stock-based compensation	144,113	16,954	6,851
Amortization of debt discount and debt issuance costs	4,729	—	—
Amortization of premium (discount) on marketable securities	4,016	(2,310)	(412)
Benefit from income tax differences	—	(1,597)	—
Credit loss adjustment and others	7,151	—	(13)
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	(5,463)	(7,389)	(22,903)
Inventory	(7,535)	(6,045)	(1,849)
Prepaid expenses and other current assets	(6,077)	(6,185)	(3,663)
Other assets	(19,326)	(2,852)	(451)
Accounts payable	(7,859)	4,341	5,046
Accrued compensation	9,723	5,571	8,075
Accrued expenses and other current liabilities	(1,359)	9,289	286
Operating lease liabilities	(6,042)	(1,172)	—
Deferred rent	—	—	1,307
Deferred revenue	(3,727)	(3,861)	13,025
Net cash used in operating activities	(103,927)	(47,134)	(72,185)
INVESTING ACTIVITIES:			
Purchase of marketable securities	(1,125,575)	(614,290)	(287,450)
Maturity of marketable securities	562,548	325,333	154,625
Business acquisition, net of cash acquired	—	(7,328)	—
Purchase of property and equipment	(36,173)	(18,717)	(20,203)
Purchase of intangible assets and capitalized license obligations	(17,886)	(2,500)	—
Payment in connection with a license agreement	—	(68)	—
Net cash used in investing activities	(617,086)	(317,570)	(153,028)
FINANCING ACTIVITIES:			
Payments made on royalty obligations	—	(311)	—
Payments made on finance lease obligations	(174)	(127)	(443)
Proceeds from issuance of common stock under employee stock purchase plan	7,095	6,395	—
Proceeds from issuance of common stock upon exercise of stock options	9,528	11,638	3,111
Proceeds from issuance of common stock upon the exercise of warrants	—	—	45
Taxes paid related to net share settlement of restricted stock units	(3,447)	—	—

	Year Ended December 31,		
	2020	2019	2018
Repurchase of common stock	—	—	(172)
Proceeds from public offerings of common stock	355,730	350,432	254,006
Payment of offering costs related to public offerings of common stock	(1,130)	(723)	(4,386)
Proceeds from borrowings on convertible senior notes, net	1,132,750	—	—
Purchase of convertible note hedges	(90,045)	—	—
Net proceeds from issuance of equity interests in redeemable noncontrolling interest	—	—	41,000
Net cash provided by financing activities	1,410,307	367,304	293,161
Net effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	455	84	—
Net increase in cash, cash equivalents and restricted cash	689,749	2,684	67,948
Cash, cash equivalents and restricted cash – Beginning of period	143,228	140,544	72,596
Cash and cash equivalents – End of period	$ 832,977	$ 143,228	$ 140,544
Supplemental Disclosures of Cash Flow Information:			
Operating lease liabilities arising from obtaining right-of-use assets	$ 13,123	$ 16,714	$ —
Cash paid for interest	$ —	$ 1,181	$ 1,251
Cash paid for income taxes	$ 331	$ 298	$ 102
Supplemental Disclosures of Noncash Investing and Financing Activities:			
Purchases of property and equipment included in accounts payable and accrued expenses	$ 1,986	$ 4,818	$ 1,522
Vesting of common stock exercised early	$ 52	$ 95	$ —
Initial fair value of contingent consideration at acquisition date	$ —	$ 1,065	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ —	$ 89
Debt issuance costs included in accounts payable and accrued expenses	$ 784	$ —	$ —
Conversion of convertible preferred stock to common stock upon initial public offering	$ —	$ —	$ 499,974

The accompanying notes are an integral part of these consolidated financial statements.

Guardant Health, Inc.
Notes to Consolidated Financial Statements

1. Description of Business

Guardant Health, Inc. (the "Company") is a leading precision oncology company focused on helping conquer cancer globally through use of its proprietary blood tests, vast data sets and advanced analytics. The key to conquering cancer is unprecedented access to its molecular information throughout all stages of the disease, which the Company enables by a routine blood draw, or liquid biopsy. The Guardant Health Oncology Platform is designed to leverage the Company's capabilities in technology, clinical development, regulatory and reimbursement to drive commercial adoption, accelerate drug development, improve patient clinical outcomes and lower healthcare costs. In pursuit of its goal to manage cancer across all stages of the disease, the Company has launched its Guardant360, Guardant 360 CDx, and GuardantOMNI liquid biopsy-based tests for advanced stage cancer and in February 2021, launched its Guardant Reveal liquid biopsy-based tests for residual and recurring cancer to first address the need in Stage II-III colorectal cancer, and is developing tests from its Guardant360 tissue program which aims to address challenges with tissue genotyping products currently available in the market and its LUNAR program which aim to address the needs of early stage cancer patients with neoadjuvant and adjuvant treatment selection, cancer survivors with surveillance, and asymptomatic individuals eligible for cancer screening and individuals at a higher risk for developing cancer with early detection. Using data collected from the Company's tests, the Company has also developed GuardantINFORM platform to further accelerate precision oncology drug development by biopharmaceutical companies by offering them an in-silico research platform to further unlock insights into tumor evolution and treatment resistance across various biomarker-driven cancers.

The Company was incorporated in Delaware in December 2011 and is headquartered in Redwood City, California. In May 2018, the Company formed and capitalized Guardant Health AMEA, Inc. (the "Joint Venture") in the United States with an affiliate of SoftBank Vision Fund (AIV M1) L.P. ("SoftBank"). Under the terms of the joint venture agreement, the Company held a 50% ownership interest in the Joint Venture. As of December 31, 2020, the Joint Venture has subsidiaries in Singapore and Japan (see Note 3, Investment in Joint Venture) and the Company has a subsidiary in Switzerland which was incorporated in 2019.

Approval of Amended and Restated Certificate of Incorporation

In September 2018, the Company's Board of Directors and stockholders approved an amended and restated certificate of incorporation, which authorized 350,000,000 shares of common stock and 10,000,000 shares of preferred stock. The amended and restated certificate of incorporation became effective on October 9, 2018.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of Guardant Health, Inc. and its consolidated Joint Venture. Other stockholders' interests in the Joint Venture are shown in the consolidated financial statements as redeemable noncontrolling interest. All significant intercompany balances and transactions have been eliminated in consolidation.

The Company believes that its existing cash and cash equivalents and marketable securities as of December 31, 2020 will be sufficient to allow the Company to fund its current operating plan through at least a period of one year after the date the accompanying consolidated financial statements are issued. As the Company continues to incur losses, its transition to profitability is dependent upon a level of revenues adequate to support the Company's cost structure. If the Company's transition to profitability is not consistent with its current operating plan, the Company may have to seek additional capital.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the related disclosures at the date of the consolidated financial statements, as well as the reported amounts of revenues and expenses during the periods presented. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Estimates are used in several areas including, but not limited to, estimation of variable consideration, estimation of credit losses, standalone selling price allocation included in contracts with multiple performance obligations, the fair value of

assets acquired and liabilities assumed for business combinations, goodwill and identifiable intangible assets, stock-based compensation, contingencies, certain inputs into the provision for (benefit from) income taxes, including related reserves, valuation of redeemable noncontrolling interest, among others. These estimates generally involve complex issues and require judgments, involve the analysis of historical results and prediction of future trends, can require extended periods of time to resolve and are subject to change from period to period. Actual results may differ materially from management's estimates. The extent to which the coronavirus 2019, or COVID-19 pandemic will ultimately impact the Company's business, results of operations, financial conditions, or cash flows is highly uncertain and difficult to predict because it will depend on many factors that are outside the Company's control, such as the duration, scope and severity of the pandemic, steps required or mandated by governments to mitigate the impact of the pandemic, and whether COVID-19 can be effectively prevented, detected, contained and treated, particularly in the markets where the Company operates.

JOBS Act Accounting Election

Effective December 31, 2019, the Company is no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

Foreign Currency Translation

The functional currency of the subsidiaries of the consolidated Joint Venture is the local currency. The assets and liabilities of the subsidiaries are translated into U.S. dollars at exchange rates in effect at each balance sheet date, with the resulting translation adjustments recorded to a separate component of accumulated other comprehensive loss within stockholders' equity. Income and expense accounts are translated at average exchange rates during the period. Foreign currency transaction gains and losses resulting from transactions denominated in a currency other than the functional currency are recognized in the consolidated statements of operations. For the year ended December 31, 2020, 2019 and 2018, foreign currency translation adjustment was immaterial.

Segment Information

The Company operates as one operating and reportable segment. The Company's chief operating decision makers, the Chief Executive Officer, and the President and Chief Operating Officer, manage the Company's operations on an aggregate basis for purposes of allocating resources.

Cash and Cash Equivalents and Restricted Cash

Cash equivalents consist of highly liquid investments with original maturities at the time of purchase of three months or less. Cash equivalents include bank demand deposits and money market accounts that invest primarily in U.S. government-backed securities and treasuries. Cash equivalents are carried at cost, which approximates their fair value.

The Company did not have any restricted cash as of December 31, 2020 and 2019.

Marketable Securities

Marketable securities consist primarily of high-grade U.S. government and agency securities and corporate bonds. Marketable securities with original maturities at the time of purchase between three and twelve months from balance sheet dates are classified as short-term marketable securities and those with maturities over twelve months from balance sheet dates are classified as long-term marketable securities. The Company classifies all marketable securities as available-for-sale, which are recorded at fair value. Unrealized gains and losses are included in accumulated other comprehensive gain (loss) in stockholders' equity. Any premium or discount arising at purchase is amortized or accreted to interest income or expense.

The Company periodically evaluates its available-for-sale marketable securities for impairment. Prior to the adoption of Accounting Standards Update ("ASU") 2016-13, *Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*, the Company assesses whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not that it will be required to sell any marketable securities before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and management's strategy and intentions for

holding the marketable security. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are reported in other income (expense), net on the consolidated statements of operations. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity is reclassified out of stockholders' equity on a specific-identification basis and recorded in earnings for the period.

Starting January 1, 2020, upon adoption of ASU 2016-13, when the fair value of a marketable security is below its amortized cost, the amortized cost is reduced to its fair value if it is more likely than not that the Company is required to sell the impaired security before recovery of its amortized cost basis, or the Company has the intention to sell the security. If neither of these conditions are met, the Company determines whether the impairment is due to credit losses by comparing the present value of the expected cash flows of the security with its amortized cost basis. The amount of impairment recognized is limited to the excess of the amortized cost over the fair value of the security. An allowance for credit losses for the excess of amortized cost over the expected cash flows is recorded in other income (expense), net on the consolidated statements of operations. Impairment losses that are not credit-related are included in accumulated other comprehensive gain (loss) in stockholders' equity.

Concentration of Risk

The Company is subject to credit risk from its portfolio of cash equivalents held at one commercial bank and investments in marketable securities. The Company limits its exposure to credit losses by investing in money market funds through a U.S. bank with high credit ratings. The Company's cash may consist of deposits held with banks that may at times exceed federally insured limits, however, its exposure to credit risk in the event of default by the financial institution is limited to the extent of amounts recorded on the consolidated balance sheets. The Company performs evaluations of the relative credit standing of these financial institutions to limit the amount of credit exposure.

The Company also invests in investment-grade debt instruments and has policy limits for the amount it can invest in any one type of security, except for securities issued or guaranteed by the U.S. government. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, investment type and issuer, as a result, the Company is not exposed to any significant concentrations of credit risk from these financial instruments.

The Company is subject to credit risk from its accounts receivable. The majority of the Company's accounts receivable arises from the provision of precision oncology services and development services in the United States and are primarily with biopharmaceutical companies with high credit ratings. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company does not require collateral. Accounts receivable are recorded at net amounts.

A significant customer is a biopharmaceutical customer or a clinical testing payer that represents 10% or more of the Company's total revenue or accounts receivable balance. Revenue attributable to each significant customer, including its affiliated entities, as a percentage of the Company's total revenue, for the respective period, and accounts receivable balance attributable to each significant customers, including its affiliated entities, as a percentage of the Company's total accounts receivable balance, at the respective consolidated balance sheet date, are as follows:

	Revenue			Accounts Receivable	
	Year Ended December 31,			As of December 31,	
	2020	2019	2018	2020	2019
Customer A	10 %	26 %	18 %	11 %	40 %
Customer B	25 %	14 %	*	13 %	*
Customer C	*	*	*	*	10 %
Customer D	*	*	*	12 %	*
Customer E	*	*	*	11 %	*

* less than 10%

The Company is also subject to credit risk from its other receivables and other assets. The Company's other receivables and other assets include payments due from a third-party in relation to the settlement of a patent dispute reached in August 2020 for $8.0 million payable over a period of 6 years. In December 2020, the Company received the first installment payment of $1.0 million and recorded a gain in other income (expense), net on the consolidated statements of operations. The Company has evaluated and recorded a credit loss for the remaining $7.0 million considering the third-party's credit worthiness and lack of collection history. The following table presents the receivable and the related credit loss amounts:

	Gross Amount		Allowance for Credit Losses			Net Amount	
			Year Ended December 31, 2020				
	December 31, 2020	December 31, 2019	Beginning Balance	Charged to (Reversed from) Other Income (Expense), Net	Ending Balance	December 31, 2020	December 31, 2019
				(in thousand)			
Prepaid expenses and other current assets	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Other assets	7,000	—	—	(7,000)	(7,000)	—	—

Accounts Receivable, Net

Accounts receivable represent valid claims against biopharmaceutical companies, research institutes and international distributors. The Company evaluates the collectability of its accounts receivable based on historical collection trends, the financial condition of payment partners, and external market factors and provides for an allowance for potential credit losses based on management's best estimate of the amount of probable credit losses. As of December 31, 2020 and 2019, the Company had immaterial allowance for credit losses related to its accounts receivable.

Inventory

Inventories are stated at the lower of cost or net realizable value on a first-in, first-out basis. Inventory consisted entirely of supplies, which are consumed when providing liquid biopsy tests, and therefore the Company does not maintain any finished goods inventory.

In order to assess the ultimate realization of inventories, the Company is required to make judgments as to future demand requirements compared to current or committed inventory levels. The Company periodically reviews its inventories for excess or obsolescence and writes-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated by the Company, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Amounts written-down due to unmarketable inventory are recorded in cost of precision oncology testing and cost of development services and other, as appropriate.

Property and Equipment, Net

Property and equipment are recorded at cost. Depreciation is computed over estimated useful lives of the related assets using the straight-line method. Leasehold improvements are amortized using the straight-line method over the estimated useful lives of the assets or the remaining term of the lease, whichever is shorter. The Company periodically reviews the depreciable lives assigned to property and equipment placed in service and changes the estimates of useful lives, if necessary. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed as incurred.

Estimated useful lives for property and equipment are as follows:

Property and Equipment	Estimated Useful Life
Machinery and equipment	3 – 5 years
Furniture and fixtures	7 years
Computer hardware and computer software	3 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

Business Combinations

The Company includes the results of operations of the businesses that are acquired as of the acquisition date. The Company allocates the purchase price of acquisitions to the assets acquired and liabilities assumed based on the estimated fair values. The excess of the purchase price over the fair values of the identifiable assets and liabilities is recorded as goodwill. Acquisition related costs are recognized separately from the business combination and are expensed as incurred.

Asset Acquisition

If an acquisition of an asset or group of assets does not meet the definition of a business, the transaction is accounted for as an asset acquisition rather than a business combination. An asset acquisition does not result in the recognition of goodwill and transaction costs are capitalized as part of the cost of the asset or group of assets acquired. Transaction costs allocated to in-process research and development technology with no future alternate use is expensed as incurred. The total consideration is allocated to the various intangible assets acquired on a relative fair value basis. Cash paid in connection of purchase of in-process research and development technology in an asset acquisition is presented within the investing activities of the consolidated statement of cash flows.

Goodwill and Intangible Assets, net

Intangible assets related to in-process research and development costs ("IPR&D") are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. Prior to completion of the research and development efforts, the assets are considered indefinite-lived. During this period, the assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill and IPR&D are not amortized but are tested for impairment at least annually during the fourth fiscal quarter, or if circumstances indicate their value may no longer be recoverable. The Company continues to operate in one segment, which is considered to be the sole reporting unit and, therefore, goodwill was tested for impairment at the enterprise level. As of December 31, 2020, there has been no impairment of goodwill.

Intangible assets are carried at cost, net of accumulated amortization. The Company does not have intangible assets with indefinite useful lives other than goodwill and the acquired IPR&D. Amortization is recorded on a straight-line basis over the intangible asset's useful life, which is approximately 6—12 years.

Obligation Related to Royalty

Certain of the Company's asset acquisitions involve the potential for future payment of consideration that is contingent upon the royalty payments due on future product net sales, subject to annual minimums. The fair value of such liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows and the risk-adjusted discount rate used to present value the cash flows.

In March 2020, after the settlement of an arbitration and patent license acquisition as discussed in Note 6, *Acquisitions*, the Company no longer has such royalty obligations.

Impairment for Long-Lived Assets

The Company evaluates long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the asset may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value.

Leases

The Company determines if an arrangement contains a lease at inception. Operating lease right-of-use ("ROU") assets and operating leases liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received or receivable. The Company uses its incremental borrowing rate based on the information available at the commencement date in

determining the lease liabilities, as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term. The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's facility leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for leases with terms of 12 months or less.

Convertible Senior Notes

In accounting for the issuance of the convertible senior notes, the Company separates the notes into liability and equity components. The carrying amount of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated convertible feature, using a discounted cash flow model with a risk adjusted yield. The carrying amount of the equity component representing the conversion option is determined by deducting the fair value of the liability component from the par value of the notes as a whole. This difference represents a debt discount that is amortized to interest expense using the effective interest method over the term of the notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. In accounting for the transaction costs related to the issuance of the notes, the Company allocated the total amount incurred to the liability and equity components based on their relative fair values. Transaction costs attributable to the liability component are netted with the liability component and amortized to interest expense using the effective interest method over the term of the notes. Transaction costs attributable to the equity component are netted with the equity component of the notes in additional paid-in capital in the consolidated balance sheets.

Revenue Recognition under ASC 606

The Company derives revenue from the provision of precision oncology testing services provided to its ordering physicians and biopharmaceutical customers, as well as from biopharmaceutical research and development services provided to its biopharmaceutical customers. Precision oncology testing services include genomic profiling and the delivery of other genomic information derived from the Company's platform. Development services and other include companion diagnostic development, clinical trial setup, monitoring and maintenance, information solutions and laboratory services, and other miscellaneous revenue streams. The Company currently receives payments from third-party commercial and governmental payers, certain hospitals and oncology centers and individual patients, as well as biopharmaceutical companies and research institutes.

Effective January 1, 2019, the Company adopted the new revenue recognition standard Financial Accounting Standards Board ("FASB") ASC Topic 606, *Revenue from Contracts with Customers, or ASC 606*. Revenues are recognized when control of services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services. ASC 606 provides for a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation.

Precision oncology testing

The Company recognizes revenue from the sale of its precision oncology tests for clinical customers, including certain hospitals, cancer centers, other institutions and patients, at the time results of the test are reported to physicians. Most precision oncology tests requested by clinical customers are sold without a written agreement; however, the Company determines an implied contract exists with its clinical customers. The Company identifies each sale of its liquid biopsy test to clinical customer as a single performance obligation. With the exception of certain limited contracted arrangements with insurance carriers and other institutions where the transaction price is fixed, a stated contract price does not exist and the transaction price for each implied contract with clinical customers represents variable consideration. The Company estimates the variable consideration under the portfolio approach and considers the historical reimbursement data from third-party commercial and governmental payers and patients, as well as known or anticipated reimbursement trends not reflected in the historical data. The Company monitors the estimated amount to be collected in the portfolio at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the estimate and any subsequent revision contain uncertainty and require the use of significant judgment in the estimation of the variable consideration and application of the constraint for such variable consideration. The Company analyzes its actual cash collections over the expected reimbursement period and compares it with the estimated variable consideration for each portfolio and any difference is recognized as an adjustment to estimated revenue after the expected reimbursement period, subject to assessment of the risk of future revenue reversal. For the year ended December 31, 2020 and 2019, the Company recorded $26.0 million and $16.8 million as revenue, respectively, resulting from cash

collections over the expected reimbursement period exceeding the estimated variable consideration related to samples processed in the previous years, including revenue received from successful appeals of reimbursement denials.

Revenue from sales of precision oncology tests to biopharmaceutical customers are based on a negotiated price per test or on the basis of an agreement to provide certain testing volume over a defined period. The Company identifies its promise to transfer a series of distinct liquid biopsy tests to biopharmaceutical customers as a single performance obligation. Precision oncology tests to biopharmaceutical customers are generally billed at a fixed price for each test performed. For agreements involving testing volume to be satisfied over a defined period, revenue is recognized over time based on the number of tests performed as the performance obligation is satisfied over time. Results of the Company's precision oncology services are delivered electronically, and as such there are no shipping or handling fees incurred by the Company or billed to customers.

Development services and other

The Company performs development services for its biopharmaceutical customers utilizing its precision oncology information platform. Development services typically represent a single performance obligation as the Company performs a significant integration service, such as analytical validation and regulatory submissions. The individual promises are not separately identifiable from other promises in the contracts and, therefore, are not distinct. However, under certain contracts, a biopharmaceutical customer may engage the Company for multiple distinct development services which are both capable of being distinct and separately identifiable from other promises in the contracts and, therefore, distinct performance obligations.

The Company collaborates with pharmaceutical companies in the development of new drugs. As part of these collaborations, the Company provides services related to regulatory filings to support companion diagnostic device submissions for the Company's liquid biopsy panels. Under these collaborations, the Company generates revenue from achievement of milestones, as well as provision of on-going support. For development services performed, the Company is compensated through a combination of an upfront fee and performance-based, non-refundable regulatory and other developmental milestone payments. The transaction price of the Company's development services contracts typically represents variable consideration. Application of the constraint for variable consideration to milestone payments is an area that requires significant judgment. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be managed to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone. In making this assessment, the Company considers its historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether achievement of the milestone is dependent on parties other than the Company. The constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is assessed and updated at each reporting period as a revision to the estimated transaction price.

The Company recognizes development services over the period in which biopharmaceutical research and development services are provided. Specifically, the Company recognizes revenue using an input method to measure progress, utilizing costs incurred to-date relative to total expected costs as its measure of progress. The Company assesses the changes to the total expected cost estimates as well as any incremental fees negotiated resulting from changes to the scope of the original contract in determining the revenue recognition at each reporting period. The Company revised and increased its total estimated costs relating to one of the development services contracts during the year ended December 31, 2020. Had the Company included such additional costs in the original estimated costs, revenues for the year ended December 31, 2019 would have been lower by $1.8 million. For development of new products or services under these arrangements, costs incurred before technological feasibility is reached are included as research and development expenses in the Company's consolidated statements of operations, while costs incurred thereafter are recorded as cost of development services and other.

The Company also has other miscellaneous revenue streams that are recognized in addition to development services noted above such as clinical trial setup, monitoring and maintenance, referral fees, liquid biopsy testing development and support, GuardantConnect, GuardantINFORM and Guardant-19, and kits fulfillment related revenues. Revenues related to clinical trial setup, monitoring and maintenance, referral fees, liquid biopsy testing development and support, GuardantConnect, GuardantINFORM are generally recognized overtime based on an input method to measure progress in the period when the associated services have been performed. Guardant-19 and kits fulfillment related revenues are recognized when such products are delivered.

Contracts with multiple performance obligations

Contracts with biopharmaceutical customers may include multiple distinct performance obligations, such as provision of precision oncology testing, biopharmaceutical research and development services, and clinical trial enrollment assistance, among others. The Company evaluates the terms and conditions included within its contracts with biopharmaceutical customers to ensure appropriate revenue recognition, including whether services are considered distinct performance obligations that should be accounted for separately versus together. The Company first identifies material promises, in contrast to immaterial promises or administrative tasks, under the contract, and then evaluates whether these promises are both capable of being distinct and distinct within the context of the contract. In assessing whether a promised service is capable of being distinct, the Company considers whether the customer could benefit from the service either on its own or together with other resources that are readily available to the customer, including factors such as the research, development, and commercialization capabilities of a third party as well as the availability of the associated expertise in the general marketplace. In assessing whether a promised service is distinct within the context of the contract, the Company considers whether it provides a significant integration of the services, whether the services significantly modify or customize one another, or whether the services are highly interdependent or interrelated.

For contracts with multiple performance obligations, the transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The Company determines standalone selling price by considering the historical selling price of these performance obligations in similar transactions as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing of other vendors, industry publications and current pricing practices, and expected costs of satisfying each performance obligation plus appropriate margin.

Contract assets

Contract assets consists primarily of: i) precision oncology testing revenues to clinical customers that are recognized upon delivery of the test results prior to cash collection; and ii) development services and other revenues to biopharmaceutical customers that are recognized upon the achievement of performance-based milestones but prior to the establishment of billing rights. Contract assets are relieved when the Company receives payments from clinical customers, or when it invoices the biopharmaceutical customers when milestones are achieved, thereby reclassifying the balances from contract assets to accounts receivable. Contract assets are presented under accounts receivable, net and other assets, net on the Company's consolidated balance sheets. As of December 31, 2020, the Company had contract assets of $15.6 million which was recorded in accounts receivable, net, which included $8.4 million of unbilled receivable relating to Guardant360 CDx. As of December 31, 2019, the Company had contract assets of $6.2 million of which $1.0 million was recorded in other assets, net.

Deferred revenue

Deferred revenue, which is a contract liability, consists primarily of payments received in advance of revenue recognition from contracts with customers. For example, development services and other contracts with biopharmaceutical customers often contain upfront payments which results in the recording of deferred revenue to the extent cash is received prior to the Company's performance of the related services. Contract liabilities are relieved as the Company performs its obligations under the contract and revenue is consequently recognized. As of December 31, 2020 and 2019, the deferred revenue balance was $8.6 million and $12.3 million, respectively, which included $3.0 million and $4.8 million, respectively, related to collaboration development efforts with pharmaceutical companies to be recognized as the Company performs research and development services in the future periods. Revenue recognized in the year ended December 31, 2020 that was included in the deferred revenue balance as of December 31, 2019 was $10.2 million, of which $4.8 million represented revenue from provision of development services under the collaboration agreements with biopharmaceutical customers. Revenue recognized in the year ended December 31, 2019 that was included in the deferred revenue balance as of January 1, 2019 was $15.2 million, which primarily represented revenue from provision of development services under the collaboration agreements with biopharmaceutical customers.

Transaction price allocated to the remaining performance obligations

Transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes deferred revenue and non-cancelable amounts that will be invoiced and recognized as

revenues in future periods. The Company expects to recognize substantially all of the remaining transaction price in the next 12 months.

Revenue Recognition under ASC 605

The Company derives revenue from the provision of precision oncology testing services provided to its ordering physicians and biopharmaceutical customers, as well as from biopharmaceutical research and development services provided to its biopharmaceutical customers. Precision oncology services include genomic profiling and the delivery of other genomic information derived from the Company's platform. Development services include the development of new platforms and information solutions, including companion diagnostic development and laboratory services. The Company currently receives payments from commercial third-party payers, certain hospitals and oncology centers and individual patients, as well as biopharmaceutical companies and research institutes.

The Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. Criterion (i) is satisfied when the Company has an arrangement or contract in place. Criterion (ii) is satisfied when the Company delivers a test report corresponding to each sample, without further commercial obligations. Determination of criteria (iii) and (iv) are based on management's judgments regarding whether the fee is fixed or determinable, and whether the collectability of the fee is reasonably assured. The Company recognizes revenue from the sale of its precision oncology tests for clinical customers, including certain hospitals, cancer centers, other institutions and patients, at the time results of the test are reported to physicians, if criteria (i) through (iv) above are met. The Company recognizes revenue on a cash basis when it cannot conclude that criteria (iii) and (iv) have been met. Most of precision oncology tests requested by clinical customers are sold without a contracted engagement with a third-party payer; therefore, the Company experiences significant variability in collections and does not have sufficient history to establish a predictable pattern of payment. Because the price is not fixed or determinable and collectability is not reasonably assured, the Company recognizes revenue on a cash basis for sales of its liquid biopsy tests to clinical customers where collection depends on a third-party payer or the individual patient. The Company uses judgment in its assessment of whether the fee is fixed or determinable and whether collectability is reasonably assured in determining when to recognize revenue. Accordingly, the Company expects to recognize revenue on a cash basis for these clinical customers until it has sufficient history to reliably estimate payment patterns. The Company's precision oncology information services are delivered electronically, and as such there are no shipping or handling fees incurred by the Company or billed to customers.

Revenue from sales of the Company's tests to biopharmaceutical customers are based on a negotiated price per test or on the basis of an agreement to provide certain testing volume, data access or biopharmaceutical research and development services over a defined period. The Company recognizes revenue upon delivery of the test results, or over the period in which biopharmaceutical research and development services are provided, as appropriate.

Multiple-element arrangements

The Company performs development services for its biopharmaceutical customers utilizing its precision oncology information platform. Contracts with biopharmaceutical customers are primarily analyzed as multiple-element arrangements given the nature of the service deliverables. For development services performed, the Company is compensated in various ways, including (i) through non-refundable regulatory and other developmental milestone payments; and (ii) through royalty and sales milestone payments. The Company performs development services as part of its normal activities. The Company records these payments as development services revenue in the consolidated statements of operations using a proportional performance model over the period which the unit of accounting is delivered or based on the level of effort expended to date over the total expected effort, whichever is considered the most appropriate measure of performance. For development of new products or services under these arrangements, costs incurred before technological feasibility is assured are included as research and development expenses in the Company's consolidated statements of operations, while costs incurred thereafter are recorded as cost of development services. The Company collaborates with pharmaceutical companies in the development and clinical trials of new drugs. As part of these collaborations, the Company provides services related to regulatory filings with the FDA to support companion diagnostic device submissions for the Company's liquid biopsy panels. Under these collaborations the Company generates revenue from achievement of milestones, as well as provision of on-going support. These collaboration arrangements include no royalty obligations.

For revenue arrangements with multiple deliverables, the Company evaluates each deliverable to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has stand-alone value to the customer and whether a general right of return exists. In assessing whether an item has standalone value, the Company considers factors such as the research, development and commercialization capabilities of a third party and the availability of the associated expertise in the general marketplace. In addition, the Company considers

whether the other party in the arrangement can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The Company allocates the arrangement consideration following a hierarchy to determine the relative selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence of fair value ("VSOE"), (ii) third-party evidence of selling price ("TPE"), and (iii) best estimate of the selling price ("BESP") if neither VSOE nor TPE is available. The Company typically uses BESP to estimate the selling price, since it generally does not have VSOE or TPE of selling price for its units of accounting under multiple-element arrangements. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. The Company uses judgment in identifying the deliverables in its arrangements, assessing whether each deliverable is a separate unit of accounting and in determining the best estimate of selling price for certain deliverables. The Company also uses judgment in determining the period over which the deliverables are recognized in certain of its arrangements. Any amounts received that do not meet the criteria for revenue recognition are recorded as deferred revenue until such criteria are met. The Company performed laboratory installation and maintenance services for one of its customers as part of a multiple-element arrangement entered into in 2017. The Company recognized certain revenue from its construction service deliverables in a multiple-element collaboration arrangement based on the completed-contract method. This method was used as the Company determined that it did not have the basis for estimating performance under the contract. Other construction service deliverables under that contract were recognized under the percentage-of-completion method due to the Company's ability to make reasonably dependable estimates of the extent of progress toward contract completion. All construction services under this arrangement were completed in March 2018.

Milestones

The Company recognizes payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered substantive milestones. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company's performance to achieve the milestone after commencement of the agreement. Any contingent payment that becomes payable upon achievement of events that are not considered substantive milestones are allocated to the units of accounting previously identified at the inception of an arrangement when the contingent payment is received and revenue is recognized based on the revenue recognition criteria for each unit of accounting. Revenue from commercial milestone payments are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Costs of Precision Oncology Testing

Cost of precision oncology testing generally consists of cost of materials, direct labor including bonus, benefit and stock-based compensation, equipment and infrastructure expenses associated with processing liquid biopsy test samples (including sample accessioning, library preparation, sequencing, quality control analyses and shipping charges to transport blood samples), freight, curation of test results for physicians and license fees due to third parties. Infrastructure expenses include depreciation of laboratory equipment, rent costs, amortization of leasehold improvements and information technology costs. Costs associated with performing the Company's tests are recorded as the tests are performed regardless of whether revenue was recognized with respect to that test. Royalties for licensed technology calculated as a percentage of revenues generated using the associated technology are recorded as expense at the time the related revenues are recognized. One-time royalty payments related to signing of license agreements or other milestones, such as issuance of new patents, are amortized to expense over the expected useful life of the applicable patent rights.

Cost of Development Services and Other

Cost of development service and other primarily includes costs incurred for the performance of development services requested by the Company's biopharmaceutical customers and other revenues included as noted above. For development of new products, costs incurred before technological feasibility has been achieved are reported as

research and development expenses, while costs incurred thereafter are reported as cost of development services and other.

Research and Development Expenses

Research and development expenses are comprised of costs incurred to develop technology and include compensation and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical companies. Research and development costs are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. Costs to develop the Company's technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs.

Advertising

The Company expenses advertising costs as incurred. The Company incurred advertising costs of $1.2 million, $1.3 million and $0.2 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Deferred Offering Costs

Deferred offering costs consist of fees and expenses incurred in connection with the anticipated sale of the Company's common stock in the IPO, including the legal, accounting, printing and other IPO-related costs. In October 2018, upon completion of the IPO, the Company reclassified deferred offering costs of $4.5 million into additional paid-in capital as a reduction of the net proceeds received from the IPO. There were no deferred offering costs as of December 31, 2020 and 2019.

Stock-Based Compensation

Stock-based compensation related to stock options granted to the Company's and the Joint Venture's employees, directors and nonemployees is measured at the grant date based on the fair value of the award. The fair value is recognized as expense over the requisite service period, which is generally the vesting period of the respective awards. Compensation expense for stock options with performance metrics is calculated based upon expected achievement of the metrics specified in the grant.

In 2018, the Company accounted for stock options issued to nonemployees consultants based on the estimated fair value at the grant date and re-measured at each reporting period. Starting January 1, 2019, upon adoption of ASU 2018-07, *Compensation - Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting*, the fair value of stock options issued to nonemployee consultants is determined as of the grant date, and compensation expense is being recognized over the period that the related services are rendered.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options granted under the 2012 Stock Plan, the 2018 Incentive Award Plan, and the Joint Venture's 2020 Equity Incentive Plan, and stock purchase rights granted under the 2018 Employee Stock Purchase Plan. The Black-Scholes option-pricing model requires assumptions to be made related to the expected term of an award, expected volatility, risk-free rate and expected dividend yield. The board of directors of the Joint Venture has determined the fair value of common stock of the Joint Venture. Forfeitures are accounted for as they occur.

For market-based restricted stock units, the Company derives the requisite service period using the Monte Carlo simulation model and the related compensation expense is recognized over the derived service period using an accelerated attribution model commencing on the grant date. Stock-based compensation expense will be recorded regardless of whether the market conditions are achieved or not. If the related market condition is achieved earlier than its estimated derived service period, the stock-based compensation expense will be accelerated, and a cumulative catch-up expense will be recorded during the period in which the market condition is met.

The Company measures the grant date fair value of its service-based and performance-based restricted stock units issued to employees based on the closing market price of the common stock on the date of grant. The expense is recognized in the Company's consolidated statement of operations on a straight-line basis over the requisite service period. Compensation expense for restricted stock units with performance metrics is calculated based upon expected achievement of the metrics specified in the grant.

Income Taxes

Income taxes are recorded using an asset and liability approach. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

The Company's tax positions are subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company recognizes interest accrued and penalties related to unrecognized tax benefits in its tax provision. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as the related net interest and penalties.

Net Loss Per Share Attributable to Common Stockholders

The Company calculates basic net loss per share attributable to common stockholders by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period determined using the treasury stock method or the as-if converted method, as appropriate. For purposes of this calculation, convertible preferred stock, common stock warrants, stock options, restricted stock units, shares issuable pursuant to the employee stock purchase plan, shares subject to repurchase from early exercised options and contingently issuable shares under our convertible senior notes are considered common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is anti-dilutive.

Prior to the closing of the Company's IPO in October 2018 and the conversion of its convertible preferred stock into common stock, the Company calculated its basic and diluted net loss per share attributable to common stockholders of the Company in conformity with the two-class method required for companies with participating securities. The Company considered its convertible preferred stock to be participating securities. In the event a dividend had been declared or paid on the Company's common stock, holders of convertible preferred stock were entitled to a share of such dividend in proportion to the holders of common stock on an as-if converted basis. Under the two-class method, net loss attributable to common stockholders is determined by allocating undistributed earnings between common and preferred stockholders. The net loss attributable to common stockholders was not allocated to the convertible preferred stock under the two-class method as the convertible preferred stock did not have a contractual obligation to share in the Company's losses.

Accounting Pronouncements Adopted

Financial Instruments

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*, in order to improve financial reporting of expected credit losses on financial instruments and other commitments to extend credit. ASU 2016-13 requires that an entity measure and recognize expected credit losses for financial assets held at amortized cost and replaces the incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to certain available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes result in earlier recognition of credit losses. The Company adopted ASU 2016-13 using the modified retrospective approach as of January 1, 2020. The cumulative effect upon adoption was not material to the Company's consolidated financial statements.

Goodwill

In January 2017, the FASB issued ASU 2017-04*, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* which eliminates Step 2 from the goodwill impairment test and instead requires entities to perform its annual or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. The Company adopted this new standard on January 1, 2020. The adoption of this standard did not have a significant impact to the Company's consolidated financial statements.

Fair Value Measurements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, adds and modifies certain disclosure requirements for fair value measurements in ASC 820, Fair Value Measurement, as part of its disclosure framework project. The Company adopted this new guidance on January 1, 2020. The adoption of this standard did not have a significant impact on the Company's consolidated financial statements.

Cloud Computing Arrangements

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal—Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC Topic 350, *Intangibles—Goodwill and Other*, to determine which implementation costs to capitalize as assets or expense as incurred. The Company adopted this new standard on January 1, 2020 on a prospective basis. The adoption of this standard did not have a significant impact on the Company's consolidated financial statements.

Collaborative Arrangements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (ASC 808)* to clarify that certain transactions between participants in a collaborative arrangement should be accounted for under R*evenue from contracts with customers (Topic ASC 606)* when the counterparty is a customer. The Company adopted this new standard on January 1, 2020. The adoption of this standard did not have a significant impact to the Company's consolidated financial statements.

Income Taxes

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The Company early adopted this new standard on January 1, 2020. The adoption of this standard did not have a significant impact to the Company's consolidated financial statements. Under prior GAAP, the Company historically allocated income tax benefit to continuing operations and an offsetting income tax expense to other comprehensive income under the applicable exception to ASC Topic 740. The new standard eliminates this exception and the Company will now determine the tax effect of pre-tax income or loss from continuing operations without regard to the tax effect of other items. The Company applied the new intraperiod tax allocation guidance prospectively in the period of adoption.

Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity (ASU 2020-06)*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Among other changes, ASU 2020-06 removes the liability and equity separation model for convertible instruments with a cash conversion feature, and as a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. Similarly, the embedded conversion feature will no longer be amortized into income as interest expense over the life of the instrument. Instead, entities will account for a convertible debt instrument wholly as debt unless (1) a convertible instrument contains features that require bifurcation as a derivative under ASC Topic 815, *Derivatives and Hedging,* or (2) a convertible debt instrument was issued at a substantial premium. Among other potential impacts, this change is expected to reduce reported interest expense, increase reported net income, and result in a reclassification of certain conversion feature balance sheet amounts from stockholders' equity to liabilities as it relates to the Company's convertible senior notes. Additionally, ASU 2020-06 requires the application of the if-converted method to calculate the impact of convertible instruments on diluted earnings per share. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early

adoption permitted for fiscal years beginning after December 15, 2020, and can be adopted on either a fully retrospective or modified retrospective basis. The Company is currently planning on early adopting ASU 2020-06 in the first quarter of fiscal 2021 using the modified retrospective approach which will result in the re-classification of the carrying amount of the equity component of the cash conversion feature as of December 31, 2020 from additional paid-in capital to long-term liabilities.

3. Investment in Joint Venture

Variable Interest Entity ("VIE")

In May 2018, the Company and an affiliate of SoftBank formed and capitalized the Joint Venture for the sale, marketing and distribution of the Company's tests in all areas worldwide, outside of North America, Central America, South America, the United Kingdom, all other member states of the European Union as of May 9, 2017, Iceland, Norway, Switzerland and Turkey. The Company expects to rely on the Joint Venture to accelerate commercialization of its products in Asia, the Middle East and Africa.

Under the terms of the joint venture agreement, the Company paid $9.0 million for 40,000 shares of common stock, or 50% ownership interest, of the Joint Venture, and the affiliate of SoftBank contributed $41.0 million for 40,000 shares of common stock, or the other 50% ownership interest, of the Joint Venture. Neither party has the obligation to provide additional financial support to the Joint Venture. Each party holds two seats on the board of the Joint Venture and has to cast through its representatives on the board at least one vote for any board resolution of the Joint Venture to pass. The representatives of the Company on the Joint Venture's board of directors have the right to appoint and remove a chief executive officer and a legal representative for the Joint Venture, in each case, subject to the approval of the full Joint Venture board of directors. The Joint Venture's board of directors has the right to appoint and remove all other members of the Joint Venture's senior management reporting to its chief executive officer and to approve the compensation of all foregoing individuals, including the compensation of the chief executive officer and legal representative.

In June 2020, an amended and restated certificate of incorporation of the Joint Venture, as approved by the board of directors of the Joint Venture, was filed with the Secretary of State of the State of Delaware. The amended and restated certificate of incorporation, among other things, increased the number of authorized shares of common stock to 89,000,000 shares consisting of 80,000,000 shares of Class A common stock and 9,000,000 shares of Class B (non-voting) common stock; and authorized 80,000,000 shares of Series A preferred stock. Pursuant to the amended and restated certificate of incorporation, each share of common stock held by the Company and the affiliate of SoftBank was reclassified and exchanged for 1,000 shares of Series A preferred stock. As a result, each of the Company and the affiliate of SoftBank held 40,000,000 shares of Series A preferred stock. The holders of Series A preferred stock are entitled to receive dividends at the rate of $0.05 per share if and when declared by the board of directors of the Joint Venture. In June 2020, the board of directors of the Joint Venture authorized the adoption of the Joint Venture's 2020 Equity Incentive Plan pursuant to which 4,595,555 shares of Class B common stock have been reserved for issuance. As of December 31, 2020, no shares of Class A and Class B common stock have been issued and outstanding and 80,000,000 shares of Series A preferred stock have been issued and outstanding.

At the inception of the arrangement and at the end of each reporting period, the Company assesses whether the Joint Venture is a variable interest entity ("VIE"), and if so, who is the primary beneficiary of the VIE. As of December 31, 2020, the Company and SoftBank had equal ownership interests and equal voting rights in the Joint Venture, and the Joint Venture's board consisted of an equal number of directors representing the interest of the Company and SoftBank, respectively. As of December 31, 2020, the Joint Venture's board had the right to vote on all critical matters that most significantly impact the Joint Venture's economic performance, except that the Company had the unilateral right to make pricing decisions. As of December 31, 2020, the Company had responsibility for the Joint Venture's daily operations, while SoftBank served as a financing partner. The Company also entered into various ancillary agreements with the Joint Venture necessary to operate its business. The Joint Venture is deemed to be a VIE, and considering the power and benefits criterion, the Company and SoftBank, collectively as a related party group, has the characteristics of the primary beneficiary of the Joint Venture, as the related party group has the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and has the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. Because the Company is most closely associated with the Joint Venture within the related party group, it has been identified as the VIE's primary beneficiary. As the primary beneficiary, the Company has consolidated the financial position, results of operations and cash flows of the Joint Venture in its financial statements and all intercompany balances have been eliminated in consolidation. The Company concluded the Joint Venture did not meet the definition of a business upon consolidation as it lacked the processes required to generate outputs. Upon consolidation no liabilities were assumed and other than cash, and any identifiable assets

were related to intellectual property rights that the Company transferred to the Joint Venture shortly before it became its primary beneficiary and therefore such transfer was treated as a common control transaction. Upon initial consolidation, the non-controlling interest of the affiliate of SoftBank was recorded at its estimated fair value of $41.0 million, which is equal to the original investment made by the affiliate of SoftBank.

As of December 31, 2020 and 2019, the Joint Venture had total assets of approximately $35.0 million and $45.1 million, respectively, which were primarily comprised of cash, property and equipment, right-of-use assets and security deposits. Although the Company consolidates the Joint Venture, the legal structure of the Joint Venture limits the recourse that its creditors will have over the Company's general credit or assets. Similarly, the assets held in the Joint Venture can be used only to settle obligations of the Joint Venture. As of December 31, 2020 and 2019, the Company has not provided financial or other support to the Joint Venture that was not previously contracted or required.

Put-call arrangements

The joint venture agreement includes a put-call arrangement with respect to the shares of the Joint Venture held by SoftBank and its affiliates. Under certain specified circumstances and on terms specified in the joint venture agreement, including timely written notice, SoftBank has the right to cause the Company to purchase all shares of the Joint Venture held by SoftBank and its affiliates (the "put right"), and the Company has a right to purchase all such shares (the "call right").

If the Company's business model were to change such that the sale, marketing and distribution of its tests in the territory covered by the joint venture agreement was no longer economical, SoftBank would have the right to cause the Company to purchase, or the Company would have the right to purchase, all of the shares of the Joint Venture held by SoftBank and its affiliates. In this instance, the Company would be required to repurchase the shares at an aggregate purchase price of $41.0 million, the original purchase price paid by SoftBank to the Joint Venture for the shares.

Additionally, each of the Company and SoftBank may exercise its respective put-call rights for the Company to purchase all shares of the Joint Venture held by SoftBank in the event of (i) certain material disagreements relating to the Joint Venture or its business that may seriously affect the ability of the Joint Venture to perform its obligations under the joint venture agreement or may otherwise seriously impair the ability of the Joint Venture to conduct its business in an effective matter, other than one relating to the Joint Venture's business plan or to factual matters that may be capable of expert determination; (ii) the effectiveness of the Company's initial public offering, a change in control of the Company, the seventh anniversary of the formation of the Joint Venture, or each subsequent anniversary of each of the foregoing events; or (iii) a material breach of the joint venture agreement by the other party that goes unremedied within 20 business days. Unless the shares of the Joint Venture are publicly traded and listed on a nationally recognized stock exchange, the purchase price per share of the Joint Venture in these situations will be determined by a third-party valuation firm on the assumption that the sale is on an arm's-length basis on the date of the put or call notice. The third-party valuation firm may evaluate a range of factors and employ assumptions that are subjective in nature, which could result in the fair value of SoftBank's interests in the Joint Venture being determined to be materially different from what has been recorded in the Company's consolidated financial statements including those included elsewhere in this Annual Report on Form 10-K. As a result of the IPO, the put-call rights for the Company to purchase all shares of the Joint Venture held by SoftBank are exercisable on each subsequent anniversary of the IPO by the Company or SoftBank.

In the event the Company exercises its call right, the fair value of the Joint Venture will be deemed to be no less than an amount that yields a 20% internal rate of return on each tranche of capital invested by SoftBank and its affiliates in the Joint Venture, taking into account all proceeds received by SoftBank and its affiliates arising from their shares through such date.

In the event SoftBank exercises its put right and the fair value of the Joint Venture is determined to be greater than 40% of the fair value of the Company, the Company will only be required to purchase the number of shares of the Joint Venture held by SoftBank and its affiliates having an aggregate value equal to the product of 40% of the Company's fair value and the pro rata portion of the outstanding shares of the Joint Venture held by SoftBank and its affiliates.

The Company may pay the purchase price for the shares of the Joint Venture in cash, in shares of its capital stock (which may be a non-voting security with senior preferences to all other classes of its equity or, if its common stock is publicly traded on a national exchange, its common stock), or in a combination thereof. In the event the Company exercises the call right, SoftBank will choose the form of consideration. In the event SoftBank exercises the put right, the Company will choose the form of consideration.

The noncontrolling interest held by SoftBank contains embedded put-call redemption features that are not solely within the Company's control and has been classified outside of permanent equity in the consolidated balance sheets. The put-call feature embedded in the redeemable noncontrolling interest do not currently require bifurcation as it does not meet the definition of a derivative and is considered to be clearly and closely related to the redeemable noncontrolling interest. The noncontrolling interest is considered probable of becoming redeemable as SoftBank has the option to exercise its put right to sell its equity ownership in the Joint Venture to the Company on or after the seventh anniversary of the formation of the Joint Venture, on each subsequent anniversary of the IPO and under certain other circumstances. The Company elected to recognize the change in redemption value immediately as they occur as if the put-call redemption feature were exercisable at the end of the reporting period. The carrying value of the redeemable noncontrolling interest is first adjusted for the earnings or losses attributable to the redeemable noncontrolling interest based on the percentage of the economic or ownership interest retained in the consolidated VIE by the noncontrolling parties, and then adjusted to equal to its redemption amount, or the fair value of the noncontrolling interest held by SoftBank, as if the redemption were to occur at the end of the reporting date.

As of December 31, 2020 and 2019, the fair value of the redeemable noncontrolling interest held by SoftBank was determined using the combination of the income approach and the market approach. Determining the fair value of the redeemable noncontrolling interest requires judgment and the use of significant estimates and assumptions. Such estimates and assumptions include future revenue growth rates, gross profit margins, EBITDA margins, future capital expenditures, weighted average costs of capital and future market conditions, among others. The fair value measurement of the redeemable noncontrolling interest is classified within Level 3 of the fair value hierarchy (see Note 5, *Fair Value Measurements, Cash Equivalents and Marketable Securities*).

4. Consolidated Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consist of the following:

	As of December 31,	
	2020	2019
	(in thousands)	
Machinery and equipment	$ 40,216	$ 29,119
Leasehold improvements	34,037	21,031
Computer hardware	10,862	6,296
Construction in progress	7,833	6,354
Furniture and fixtures	3,043	1,962
Computer software	1,136	829
Property and equipment, gross	$ 97,127	$ 65,591
Less: accumulated depreciation and amortization	(34,345)	(21,923)
Property and equipment, net	$ 62,782	$ 43,668

Depreciation and amortization expense related to property and equipment was $14.1 million, $9.3 million and $6.1 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2020	2019
	(in thousands)	
Operating lease liabilities	$ 6,632	$ 7,140
Accrued tax liabilities	4,634	3,050
Accrued professional services	3,397	3,464
Accrued clinical trials and studies	1,264	2,029
Accrued legal expenses	2,875	1,046
Purchases of property and equipment included in accrued expenses	1,156	2,424
Accrued royalty obligations	146	1,564
Others	2,535	4,986
Total accrued expenses	$ 22,639	$ 25,703

5. Fair Value Measurements, Cash Equivalents and Marketable Securities

Financial instruments consist of cash equivalents, marketable securities, accounts receivable, net, prepaid expenses and other current assets, net, accounts payable and accrued expenses. Cash equivalents and marketable securities are stated at fair value. Prepaid expenses and other current assets, net, accounts payable and accrued expenses are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date.

Fair value is defined as the exchange price that would be received from sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A financial instrument's classification within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritized the inputs into three broad levels as follows:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

	December 31, 2020			
	Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
Financial Assets:				
Money market funds	$ 620,630	$ 620,630	$ —	$ —
Total cash equivalents	$ 620,630	$ 620,630	$ —	$ —
U.S. government debt securities	$ 961,902	$ —	$ 961,902	$ —
Total short-term marketable securities	$ 961,902	$ —	$ 961,902	$ —
U.S. government debt securities	$ 246,597	$ —	$ 246,597	$ —
Total long-term marketable securities	$ 246,597	$ —	$ 246,597	$ —
Total	$ 1,829,129	$ 620,630	$ 1,208,499	$ —
Financial Liabilities:				
Contingent consideration	$ 1,245	$ —	$ —	$ 1,245
Total	$ 1,245	$ —	$ —	$ 1,245

	December 31, 2019			
	Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
Financial Assets:				
Money market funds	$ 10,734	$ 10,734	$ —	$ —
Total cash equivalents	$ 10,734	$ 10,734	$ —	$ —
Corporate bonds	$ 16,690	$ —	$ 16,690	$ —
U.S. government debt securities	362,884	—	362,884	—
Total short-term marketable securities	$ 379,574	$ —	$ 379,574	$ —
U.S. government debt securities	$ 268,783	$ —	$ 268,783	$ —
Total long-term marketable securities	$ 268,783	$ —	$ 268,783	$ —
Total	$ 659,091	$ 10,734	$ 648,357	$ —
Financial Liabilities:				
Contingent consideration	$ 1,365	$ —	$ —	$ 1,365
Total	$ 1,365	$ —	$ —	$ 1,365

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Corporate bonds, U.S. government debt securities and U.S. government agency bonds are valued taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented.

The following table summarizes the activities for the Level 3 financial instruments for the years ended December 31, 2020, 2019 and 2018:

	Redeemable Noncontrolling Interest			Contingent Consideration		
	Year Ended December 31,			Year Ended December 31,		
	2020	2019	2018	2020	2019	2018
	(in thousands)					
Fair value — beginning of period	$ 49,600	$ 41,800	$ —	$ 1,365	$ —	$ —
Initial valuation on the date of acquisition	—	—	41,000	—	1,065	—
Increase (decrease) in fair value	12,934	11,659	1,730	(120)	300	—
Net loss for the period	(5,434)	(3,859)	(930)	—	—	—
Fair value — end of period	$ 57,100	$ 49,600	$ 41,800	$ 1,245	$ 1,365	$ —

The Company considers the fair value of the Convertible Notes as of December 31, 2020 to be a Level 2 measurement. The fair value of the Convertible Notes is primarily affected by the trading price of the Company's common stock and market interest rates. As such, the carrying value of the Convertible Notes does not reflect the market rate. See Note 8, *Debt*, for additional information related to the fair value of the Convertible Notes.

Cash Equivalents and Marketable Securities

The following tables summarizes the Company’s cash equivalents and marketable securities’ amortized costs, gross unrealized gains, gross unrealized losses and estimated fair values by significant investment category:

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
	(in thousands)			
Money market fund	$ 620,630	$ —	$ —	$ 620,630
U.S. government debt securities	1,206,195	2,339	(35)	1,208,499
Total	$ 1,826,825	$ 2,339	$ (35)	$ 1,829,129

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
	(in thousands)			
Money market fund	$ 10,734	$ —	$ —	$ 10,734
Corporate bond	16,679	11	—	16,690
U.S. government debt securities	630,283	1,423	(39)	631,667
Total	$ 657,696	$ 1,434	$ (39)	$ 659,091

There have been no material realized gains or losses on marketable securities for the periods presented. None of the Company’s investments in marketable securities has been in an unrealized loss position for more than one year. The Company determined that it did have the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of credit losses in the years ended December 31, 2020, 2019 and 2018, respectively. The maturities of the Company’s long-term marketable securities range from 1.0 to 1.3 years as of December 31, 2020.

6. Acquisitions

Patent License Acquisition

In January 2017, the Company entered into a license agreement with a biotechnology company, KeyGene N.V. (“KeyGene”), for an exclusive, non-transferable right to use proprietary technology related to high-throughput screening and identification of mutations in targeted gene sequences. The payment terms of the license agreement included (i) a one-time upfront payment of €1.0 million; (ii) issuance of 141,774 shares of the Company’s Series D

convertible preferred stock; (iii) a milestone payment of €1.0 million associated with the achievement of a specified milestone event; and (iv) future royalty payments at the minimum of €13.4 million in the aggregate based on annual net sales in which the licensed technology are used. The Company made a one-time upfront payment of $1.1 million in January 2017 and a milestone payment of $1.2 million in August 2017 upon achievement of the specified milestone event. The Series D convertible preferred stock issued under the license agreement had a fair value of $1.1 million on the date of issuance. The transaction was treated as an acquisition of an asset and the Company capitalized the upfront payment, milestone payments and fair value of Series D convertible preferred stock in addition to license fees of $6.3 million related to the future minimum royalty payments discounted to the present value. The Company recorded the obligation at the estimated present value of the future payments using a discount rate of 15%, the Company's estimate of its effective borrowing rate for similar obligations.

In March 2020, the Company and KeyGene entered into a settlement and patent license agreement (the "SPLA") to resolve the dispute and to acquire an extended worldwide non-exclusive license to certain patent rights with respect to KeyGene's Next Generation Sequencing technologies along with certain covenant rights and research and development technology for a one-time payment of $18.5 million, ending all future royalty obligations to KeyGene. This transaction was accounted for as an asset acquisition as the purchase did not meet the definition of a business. The total consideration, including $0.6 million of certain capitalizable transaction costs, was allocated to various components of the SPLA.

The Company allocated $9.4 million to the patent and covenant rights granted under the SPLA, which have useful lives in the range of 6-12 years. The Company allocated $8.5 million to IPR&D technology, which have no alternative future use and was included in research and development expenses for the year ended December 31, 2020. The remaining $1.2 million was allocated to the settlement of the prior dispute between the parties and was included in general and administrative expenses for the year ended December 31, 2020.

Amortization of capitalized license fees relating to the January 2017 license agreement was immaterial, $1.0 million and $0.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Acquisition of Bellwether Bio

In April 2019, the Company purchased of all of the outstanding shares of Bellwether Bio, Inc. ("Bellwether Bio"), a privately-held company developing a method for early blood-based cancer detection. The Company accounted for the acquisition as a business combination. The total purchase consideration was $8.7 million, which consisted of i) $7.6 million in cash paid upon closing; and ii) future contingent consideration liability with a fair value of $1.1 million on the acquisition date. The contingent consideration is subject to the achievement of certain commercialization milestones with a maximum payout amount of $10.0 million. The Company will also pay additional earn-out consideration of up to $10.0 million subject to the achievement of certain commercialization milestones and the continued provision of services to the Company by certain former employees and consultants of Bellwether Bio. The contingent consideration and earn-out consideration may be paid, at the Company's election, in cash or in the Company's common stock. As of December 31, 2020, the Company did not believe the earn-out consideration is probable to be achieved, and therefore, did not record any compensation expense.

The excess purchase consideration over the fair value of assets acquired and liabilities assumed was recorded as goodwill. Goodwill is attributable to future revenue opportunities that we expect to achieve from leveraging Bellwether Bio's existing license and IPR&D, as well as the assembled workforce. The valuation of the intangible assets acquired was determined using currently available information and reasonable assumptions. The following table summarizes the allocation of the total consideration to the estimated fair values of assets acquired and liabilities assumed:

	Amount (in thousands)
Cash	$ 521
Identified intangible assets	6,700
Goodwill	3,289
Net liabilities assumed	(1,802)
Total	$ 8,708

The following table presents details of the identified intangible assets acquired from the Bellwether Bio acquisition:

	Fair Value	Estimated Useful Life
	(in thousands)	
Acquired license	$ 5,100	10 years
IPR&D	1,600	*
Total	$ 6,700	

* IPR&D assets are not subject to amortization.

In connection with the acquisition of Bellwether Bio, the Company also entered into non-compete agreements with certain key individuals based on their experience and importance to the operation of Bellwether Bio. The Company accounted for the covenants not to compete as purchases of intangible assets separate from the business combination as these non-compete agreements were initiated by the Company to protect its interests. The fair value of acquired covenants not to compete was estimated to be $2.5 million, which is recorded within intangible assets on the consolidated balance sheet and will be amortized over an estimated useful life of 6 years using the straight-line method.

Acquisition-related contingent consideration is measured at fair value on a quarterly basis based on additional information as it becomes available and change in estimated contingent consideration to be paid will be included in operating expenses in the consolidated statements of operations. The fair value of acquisition-related contingent consideration is estimated using a multiple-outcome discounted cash flow valuation technique. Contingent consideration is classified within Level 3 of the fair value hierarchy (see Note 5, *Fair Value Measurements, Cash Equivalents and Marketable Securities*), as it is based on a probability that includes significant unobservable inputs. The significant unobservable inputs include a probability-weighted estimate of achievement of certain commercialization milestones, continued services from certain former employees and consultants, resulting contingent payments, and discount rate to present value the expected payments. A significant change in any of these input factors in isolation could have a material impact to fair value measurement.

As of December 31, 2020 and 2019, contingent consideration liability of $1.2 million and $1.4 million, respectively, was recorded within other long-term liabilities on the consolidated balance sheets.

For the year ended December 31, 2019, the Company incurred acquisition-related transaction costs of $0.4 million which are included in general and administrative expenses in the consolidated statements of operations.

7. Intangible Assets, Net and Goodwill

The following table presents details of purchased intangible assets as of December 31, 2020 and 2019:

	December 31, 2020			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Remaining Weighted Average Useful Life
		(in thousands)		(in years)
Intangible assets subject to amortization:				
Acquired license	$ 11,886	$ (1,367)	$ 10,519	9.8
Non-compete agreements and other covenant rights	5,100	(1,064)	4,036	4.9
Total intangible assets subject to amortization	16,986	(2,431)	14,555	
Intangible assets not subject to amortization:				
IPR&D	1,600	—	1,600	
Goodwill	3,290	—	3,290	
Total purchased intangible assets	$ 21,876	$ (2,431)	$ 19,445	

	December 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Remaining Weighted Average Useful Life
		(in thousands)		(in years)
Intangible assets subject to amortization:				
Acquired license	$ 5,100	$ (373)	$ 4,727	9.5
Non-compete agreements	2,500	(303)	2,197	5.5
Total intangible assets subject to amortization	7,600	(676)	6,924	
Intangible assets not subject to amortization:				
IPR&D	1,600	—	1,600	
Goodwill	3,290	—	3,290	
Total purchased intangible assets	$ 12,490	$ (676)	$ 11,814	

Amortization of finite-lived intangible assets was $1.8 million and $0.7 million for the year ended December 31, 2020 and 2019, respectively. There were no intangible assets as of December 31, 2018.

The following table summarizes estimated future amortization expense of finite-lived intangible assets—net:

Year Ending December 31,	(in thousands)
2021	$ 1,947
2022	1,947
2023	1,947
2024	1,953
2025	1,705
2026 and thereafter	5,056
Total	$ 14,555

8. Debt

Convertible Senior Notes

In November 2020, the Company issued $1.15 billion principal amount of its 0% Convertible Senior Notes due 2027 (the “2027 Notes”). The 2027 Notes do not bear interest, and the principal amount of the Notes will not accrete. However, special interest and additional interest may accrue on the 2027 Notes at a rate per annum not exceeding 0.50% (subject to certain exceptions) upon the occurrence of certain events such as the failure to file certain reports to the Securities and Exchange Commission, or to remove certain restrictive legends from the Notes. The Notes will mature on November 15, 2027, unless repurchased, redeemed or converted earlier.

Before August 15, 2027, holders of the 2027 Notes will have the right to convert their 2027 Notes only under the following circumstances:

- during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on March 31, 2021, if the last reported sale price of the Company's common stock exceeds 130% of the conversion price for each of at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter (the “sale price condition”);
- during the five consecutive business days immediately after any ten consecutive trading day period (the “measurement period”) if the trading price per $1,000 principal amount of the Notes for each trading day of the measurement period is less than 98% of the product of the last reported sale price of the Company's common stock on such trading day and the conversion rate on such trading day; or
- upon the occurrence of specified corporate events

From and after August 15, 2027, holders of the 2027 Notes may convert their 2027 Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date.

The Company will settle conversions by paying or delivering, as applicable, cash, shares of its common stock or a combination of cash and shares of its common stock, at the Company's election.

The initial conversion rate is 7.1523 shares of common stock per $1,000 principal amount of 2027 Notes, which represents an initial conversion price of approximately $139.82 per share of common stock. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Company may not redeem the 2027 Notes at its option at any time before November 20, 2024. The Notes will be redeemable, in whole or in part, at the Company's option at any time, and from time to time, on or after November 20, 2024 and on or before the 25th scheduled trading day immediately before the maturity date, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid special interest and additional interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. In addition, calling any Note for redemption will constitute a Make-Whole Fundamental Change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

If certain corporate events that constitute a "Fundamental Change" occur, then, subject to a limited exception for certain cash mergers, holders of Notes may require the Company to repurchase their 2027 Notes at a cash repurchase price equal to the principal amount of the 2027 Notes to be repurchased, plus accrued and unpaid special interest and additional interest, if any, to, but excluding, the fundamental change repurchase date. The definition of Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the Company's common stock.

In accounting for the 2027 Notes, the Company separated the 2027 Notes into liability and equity components. The carrying amount of the liability component was calculated using a black scholes model by measuring the fair value of a similar instrument that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2027 Notes as a whole. This difference represents a debt discount that is amortized as interest expense using an effective interest over the term of the 2027 Notes.

Since the 2027 Notes were not convertible as of December 31, 2020, the net carrying amount of the 2027 Notes was classified as a long-term liability and the equity component was included in additional paid-in capital in the consolidated balance sheet as of December 31, 2020.

The following table sets forth the components of the 2027 Notes as of December 31, 2020:

		(in thousands)
Liability component:		
Principal	$	1,150,000
Less: debt discount, net of amortization		(331,074)
Less: debt issuance costs, net of amortization		(12,634)
Net carrying amount	$	806,292
Equity component recorded at issuance:		
2027 Notes	$	335,667
Less: issuance costs		(5,264)
Net amount recorded in equity	$	330,403

The total estimated fair value of the 2027 Notes was $1.3 billion as of December 31, 2020. The fair value was determined based on the closing trading price per $100 of the 2027 Notes as of the last day of trading for the period. We consider the fair value of the Notes as of December 31, 2020 to be a Level 2 measurement. The fair value of the 2027 Notes is primarily affected by the trading price of the Company's common stock and market interest rates.

The following table sets forth interest expense recognized related to the Notes for the year ended December 31, 2020:

	(in thousands)
Amortization of debt discount	$ 4,593
Amortization of debt issuance costs	136
Total interest expense recognized	$ 4,729
Effective interest rate of the liability component	5.2 %

Note Hedges

To minimize the impact of potential economic dilution upon conversion of the 2027 Notes, the Company entered into convertible note hedge transactions (the "2027 Note Hedges") with respect to its common stock concurrent with the issuance of the Notes. The 2027 Note Hedges cover, subject to customary adjustments, the number of shares of common stock initially underlying the Notes. The strike price of the 2027 Note Hedges will initially be approximately $182.60 per share, which represents a premium of 75% over the last reported sale price of the Company's common stock of $104.34 per share on November 16, 2020, and is subject to certain adjustments under the terms of the 2027 Note Hedges.

The 2027 Note Hedges will expire upon maturity of the 2027 Notes. The 2027 Note Hedges are separate transactions and are not part of the terms of the 2027 Notes. Holders of the 2027 Notes will not have any rights with respect to the 2027 Note Hedges. The shares receivable related to the 2027 Note Hedges are excluded from the calculation of diluted earnings per share as they are anti-dilutive.

As these transactions meet certain accounting criteria, the 2027 Note Hedges are recorded in stockholders' equity and are not accounted for as derivatives. The Company paid an aggregate amount of $90.0 million for the 2027 Note Hedges, which has been recorded as a reduction to additional paid-in capital and will not be remeasured.

9. Leases

The Company has entered into various operating lease agreements for office space, data center, lab and warehouse use, with remaining terms ranging from 1 year to 12 years some of which include one or more options to renew. As leases approach maturity, the Company considers various factors such as market conditions and the terms of any renewal options that may exist to determine whether it will renew the lease, as such, the Company does not include renewal options in its lease terms for calculating its lease liability, as the renewal options allow it to maintain operational flexibility and the Company is not reasonably certain it will exercise these renewal options at the time of the lease commencement.

Operating lease expense for the year ended December 31, 2020 and 2019 was $5.6 million and $4.4 million which includes both lease and non-lease components (primarily common area maintenance charges and property taxes).

Rent expense for the facility leases was $4.6 million for the year ended December 31, 2018.

	As of December 31,	
	2020	2019
Weighted-average remaining lease term (in years)	5.5	6.4
Weighted-average discount rate	8.07 %	7.77 %

The following table summarizes our future principal contractual obligations for operating lease commitments as of December 31, 2020:

Year Ending December 31,		(in thousands)
2021	$	9,129
2022		10,788
2023		11,415
2024		10,849
2025		10,783
2026 and thereafter		7,643
Total operating lease payments	$	60,607
Less: Imputed Interest		(12,410)
Total operating lease liabilities	$	48,197

In July 2020, the Company entered into two facility lease agreements for terms ranging from 8-12 years. One of the lease agreements provides an option to renew the lease term for an additional ten years. As of December 31, 2020, the Company has additional future minimum lease payments relating to these two facility lease agreements that have not yet commenced amounting to $239.5 million. The Company anticipates to take possession of these facilities within the second fiscal quarter of 2021.

Finance leases are not material to the Company's consolidated financial statements.

10. Commitments and Contingencies

License Agreements

The Company has patent license agreements with four different parties. Under these agreements, the Company has made one-time upfront and milestone payments, which it has capitalized and is amortizing to expense ratably over the useful life of the underlying patent right(s). Under some of these agreements, the Company is obligated to pay low single-digit percentage running royalties on net sales where the licensed patent right(s) are used in the product or service sold, subject to minimum annual royalties or fees in certain agreements.

Royalty expenses were included in cost of precision oncology testing on the accompanying consolidated statements of operations. The Company recognized royalty expenses of $1.1 million, $4.4 million and $1.4 million, or 0.4%, 2% and 2% of precision oncology testing revenue in each period, for the years ended December 31, 2020, 2019 and 2018, respectively.

Indemnification Agreements

The Company has entered into indemnification agreements with certain directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no such matters have arisen and the Company does not believe that the outcome of any claims under indemnification arrangements will have a material adverse effect on its financial positions, results of operations or cash flows. Accordingly, the Company has not recorded a liability related to such indemnifications as of December 31, 2020.

Legal Proceedings

In addition to commitments and obligations incurred in the ordinary course of business, from time to time the Company may be subject to a variety of claims and legal proceedings, including claims from customers and vendors, pending and potential legal actions for damages, governmental investigations and other matters. For example, the Company has received, and may in the future continue to receive letters, claims or complaints from others alleging false advertising, patent infringement, violation of employment practices and trademark infringement. The Company has also instituted, and may in the future institute, additional legal proceedings to enforce its rights and seek remedies, such as monetary damages, injunctive relief and declaratory relief. The Company cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact because of diversion of management time and attention as well as the financial costs related to resolving such disputes.

The Company and its affiliates are parties to the legal claims and proceedings described below. The Company is vigorously defending itself against those claims and in those proceedings. Significant developments in those matters are described below. If the Company is unsuccessful in defending, or if it determines to settle, any of these matters, it may be required to pay substantial sums, be subject to injunction and/or be forced to change how it operates its business, which could have a material adverse impact on its financial position or results of operations.

Unless otherwise stated, the Company is unable to reasonably estimate the loss or a range of possible loss for the matters described below. Often, it is not reasonably possible for the Company to determine that a loss is probable for a claim, or to reasonably estimate the amount of loss or a range of loss, because of the limited information available and the potential effects of future events and decisions by third parties, such as courts and regulators, that will determine the ultimate resolution of the claim. Many of the matters described are at preliminary stages, raise novel theories of liability or seek an indeterminate amount of damages. It is not uncommon for claims to be resolved over a number of years. The Company reviews loss contingencies at least quarterly to determine whether the loss probability has changed and whether it can make a reasonable estimate of the possible loss or range of loss. When the Company determines that a loss from a claim is probable and reasonably estimable, it records a liability in the amount of its estimate for the ultimate loss. The Company also provides disclosure when it is reasonably possible that a loss may be incurred or when it is reasonably possible that the amount of a loss will exceed its recorded liability.

Patent Disputes

In November 2017, the Company filed a lawsuit against Foundation Medicine, Inc. (“Foundation Medicine”) in the United States District Court for the District of Delaware. The Company has alleged that Foundation Medicine has infringed four of the Company’s digital sequencing technology patents. Foundation Medicine has asserted counterclaims of patent invalidity, unenforceability under the doctrine of inequitable conduct, and non-infringement. The parties are seeking damages, injunctive relief and attorneys’ fees. Discovery in the lawsuit has closed, and a number of pre-trial motions were filed in September and October 2020. The trial is presently continued pending resolution by the District Court of the pre-trial motions.

Foundation Medicine also filed six petitions for inter partes review with the PTAB, challenging the patentability of all four of the patents asserted by the Company. The PTAB denied institution of inter partes review for four of the six petitions filed by Foundation Medicine and instituted inter partes review for the remaining two petitions. The Company plans to vigorously defend its patent rights during such PTAB actions. At this time, the Company cannot reasonably ascertain the likelihood that any of the remaining challenged patents will be found to be invalid or unenforceable.

On August 31, 2020, the Company and Personal Genome Diagnostics, Inc. settled the patent infringement lawsuit brought by the Company. Under the terms of the confidential settlement, the lawsuit and counterclaims, as well as other challenges to the Company’s patents, have been dismissed.

Other Disputes

In the first quarter of 2018, the Company settled a commercial dispute. In connection with the settlement, the Company received a payment of $4.25 million, which was reported as other income in the consolidated statements of operations for the year ended December 31, 2018.

11. Common Stock

The Company’s common stockholders are entitled to dividends if and when declared by the Company’s Board of Directors (the “Board of Directors”). As of December 31, 2020 and 2019, no dividends on the Company’s common stock had been declared by the Board of Directors.

The Company's common stock has been reserved for the following potential future issuances:

	As of December 31,	
	2020	2019
Shares underlying outstanding stock options	3,101,181	4,494,889
Shares underlying unvested restricted stock units	1,118,655	496,131
Market-based restricted stock units	3,391,148	—
Performance-based restricted stock units	377,922	—
Shares available for issuance under the 2018 Incentive Award Plan	1,819,223	2,726,225
Shares available for issuance under the 2018 Employee Stock Purchase Plan	1,536,491	689,917
Total	11,344,620	8,407,162

Reverse Stock Split

In September 2018, the Board of Directors and its stockholders approved a 0.7378-for-one reverse stock split of the Company's common stock. The reverse stock split became effective on September 19, 2018. The par value of the common stock was not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the convertible preferred stock was convertible into common stock immediately prior to the closing of the IPO.

Initial Public Offering

In October 2018, the Company completed the IPO, in which it issued and sold 14,375,000 shares of its common stock at a price of $19.00 per share. The Company received net proceeds of $249.5 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. All then-outstanding warrants to purchase the Company's common stock were exercised prior to the completion of the IPO. In addition, in connection with the IPO, all shares of the Company's then-outstanding convertible preferred stock were automatically converted into 58,264,577 shares of its common stock, and all then-outstanding warrants to purchase the Company's convertible preferred stock were automatically converted into warrants to purchase 7,636 shares of the Company's common stock.

Follow-on Offering

In May 2019, the Company completed an underwritten public offering, in which it issued and sold 5,175,000 shares of its common stock at a price of $71.00 per share. The Company received net proceeds of $349.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

In June 2020, the Company completed an underwritten public offering, in which it issued and sold 4,312,500 shares of its common stock at a price of $84.00 per share. The Company received net proceeds of $354.6 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

12. Warrants

In connection with a bank loan agreement with a financial institution in September 2013, the Company issued warrants to purchase 5,386 shares of Series A convertible preferred stock at an exercise price of $0.93 per share. In October 2014, the Company issued additional warrants to the same financial institution to purchase 4,965 shares of Series B convertible preferred stock at an exercise price of $3.16 per share. These preferred stock warrants were converted to warrants to purchase common stock upon the consummation of the IPO and were net exercised into 6,548 shares of common stock in October 2018.

In 2012, the Company issued to certain investors warrants to purchase 495,775 shares of common stock. The exercise price of the warrants is $0.14 per share and the warrants have a contractual term through September 2023. For the year ended December 31, 2018, 313,741 shares were issued upon the exercise of these warrants, and these warrants were fully exercised prior to the consummation of the IPO in October 2018.

No warrants remained outstanding as of December 31, 2020 and 2019.

13. Convertible Preferred Stock

The Company previously issued convertible preferred stock in one or more series, each with such designations, rights, qualifications, limitations, and restrictions as set forth in the Company's certificate of incorporation, as in effect prior to the IPO. Immediately prior to the completion of the IPO, as described in Note 1, *Description of*

Business, all shares of convertible preferred stock then outstanding were automatically converted to 58,264,577 shares of common stock at the respective conversion ratios in October 2018.

14. Stock-Based Compensation

2012 Stock Plan and 2018 Incentive Award Plan

In June 2012 and September 2018, the Company's Board of Directors adopted and its stockholders approved the Company's 2012 Stock Plan (as amended and restated, the "2012 Plan") and the Company's 2018 Incentive Award Plan (the "2018 Plan"), respectively, under which the Company may grant cash and equity incentive awards such as stock options, restricted shares, stock units and stock appreciation rights to its employees and non-employees. Stock options granted may be either incentive stock options or nonstatutory stock options. Shares issued under the 2018 Plan may be authorized but unissued shares, or shares purchased in the open market or treasury shares. Upon effectiveness of the 2018 Plan in connection with the IPO in October 2018, the 2012 Plan was terminated and 508,847 shares reserved under the 2012 Plan were forfeited. Any outstanding awards granted under the 2012 Plan remain outstanding, subject to the terms of the 2012 Plan and applicable award agreement, and further cancellation of awards granted under the 2012 Plan are not available for grant in the future. No further grants will be made under the 2012 Plan.

Stock Option Activity

A summary of the Company's stock option activity under the 2012 Plan and the 2018 Plan and related information is as follows:

		Options Outstanding			
	Shares Available for Grant	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
					(in thousands)
Balance as of January 1, 2018	1,698,790	7,391,052	$ 3.63	8.6	$ 3,325
Shares authorized in 2018 Plan	3,658,602	—			
Shares forfeited	(508,847)	—			
Granted	(2,088,639)	2,088,639	7.19		
Exercised	—	(1,007,387)	3.09		
Canceled	795,371	(883,899)	4.57		
Repurchase of early exercised shares	1,230	—			
Balance as of December 31, 2018	3,556,507	7,588,405	4.58	8.3	250,495
Granted	(324,579)	324,579	88.18		
Exercised	—	(2,999,419)	3.87		
Canceled	12,636	(418,676)	6.64		
Restricted stock units granted	(567,425)	—			
Restricted stock units canceled	49,086	—			
Balance as of December 31, 2019	2,726,225	4,494,889	10.90	7.7	306,392
2018 Plan annual increase[(1)]	3,689,000	—			
Granted	(127,590)	127,590	81.78		
Exercised	—	(1,446,843)	6.59		
Canceled	20,370	(74,455)	12.13		
Restricted stock units granted	(823,454)	—			
Restricted stock units canceled	103,742	—			
Market-based restricted stock units granted	(3,391,148)	—			
Performance-based restricted stock units granted	(377,922)	—			
Balance as of December 31, 2020	1,819,223	3,101,181	$ 15.80	6.9	$ 350,670
Vested and Exercisable as of December 31, 2020		1,920,724	$ 8.04	6.5	$ 232,094

(1) Effective as of January 1, 2020, an additional 3,689,000 shares of common stock became available for issuance under the 2018 Plan, as a result of the operation of an automatic annual increase provision therein.

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options. The total intrinsic value of the options exercised was $120.0 million, $218.2 million and $8.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The weighted-average grant date fair value of options granted was $48.99, $52.37 and $5.17 per share for the years ended December 31, 2020, 2019 and 2018, respectively.

Future stock-based compensation for unvested options as of December 31, 2020 was $20.9 million, which is expected to be recognized over a weighted-average period of 2.7 years.

In December 31, 2020 and 2019, the Company modified one of the performance based awards issued to a nonemployee which resulted in reversal of expense of $0.7 million and $1.0 million, respectively, due to options not vested.

Restricted Stock Units

A summary of the Company's restricted stock unit activity excluding the performance-based and market-based restricted stock units under the 2012 Plan and the 2018 Plan and related information is as follows:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2018	—	$ —
Granted	567,425	78.61
Vested and released	(22,208)	47.78
Canceled	(49,086)	57.51
Balance as of December 31, 2019	496,131	82.08
Granted	823,454	96.39
Vested and released	(97,188)	81.43
Canceled	(103,742)	79.72
Balance as of December 31, 2020	1,118,655	$ 92.89

Future stock-based compensation for unvested restricted stock units as of December 31, 2020 was $93.4 million, which is expected to be recognized over a weighted-average period of 3.4 years.

Performance-based Restricted Stock Units

In November 2020, the Compensation Committee of the Board of Directors approved a total of 377,922 performance-based restricted stock units ("PSUs") which have a grant date fair value of approximately $42.9 million. The PSUs consist of financial and operational metrics to be met over a performance period of 4 years and an additional service period requirement of six months after the performance metrics are met. These equity awards are expected to be expensed over a period of approximately 4.5 years subject to meeting the performance metrics and service requirements. As of December 31, 2020, a significant portion of these PSUs are not expected to achieve the related performance metrics, and therefore, no stock-based compensation expense was recorded for the PSUs that were not probable to vest.

Stock-based compensation recorded for the PSUs for the year ended December 31, 2020 was $0.1 million. Future stock-based compensation for unvested PSUs that are probable to vest as of December 31, 2020 was $2.1 million, which is expected to be recognized over a weighted-average period of 4.3 years.

Market-based Restricted Stock Units

In May 2020, the Board of Directors approved and granted 1,695,574 market-based restricted stock units ("MSUs") under the 2018 Plan to each of the Company's Chief Executive Officer and the Company's President and Chief Operating Officer, which is subject to the achievement of market-based share price goals established by the Board of Directors. The MSUs consist of three separate tranches and the vesting of each tranche is subject to the Company's common stock closing price being maintained at or above a predetermined share price goal for a period of 30 consecutive calendar days. The share price goal can be met any time during the seven-year performance period from the date of grant. Upon vesting, the MSUs must be held for a period of six to twelve months depending on the time of vesting within the seven-year performance period. The vesting of the MSUs can also be triggered upon a change in control event and achievement of a certain change in control price goal, or when there is a qualifying termination or in the event of death or disability. The following table presents additional information relating to each MSU award:

Tranche	Price Goal	Number of RSUs
Tranche 1	$120 per share	565,192
Tranche 2	$150 per share	565,191
Tranche 3	$200 per share	565,191

The grant date fair values of the MSUs were determined using a Monte Carlo valuation model for each tranche. The related stock-based compensation expense for each tranche is recognized based on an accelerated attribution method

over the estimated derived service period. If the related share price goal is achieved earlier than its expected derived service period, the stock-based compensation expense will be recognized as a cumulative catch-up expense from the grant date to that point in time in achieving the share price goal. The derived service period is the median duration of the successful stock price paths to meet the price goal for each tranche as simulated in the Monte Carlo valuation model. The Monte Carlo valuation model uses assumptions such as volatility, risk-free interest rate, cost of equity and dividend estimated for the performance period of the MSU. The weighted average grant date fair value of the MSUs was $67.00 and the weighted average derived service period was estimated to be in the range of 0.83 – 2.07 years.

Stock-based compensation recorded for the MSUs for the year ended December 31, 2020 was $111.9 million and is recorded in general and administrative expenses in our consolidated statement of operations. Future stock-based compensation for unvested MSUs as of December 31, 2020 was $115.3 million, which is expected to be recognized over a weighted-average period of 1.0 years. In the event of a change in control, a qualifying termination, death, disability or the share price goal occurring earlier than the estimated derived service period, the stock-based compensation relating to these MSUs could be accelerated. On January 1, 2021, Tranche 1 of the MSUs became vested because it has met both service requirement and market-based performance metrics as the predetermined share price goal of $120 per share was achieved for a period of 30 consecutive calendar days. Any MSUs that remain unvested at the end of the 7-year performance period will automatically be forfeited and terminated without further consideration.

AMEA 2020 Equity Incentive Plan

In August 2020, the board of directors of the Joint Venture approved its 2020 Equity Incentive Plan (the "AMEA 2020 Plan"), under which the Joint Venture may grant equity incentive awards such as stock options, restricted stock, restricted stock units, stock appreciation rights and cash-based awards to its employees and non-employees. Stock options granted may be either incentive stock options or nonstatutory stock options. Incentive stock options may be granted only to employees of the Joint Venture or its affiliates. Nonstatutory stock options may be granted to employees, directors and non-employee consultants. Stock options may be granted at an exercise price of not less than the fair market value of the Joint Venture's common stock on the date of grant, determined by the board of directors of the Joint Venture. Options generally vest over 4 years and expire as determined by the board of directors of the Joint Venture, provided that the term of options may not exceed 10 years from the date of grant. For individuals holding more than 10% of the total combined voting power of all classes of stock of the Joint Venture, the exercise price of an option will not be less than 110% of the fair market value of the Joint Venture's common stock on the date of grant, and the term of the option will not exceed 5 years. A total of 4,595,555 shares of the Joint Venture's Class B common stock are initially reserved for issuance under the AMEA 2020 Plan, and the number of shares may be increased in accordance with the terms of the AMEA 2020 Plan.

A summary of the Joint Venture's stock option activity under the AMEA 2020 Plan and related information is as follows:

		Options Outstanding			
	Shares Available for Grant	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
					(in thousands)
Balance as of December 31, 2019	—	—	$ —	0.0	$ —
Shares authorized	4,595,555	—	—		
Granted	(4,062,224)	4,062,224	0.58		
Canceled	8,889	(8,889)	—		
Balance as of December 31, 2020	542,220	4,053,335	$ 0.58	9.6	$ —
Vested and Exercisable as of December 31, 2020		1,980,707	$ 0.58	9.6	$ —

The weighted-average grant date fair value of options granted was $0.33 per share for the year ended December 31, 2020. Future stock-based compensation for unvested options as of December 31, 2020 was $0.7 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Stock-Based Compensation Expense

The following table presents the effect of employee and non-employee related stock-based compensation expense including the Joint Venture:

	Year Ended December 31,		
	2020	2019	2018
		(in thousands)	
Cost of precision oncology testing	$ 1,839	$ 863	$ 512
Research and development expense	10,024	5,907	1,684
Sales and marketing expense	9,279	4,716	1,727
General and administrative expense	122,971	5,468	2,928
Total stock-based compensation expense	$ 144,113	$ 16,954	$ 6,851

Valuation of Stock Options

Starting January 1, 2019, the Company adopted ASU 2018-07 which aligns the accounting treatment of nonemployee awards with employee awards, and the fair value of stock options issued to employees and nonemployee consultants are both determined as of the grant date.

The grant date fair value of employee and nonemployee stock options was estimated using a Black-Scholes option-pricing model with the following weighted-average assumptions including the Joint Venture:

	Year Ended December 31,		
	2020	2019	2018
Expected term (in years)	5.50 – 6.10	5.50 – 6.22	5.01 – 6.51
Expected volatility	63.6% – 73.3%	63.2% – 68.7%	68.7% – 78.8%
Risk-free interest rate	0.3% – 1.6%	1.6% – 2.7%	2.5% – 3.0%
Expected dividend yield	—%	—%	—%

The determination of the fair value of stock options on the date of grant using a Black-Scholes option-pricing model is affected by the estimated fair value of common stock of the Company and the Joint Venture, as well as assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. The valuation assumptions were determined as follows:

Fair Value of Common Stock

Prior to the IPO, the grant date fair value of the Company's common stock was determined by the Board of Directors with the assistance of management and an independent third-party valuation specialist. Subsequent to the IPO, the fair value of the Company's common stock is determined by the closing price, on the date of grant, of its common stock, which is traded on the Nasdaq Global Select Market.

The grant date fair value of the Joint Venture's common stock has been determined by the board of directors of the Joint Venture. The grant date fair value of the Joint Venture's common stock was determined using valuation methodologies which utilize certain assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability. In determining the fair value of the Joint Venture's common stock, the methodologies used to estimate the enterprise value of the Joint Venture were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Expected Term

The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility

Prior to the commencement of trading of the Company's common stock on the Nasdaq Global Select Market on October 4, 2018 in connection with the IPO, there was no active trading market for the Company's common stock. Due to limited historical data for the trading of the Company's common stock, expected volatility is estimated based on the average volatility for comparable publicly traded peer group companies in the same industry plus the Company's expected volatility for the available periods. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.

The Joint Venture derived the expected volatility from the average historical volatility over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends as the Joint Venture does not have any trading history for its common stock. The Joint Venture will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate

The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the stock options.

Expected Dividend Yield

The Company and the Joint Venture does not anticipate paying any dividends in the foreseeable future and, therefore, uses an expected dividend yield of zero.

Valuation of MSUs

The estimated fair value of the MSUs was determined using a Monte Carlo simulation model. The valuation assumptions used were substantially consistent with the assumption used to value stock options with the exception of the following:

Expected Volatility

Due to limited historical data for the trading of the Company's common stock, expected volatility is estimated based on the average volatility for comparable publicly traded peer group companies and implied volatility of publicly traded options in the same industry plus the Company's expected volatility for the available periods. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.

Expected Term

The expected term represents the derived service period for the respective tranches which has been estimated using the Monte Carlo simulation model.

Risky Rate

The risky rate represents the Company's cost of equity.

Discount for Lack of Marketability

The discount for lack of marketability represents the discount applied for post vest term restrictions and has been derived using the Monte Carlo simulation model.

The following assumptions were used to calculate the stock-based compensation for MSUs: a weighted-average expected term of 0.83 – 2.07 years; expected volatility of 65.5%; a risk-free interest rate of 0.53%; a zero dividend yield; a risky rate (cost of equity) of 16%; and a discount for post-vesting restrictions of 10.4% – 14.5%.

2018 Employee Stock Purchase Plan

In September 2018, the Company's Board of Directors adopted and its stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"). A total of 922,250 shares of common stock were initially reserved for issuance under the ESPP. Effective as of January 1, 2020, an additional 942,614 shares of common stock became available for issuance under the ESPP, as a result of the operation of an automatic annual increase provision therein.

Subject to any plan limitations, the ESPP allows eligible employees to contribute, normally through payroll deductions, up to 10% of their earnings for the purchase of the Company's common stock at a discounted price per share. The price at which common stock is purchased under the ESPP is equal to 85% of the fair market value of the

Company's common stock on the first or last day of the offering period, whichever is lower. The initial offering period ran from October 2, 2018 to January 31, 2019, the second offering period ran from February 1, 2019 to July 31, 2019, and the third offering period began on August 1, 2019 and ran to November 14, 2019. For subsequent years starting with 2020, the ESPP provides for separate six-month offering periods beginning on May 15 and November 15 of each year.

Shares of common stock purchased under the ESPP were 96,040 and 232,333 for the years ended December 31, 2020 and 2019, respectively. No shares were purchased under the ESPP for the year ended December 31, 2018. The total compensation expense related to the ESPP was $3.0 million, $2.3 million and $0.3 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The fair value of the stock purchase right granted under the ESPP was estimated on the first day of each offering period using the Black-Scholes option pricing model. The valuation assumptions used were substantially consistent with the assumption used to value stock options with the exception of the expected term which was based on the term of each purchase period.

The grant date fair value of the stock purchase right granted under the ESPP was estimated using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected term (in years)	0.50	0.29 – 0.50	0.33
Expected volatility	45.7% – 73.2%	58.8% – 60.3%	43.6%
Risk-free interest rate	0.1% – 0.2%	1.6% – 2.5%	2.4%
Expected dividend yield	—%	—%	—%

As of December 31, 2020, the unrecognized stock-based compensation expense related to the ESPP was $1.2 million, which is expected to be recognized over the remaining term of the offering period of 0.4 years.

Liabilities for Early Exercise of Employee Options

The Company allowed certain stock option holders to exercise unvested options to purchase shares of the Company's common stock. Shares received from such early exercises are subject to repurchase in the event of the optionee's employment termination, at the original issuance price, until the options are fully vested. As of December 31, 2020 and 2019, 12,914 shares and 23,981 shares of common stock were subject to repurchase at weighted-average price of $4.66 per share, respectively. As of December 31, 2020 and 2019, the cash proceeds received for unvested shares of common stock of $0.1 million and $0.1 million was recorded within other long-term liabilities on the consolidated balance sheet, respectively. The shares issued pursuant to unvested options have been included in shares issued and outstanding on the consolidated balance sheet and consolidated statement of redeemable noncontrolling interest and stockholders' equity as such shares are considered legally outstanding.

15. Net Loss Per Share Attributable to Guardant Health, Inc. Common Stockholders

The following table sets forth the computation of the basic and diluted net loss per share attributable to Guardant Health, Inc. common stockholders:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands, except per share data)		
Net loss	$ (246,283)	$ (67,851)	$ (84,263)
Adjustment of redeemable noncontrolling interest	(7,500)	(7,800)	(800)
Net loss attributable to Guardant Health, Inc. common stockholders, basic and diluted	$ (253,783)	$ (75,651)	$ (85,063)
Net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	$ (2.60)	$ (0.84)	$ (2.80)
Weighted-average shares used in computing net loss per share attributable to Guardant Health, Inc. common stockholders, basic and diluted	97,504	90,597	30,403

Since the Company was in a loss position for all periods presented, basic net loss per share attributable to Guardant Health, Inc. common stockholders is the same as diluted net loss per share attributable to Guardant Health, Inc. common stockholders, as the inclusion of all potential shares of common stock outstanding would have been anti-dilutive. The following weighted-average common stock equivalents were excluded from the calculation of diluted net loss per share attributable to Guardant Health, Inc. common stockholders for the periods presented as they had an anti-dilutive effect:

	Year Ended December 31,		
	2020	2019	2018
		(in thousands)	
Convertible preferred stock (on an as if converted basis)	—	—	43,898
Preferred stock warrants (on an as if converted basis)	—	—	6
Common stock warrants	—	—	208
Stock options issued and outstanding [1]	3,830	5,976	7,527
Restricted stock units	687	252	—
MSUs	2,031	—	—
PSUs	60	—	—
ESPP obligation	37	52	22
Common stock subject to repurchase	18	31	46
Convertible senior notes	961	—	—
Total	7,624	6,311	51,707

(1) Excludes stock options of 4,053,335 shares of the Joint Venture's Class B common stock granted under the AMEA 2020 Plan as of December 31, 2020.

16. Income Taxes

The components of loss before provision for income taxes were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
		(in thousands)	
United States	$ (246,463)	$ (69,930)	$ (84,313)
Foreign	559	207	88
Total	(245,904)	(69,723)	(84,225)

The components of the provision for income taxes are as follows:

	Year Ended December 31,		
	2020	2019	2018
		(in thousands)	
Current:			
State	$ 5	$ 3	$ 4
Foreign	242	266	34
Total current tax expense	$ 247	$ 269	$ 38
Deferred:			
Federal	$ 184	$ (1,652)	$ —
State	34	(311)	—
Foreign	(86)	(178)	—
Total deferred tax expense	$ 132	$ (2,141)	$ —
Total provision for income taxes	$ 379	$ (1,872)	$ 38

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	As of December 31,	
	2020	2019
	(in thousands)	
Deferred tax assets:		
Net operating losses carryforwards	$ 133,015	$ 90,534
Intangible assets	14,198	14,165
Accruals and reserves	10,117	4,936
Research and development credits	19,022	11,031
Stock-based compensation	28,745	3,143
Lease liabilities	12,092	10,195
Other	65	160
Total deferred tax asset	$ 217,254	$ 134,164
Deferred tax liabilities:		
Property and equipment	$ —	$ (119)
Section 481 (a) adjustment	(607)	(914)
Right-of-use asset	(9,383)	(7,363)
Unrealized gain/loss on investments	(571)	(346)
Debt discount	(81,964)	—
Total deferred tax liabilities	(92,525)	(8,742)
Less: valuation allowance	(124,433)	(125,245)
Net deferred tax assets	$ 296	$ 177

The following table presents a reconciliation of the income tax expense computed at the statutory federal rate and the Company's income tax expense for the periods presented:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Tax at the statutory federal rate	$ (51,639)	$ (14,642)	$ (17,690)
Other nondeductible items	786	887	329
Stock-based compensation	(13,382)	(33,042)	497
Research and development credits	(7,890)	(5,266)	(1,726)
Change in valuation allowance	81,395	59,049	22,516
State taxes, net of federal benefits	(11,119)	(8,253)	(4,231)
Change in tax rate due to Tax Act	—	—	—
Other	2,228	(605)	343
Total provision for (benefit from) income taxes	$ 379	$ (1,872)	$ 38

The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the year ended December 31, 2020, 2019 and 2018 primarily due to state and foreign income taxes, nondeductible expenses, research and development tax credits, the acquisition of Bellwether Bio, and the change in valuation allowance. The benefit from income taxes for the year ended December 31, 2019 included a release of a valuation allowance of $1.6 million associated with nondeductible intangible assets recorded as a result of the acquisition of Bellwether Bio. In connection with the acquisition of Bellwether Bio, a deferred tax liability was established for the book-tax basis differences related to the non-goodwill intangible assets. The net deferred tax liability from this acquisition creates an additional source of income to offset the Company's deferred tax assets. The benefit from income taxes for the year ended December 31, 2019 also included a benefit of $0.4 million associated

with the utilization of tax losses from continuing operations against other comprehensive income gains in accordance with intra-period tax allocation under ASC Topic 740.

As of December 31, 2020 and 2019, the Company had a net operating loss carryforwards of $547.3 million and $365.3 million for federal purposes, $306.7 million and $223.2 million for state and local purposes, respectively, which may be subject to limitations as described below. If not utilized, these carryforwards will begin to expire in 2031 for federal, and 2021 for state and local purposes. Federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. Some but not all states conform to the federal treatment of net operating losses.

As of December 31, 2020 and 2019, the Company had research and development tax credit carryforwards for federal tax purposes of $11.9 million and $6.8 million, and state research and development tax credit carryforwards of $9.1 million and $5.3 million, respectively. The federal research and development tax credit carryforwards will expire at various dates beginning in the year 2032. The Company's state research and development tax credit carryforwards do not expire.

Utilization of the net operating loss ("NOL") carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of NOL carryforwards and credits before utilization. Current laws impose substantial restrictions on the utilization of NOL carryforwards and credits in the event of an "ownership change" within a three-year period as defined by the Internal Revenue Code Section 382 ("Section 382"). If there should be an ownership change, the Company's ability to utilize its NOL carryforwards and credits could be limited. The Company has not performed a Section 382 analysis.

Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Due to the Company's history of U.S. operating losses, the Company believes that the recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not more likely than not to be realized and, accordingly, have provided a full valuation allowance against net U.S. deferred tax assets. The net change in total valuation allowance was a decrease of $0.8 million, and an increase of $59.0 million and $22.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The Company has not recorded a provision for deferred U.S. tax expense that could result from the remittance of foreign undistributed earnings since the Company intends to reinvest the earnings in its foreign subsidiaries indefinitely.

The Company has made an accounting policy election to treat Global Intangible Low-Taxed Income ("GILTI") taxes as a current period expense rather than including these amounts in the measurement of deferred taxes.

Uncertain Tax Positions

The Company records unrecognized tax benefits, where appropriate, for all uncertain income tax positions. The Company recorded unrecognized tax benefits for uncertain tax positions of $11.3 million and $6.5 million as of December 31, 2020 and 2019, respectively, none of which would impact the Company's effective tax rate if recognized, because the benefit would be offset by an increase in the valuation allowance.

A reconciliation of the beginning and ending balance of total unrecognized tax benefits is as follows:

	Year Ended December 31,		
	2020	2019	2018
		(in thousands)	
Unrecognized tax benefits - Beginning of period	$ 6,543	$ 3,427	$ 1,712
Increases related to current year's tax positions	4,666	3,116	1,635
Increases related to prior years' tax positions	60	—	80
Unrecognized tax benefits - End of period	$ 11,269	$ 6,543	$ 3,427

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the years ended December 31, 2020, 2019 and 2018, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

Due to the net operating loss carryforwards, all years remain open for income tax examination by tax authorities in the United States, various states and foreign tax jurisdictions in which the Company files tax returns.

17. Employee Benefit Plan

The Company sponsors a 401(k) plan, and pursuant to its terms, eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100% of eligible compensation on a pre-tax basis. For the years ended December 31, 2020 and 2019, the Company contributed $2.8 million and $0.3 million, respectively, to match employee contributions as permitted by the plan. For the year ended December 31, 2018, the Company did not elect to match employee contributions as permitted by the plan. The Company pays the administrative costs for the plan.

18. Segment and Geographic Information

The following table sets forth the Company's revenue by geographic areas based on the customers' locations:

	Year Ended December 31,		
	2020	2019	2018
		(in thousands)	
United States [2]	$ 264,657	$ 194,312	$ 77,916
International[1] [2]	22,073	20,063	12,723
Total revenue	$ 286,730	$ 214,375	$ 90,639

(1) No single country outside of the United States accounted for more than 10% of total revenue during each of the years ended December 31, 2020, 2019 and 2018.

(2) Fiscal years 2018 results do not reflect the impact of the adoption of the new revenue accounting standard in fiscal year 2019.

As of December 31, 2020 and 2019, 94% and 97%, respectively, of the Company's long-lived assets and right-of-use assets are located in the United States.

19. Related Party Transactions

As discussed in Note 3, *Investment in Joint Venture*, the Company and an affiliate of SoftBank formed and capitalized the Joint Venture to accelerate commercialization of its products in Asia, the Middle East and Africa. The Company has consolidated the financial position, results of operations and cash flows of the Joint Venture in its financial statements and all intercompany balances have been eliminated in consolidation.

The Company and its subsidiaries may, in the ordinary course of business, have transactions with unaffiliated companies of which certain of the Company's directors are directors and/or executive officers. The Company believes that such transactions are on the same terms generally offered by such other companies to other entities in comparable transactions. The Company does not consider the amounts involved in such transactions to be material in relation to its businesses, the businesses of such other companies or the interests of the directors involved. Revenue from an entity affiliated with a member of the Company's Board of Directors was $2.4 million and $2.6 million for the years ended December 31, 2020 and 2019. There was no revenue recognized by the Company from this entity for the year ended December 31, 2018. As of December 31, 2020 and 2019, the Company has accounts receivable from this entity of $1.8 million and $1.4 million, respectively.

In October 2020, SoftBank entered into an underwriting agreement with an independent third party and sold 7,700,000 shares of the Company's common stock. The Company did not sell any shares of its common stock in this transaction.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our CEO and CFO have concluded that as of December 31, 2020, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures.

Management report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment under the framework in the Internal Control—Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of December 31, 2020.The effectiveness of our internal control over financial reporting as of December 31, 2020, has been audited by an independent registered public accounting firm, as stated in their report included in Part II, Item 8, *"Financial Statements"* of this Annual Report on Form 10-K.

Changes in internal control

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations Over Internal Controls

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Management, including our CEO and CFO, do not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become

inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Guardant Health, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Guardant Health, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Guardant Health, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31,2020 and 2019 and consolidated statements of operations, comprehensive loss, redeemable noncontrolling interest and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 24, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California
February 25, 2021

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 of Form 10-K will be included in our 2021 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2021 Annual Meeting of Stockholders and is incorporated herein by reference. The 2021 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K will be included in our 2021 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 of Form 10-K will be included in our 2021 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 of Form 10-K will be included in our 2021 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 of Form 10-K will be included in our 2021 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report

(1) All financial statements

See Index to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules have been omitted since the required information was not applicable or was not present in amounts sufficient to require submission of the schedules, or because the information required is included in the consolidated financial statements or the accompanying notes.

(3) Exhibits required by Item 601 of Regulation S-K

The exhibits listed in the following Index to Exhibits are filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38683	3.1	10/9/2018	
3.2	Amended and Restated Bylaws	8-K	001-38683	3.2	10/9/2018	
4.1	Description of Registrant's Securities Registered under Section 12 of the Exchange Act	10-K	001-38683	4.1	3/2/2020	
4.2	Indenture, dated as of November 19, 2020, between Guardant Health, Inc. and U.S. Bank National Association, as trustee	8-K	001-38683	4.1	11/20/2020	
10.1	Amended and Restated Investors' Rights Agreement, dated May 9, 2017, by and among Guardant Health, Inc. and the investors listed therein	S-1	333-227206	10.1	9/6/2018	
10.2#	Amended and Restated 2012 Stock Plan	S-1	333-227206	10.3	9/6/2018	
10.2(a)#	Form of Notice of Stock Option Grant and Stock Option Agreement under the Amended and Restated 2012 Stock Plan	S-1	333-227206	10.4	9/6/2018	
10.3#	2018 Incentive Award Plan	S-8	333-227762	99.2(a)	10/10/2018	
10.3(a)#	Form of Stock Option Agreement under the 2018 Incentive Award Plan	S-1/A	333-227206	10.9(a)	9/21/2018	
10.3(b)#	Form of Restricted Stock Award Agreement under the 2018 Incentive Award Plan	S-1/A	333-227206	10.9(b)	9/21/2018	
10.3(c)#	Form of Restricted Stock Unit Award Agreement under the 2018 Incentive Award Plan	S-1/A	333-227206	10.9(c)	9/21/2018	
10.3(d)#	Forms of Performance-Based Restricted Stock Unit Award Agreement under the 2018 Incentive Award Plan					*
10.4#	2018 Employee Stock Purchase Plan	S-8	333-227762	99.3	10/10/2018	
10.4(a)#	First Amendment to 2018 Employee Stock Purchase Plan	10-K	001-38683	10.4(a)	3/29/2019	
10.5#	Executive Severance Plan	S-1/A	333-227206	10.13	9/21/2018	
10.5(a)#	First Amendment to Executive Severance Plan	10-K	001-38683	10.5(a)	3/29/2019	
10.6#	Non-Employee Director Compensation Program, effective as of June 12, 2020	10-Q	001-38683	10.1	8/6/2020	
10.7#	Amended and Restated Offer Letter Agreement, dated September 16, 2018, by and between Guardant Health, Inc. and Ian Clark	10-Q	001-38683	10.9	11/19/2018	
10.8#	Amended and Restated Offer Letter Agreement, dated September 16, 2018, by and between Guardant Health, Inc. and Stanley Meresman	10-Q	001-38683	10.10	11/19/2018	
10.9	Form of Indemnification Agreement between Guardant Health, Inc. and its directors and officers	S-1/A	333-227206	10.8	9/18/2018	
10.10	Lease, dated November 1, 2014, by and between the Registrant and Metropolitan Life Insurance Company	S-1	333-227206	10.2	9/6/2018	
10.11	First Amendment to Lease, dated October 17, 2017, by and between the Registrant and Metropolitan Life Insurance Company	S-1	333-227206	10.2(a)	9/6/2018	
10.12	Sublease Agreement, dated July 31, 2020, by and between Guardant Health, Inc. and 3000 Hanover, LLC	10-Q	001-38683	10.1	11/5/2020	
10.13§	Joint Venture Agreement, dated May 9, 2017, by and between the Registrant and SoftBank Vision Fund (AIV M1) L.P., as assignee from SoftBank Group Capital Limited	S-1	333-227206	10.5	9/6/2018	

10.14§	Supply Agreement, dated September 15, 2014, by and between the Registrant and Illumina, Inc.	S-1	333-227206	10.7	9/6/2018	
10.15§	Amendment to Supply Agreement, dated August 11, 2015, by and between the Registrant and Illumina, Inc.	S-1	333-227206	10.7(a)	9/6/2018	
10.16§	Amendment #2 to Supply Agreement, dated December 24, 2016, by and between the Registrant and Illumina, Inc.	S-1	333-227206	10.7(b)	9/6/2018	
10.17§	Amendment #3 to Supply Agreement, dated August 14, 2017, by and between the Registrant and Illumina, Inc.	S-1	333-227206	10.7(c)	9/6/2018	
10.18§	Amendment #4 to Supply Agreement, dated June 26, 2018, by and between the Registrant and Illumina, Inc.	S-1	333-227206	10.7(d)	9/6/2018	
10.19§	Amendment #5 to Supply Agreement, dated January 1, 2021, by and between the Registrant and Illumina, Inc.					*
10.20#	Form of letter agreement relating to certain time-based equity awards held by Helmy Eltoukhy and AmirAli Talasaz	10-K	001-38683	10.19	3/29/2019	
10.21#	Form of Waiver Letter Agreement	8-K	001-38683	10.2	5/27/2020	
10.22#	Offer Letter, dated December 4, 2020, by and between Guardant Health, Inc. and Michael Bell	8-K	001-38683	10.1	12/11/2020	
10.23	Form of Capped Call Confirmation	8-K	001-38683	10.1	11/20/2020	
21.1	List of Subsidiaries					*
23.1	Consent of Independent Registered Public Accounting Firm					*
24.1	Power of Attorney (included on the signatures page of this Annual Report on Form 10-K)					*
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*

104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)	*

* Filed herewith.
** Furnished herewith.
# Indicates management contract or compensatory plan.
§ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to, a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, or Item 601(a)(5) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GUARDANT HEALTH, INC.

Dated: February 25, 2021

By: /s/ Helmy Eltoukhy
Name: Helmy Eltoukhy
Title: Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Helmy Eltoukhy, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Helmy Eltoukhy Helmy Eltoukhy	Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2021
/s/ Michael Bell Michael Bell	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	February 25, 2021
/s/ AmirAli Talasaz AmirAli Talasaz	President, Chief Operating Officer and Chairman of the Board of Directors	February 25, 2021
/s/ Ian Clark Ian Clark	Director	February 25, 2021
/s/ Vijaya Gadde Vijaya Gadde	Director	February 25, 2021
/s/ Bahija Jallal Bahija Jallal	Director	February 25, 2021
/s/ Samir Kaul Samir Kaul	Director	February 25, 2021
/s/ Stanley Meresman Stanley Meresman	Director	February 25, 2021

EXHIBIT 10.3(d)

Founder PSU Award Agreement

GUARDANT HEALTH, INC.
2018 INCENTIVE AWARD PLAN

PERFORMANCE-BASED RESTRICTED STOCK UNIT GRANT NOTICE (FOUNDERS)

Guardant Health, Inc., a Delaware corporation (the "***Company***"), has granted to the participant listed below ("***Participant***") the performance-based Restricted Stock Units (the "***PSUs***") described in this Performance-Based Restricted Stock Unit Grant Notice (Founders) (this "***Grant Notice***"), subject to the terms and conditions of the 2018 Incentive Award Plan (as amended from time to time, the "***Plan***"), the Performance-Based Restricted Stock Unit Agreement attached as **Exhibit A**, the Vesting Schedule attached as **Exhibit B**, the Transferability Schedule attached as **Exhibit C**, and the Release attached as **Exhibit D** (**Exhibits A**, **B**, **C**, and **D**, collectively, the "***Agreement***"), all of which are incorporated into this Grant Notice by reference. Capitalized terms not specifically defined in this Grant Notice or the Agreement have the meanings given to them in the Plan.

Participant:	[Helmy Eltoukhy / AmirAli Talasaz]
Grant Date:	May 26, 2020
Expiration Date:	May 26, 2027
Baseline Price:	$89.04 per Share
Number of PSUs:	1,695,574
Vesting Schedule:	**Exhibit B**

By accepting (whether in writing, electronically or otherwise) the PSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Subject to the terms of this Grant Notice and the Agreement, Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

GUARDANT HEALTH, INC.		**PARTICIPANT**
By:		
Name:	Ian Clark	[Helmy Eltoukhy / AmirAli Talasaz]
Title:	Lead Independent Director, Board of Directors	

EXHIBIT A

PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Performance-Based Restricted Stock Unit Agreement have the meanings specified in the Grant Notice or the exhibits to the Grant Notice or, if not defined in the Grant Notice and its exhibits, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of PSUs. The Company has granted the PSUs to Participant effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"). Each PSU represents the right to receive one Share as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the PSUs have vested.

1.2 Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions set forth in the Grant Notice, this Agreement and the Plan, which is incorporated herein by reference.

1.3 Unsecured Promise. The PSUs will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

1.4 Definitions.

(a) "***Assumed***" means that, with respect to the PSUs, an Assumption has occurred in connection with a Change in Control.

(b) "***Cause***" means the occurrence of any one or more of the following events unless, to the extent capable of correction, Participant fully corrects the circumstances constituting Cause within 30 days after receipt of written notice thereof:

(i) Participant's willful failure to substantially perform his lawful and reasonable duties with the Company (other than any such failure resulting from Participant's incapacity due to physical or mental illness or any such actual or anticipated failure after his or her issuance of a notice of termination for Good Reason), after a written demand for performance is delivered to Participant by the Board, which demand specifically identifies the manner in which the Board believes that Participant has not performed his duties, but in all cases excluding conduct or activities undertaken in good faith by Participant in the ordinary course of Participant performing his duties;

(ii) Participant's commission of an act of fraud or material dishonesty, in either case, that could result in material reputational, material economic or material financial injury to the Company;

(iii) Participant's material misappropriation or material embezzlement of the property of the Company or any of its affiliates;

(iv) Participant's commission of, including any entry by Participant of a guilty or no contest plea to, a felony (other than a traffic violation) or other crime involving moral turpitude;

(v) Participant's willful misconduct or gross negligence with respect to any material aspect of the Company's business or a material breach by Participant of his fiduciary duty to the Company, which willful misconduct, gross negligence or material breach has a material and demonstrable adverse effect on the Company;

(vi) Participant's material breach of Participant's obligations under a material written agreement between the Company and Participant (including this Agreement) or of the Company's Business Code of Conduct and Ethics or any other material written Company policy (but in all cases, only if such code or policy was provided to Participant (which includes making such code or policy available on the Company's website or intranet site following electronic notice to Participant that includes a link to such code or policy) a reasonable period in advance of the act constituting the alleged material breach).

(c) "***Disability***" means a permanent and total disability under Code Section 22(e)(3).

(d) "***Good Reason***" means the occurrence of any one or more of the following events without Participant's prior written consent, unless the Company fully corrects the circumstances constituting Good Reason (provided such circumstances are capable of correction) as provided below:

(i) a material diminution in Participant's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities, including (without limitation) Participant's ceasing to be [Chief Executive Officer / President and Chief Operating Officer] of a public company following the occurrence of a Change in Control, but excluding for this purpose any isolated, insubstantial or inadvertent actions not taken in bad faith and which are remedied by the Company promptly after receipt of notice thereof given by Participant;

(ii) a change in the geographic location at which Participant performs his principal duties for the Company to a new location that is more than 30 miles from the location at which Participant performs his principal duties for the Company as of the Grant Date; or

(iii) the Company's material breach of a material written agreement between the Company and Participant (including this Agreement).

Notwithstanding the foregoing, Participant will not be deemed to have resigned for Good Reason unless (1) Participant provides the Company with written notice setting forth in reasonable detail the facts and circumstances claimed by Participant to constitute Good Reason within 90 days after the date of the occurrence of any event that Participant knows or should reasonably have known to constitute Good Reason, (2) the Company fails to cure such acts or omissions within 30 days following its receipt of such notice, and (3) the effective date of Participant's termination for Good Reason occurs no later than 60 days after the expiration of the Company's cure period.

(e) "***Qualifying Termination***" means a termination of Participant's employment either by the Company without Cause or by Participant for Good Reason.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 General Vesting; Forfeiture.

(a) The PSUs will vest based on the achievement of Price Per Share Goals as defined in and as set forth in **Exhibit B**, subject to Participant's continued employment with the Company or its Affiliates through the applicable Vesting Date(s) (as defined in **Exhibit B**), except to the extent specifically provided in Sections 2.2 and 2.3 below.

(b) In no event will Participant vest in more than 100% of the total PSUs granted under this Award (as adjusted for stock dividends, etc.).

(c) Notwithstanding anything to the contrary contained herein, all PSUs that have not become vested prior to or on the Expiration Date automatically will be forfeited and terminated as of the Expiration Date without consideration therefor.

2.2 Change in Control. If (i) a Change in Control occurs during the Performance Period, (ii) Participant remains in continued employment until at least immediately prior to the Change in Control or Participant previously experienced a termination of employment due to his Qualifying Termination or Disability, and (iii) some or all PSUs remain outstanding as of immediately prior to such Change in Control, then the treatment of the PSUs shall be determined as set forth below based on (x) the CIC Price (as defined in **Exhibit B**) and (y) whether the PSUs are Assumed.

(a) If the CIC Price is less than the first Price Per Share Goal (as set forth on **Exhibit B**), but is greater than the Baseline Price, then one-third of the total number of PSUs originally granted (as such number may be adjusted for stock dividends, etc.) shall vest as of immediately prior to the closing of such Change in Control. Notwithstanding the generality of the foregoing, in the event that the first Price Per Share Goal was achieved prior to the Change in Control, no additional PSUs shall become vested pursuant to the preceding sentence but, for the avoidance of doubt, additional PSUs may become vested pursuant to the other provisions of this Agreement.

(b) If a Price Per Share Goal is achieved based on the CIC Price, then the PSUs that are eligible to vest as a result of achieving such Price Per Share Goal shall vest as of immediately prior to the closing of such Change in Control. In addition, if the CIC Price falls between two Price Per Share Goals, then an additional number of PSUs shall vest immediately prior to the closing of such Change in Control equal to a number of PSUs as set forth in the following table:

CIC Price per Share	Number of Additional PSUs that Vest
≥ $120 per Share but < $135 per Share	**50% of the Second Tranche PSUs (as defined on Exhibit B)**
≥ $135 per Share but < $150 per Share	100% of the Second Tranche PSUs
≥ $150 per Share but < $175 per Share	**50% of the Third Tranche PSUs (as defined on Exhibit B)**
≥ $175 per Share	100% of the Third Tranche PSUs

Notwithstanding the generality of the foregoing, in the event that (i) the first Price Per Share Goal was achieved prior to the Change in Control or the PSUs that are eligible to vest as a result of achieving such Price Per Share Goal previously became vested pursuant to Section 2.2(a), no additional PSUs shall become vested pursuant to the first sentence of this Section 2.2(b) with respect to such particular Price Per Share Goal; (ii) the second or third Price Per Share Goal was achieved prior to the Change in Control, no additional PSUs shall become vested pursuant to the first sentence of this Section 2.2(b) with respect to such Price Per Share Goal; and (iii) for clarity, to the extent that any portion of the Second Tranche PSUs or the Third Tranche PSUs remains outstanding and unvested following the accelerated vesting described in the second sentence of this Section 2.2(b), (i.e., because only a portion of the tranche becomes vested in connection with the Change in Control), such PSUs shall remain eligible to vest following the Change in Control if such PSUs are Assumed as set forth in Section 2.2(c).

(c) If, following the application of Sections 2.2(a) and 2.2(b), any PSUs remain outstanding and unvested after the Change in Control occurs and such PSUs are Assumed, then (i) the number of and kind of shares subject to the PSUs shall be adjusted as determined by the Administrator in its sole discretion in order to preserve the material economic and other material rights and interests of Participant under this Award, (ii) the Baseline Price and the Price Per Share Goals set forth on **Exhibit B** shall be equitably adjusted in the sole discretion of the Administrator in order to preserve the material economic and other material rights and interests of Participant under this Award and (iii) such PSUs shall remain outstanding and eligible to vest on the applicable Vesting Date(s) based on the achievement of the Price Per Share Goals (as may be adjusted) or as set forth in Section 2.3 and, with respect to any subsequent Change in Control, Section 2.2.

(d) Notwithstanding anything to the contrary contained in Section 8(d) of the Plan, if, following the application of Sections 2.2(a) and 2.2(b), any PSUs remain outstanding and unvested after the Change in Control occurs, and such PSUs are not Assumed, then such PSUs automatically will be forfeited and terminated as of immediately prior to such Change in Control without consideration therefor.

2.3 Termination of Employment.

(a) If Participant experiences a Qualifying Termination during the Performance Period, then one-third of the total number of PSUs originally granted (as such number may be adjusted for stock dividends, etc.) shall vest as of such termination of employment. Any PSUs that, after application of the preceding sentence, remain unvested as of the date of such Qualifying Termination shall remain outstanding and eligible to vest on the applicable Vesting Date(s) based on the achievement of the Price Per Share Goals set forth on **Exhibit B** (as may be adjusted pursuant to Section 2.2(c)) or pursuant to Section 2.2(a) or (b), as applicable. Such PSUs shall remain outstanding and eligible to vest until the earlier to occur of (i) the Expiration Date and (ii) the six-month anniversary of such termination of employment (such earlier date, the "***Qualifying Termination End Date***"). Notwithstanding the generality of the foregoing, in the event that a Price Per Share Goal was achieved prior to a Qualifying Termination, no additional PSUs shall become vested with respect to such Price Per Share Goal pursuant to the preceding sentence if such Price Per Share Goal again is achieved during the period between and (including) the date of the Qualifying Termination and the Qualifying Termination End Date. To the extent any PSUs have not become vested on or prior to the Qualifying Termination End Date, such PSUs automatically will be forfeited and terminated as of the Qualifying Termination End Date without consideration therefor.

(b) If Participant experiences a termination of employment due to Participant's death during the Performance Period, then any PSUs that remain outstanding and unvested as of such termination of employment shall vest in full.

(c) If Participant experiences a termination of employment due to Participant's Disability during the Performance Period, then any PSUs that remain outstanding and unvested as of such termination of employment shall remain outstanding and eligible to vest on the applicable Vesting Date(s) based on the achievement of the Price Per Share Goals set forth on **Exhibit B** (as may be adjusted pursuant to Section 2.2(c)) or pursuant to Section 2.2(a) or (b), as applicable. Such PSUs shall remain outstanding and eligible to vest until the earlier to occur of (i) the Expiration Date and (ii) the later to occur of (x) the one-year anniversary of such termination of employment and (y) the four-year anniversary of the Grant Date (such earlier date, the "***Disability End Date***"). Notwithstanding the generality of the foregoing, in the event that a Price Per Share Goal was achieved prior to the termination of employment due to Disability, no additional PSUs shall become vested with respect to such Price Per Share Goal pursuant to the preceding sentence if such Price Per Share Goal again is achieved during the period between (and including) the termination date and the Disability End Date. To the extent any PSUs have not become vested on or prior to the Disability End Date, such PSUs automatically will be forfeited and terminated as of the Disability End Date without consideration therefor.

(d) The treatment set forth in each of Sections 2.3(a), (b) and (c) is subject to and conditioned upon Participant's (or Participant's estate's) timely execution, delivery and non-revocation of a general release of claims in the form attached hereto as **Exhibit D** (the "***Release***"). The Release shall be delivered to Participant (or Participant's estate's) within five business days following the termination of employment, and Participant shall have 21 days thereafter (or 45 days, if necessary to comply with Applicable Law) to execute and deliver the Release to the Company. The Company may update the Release attached hereto to the extent necessary to reflect changes in law but without increasing the scope of the Release. In no event shall any covenant or obligation on the part of Participant be added to the Release.

(e) If Participant experiences a termination of employment for any reason other than a Qualifying Termination and other than due to Participant's death or Disability, all PSUs that have not become vested on or prior to the date of such termination of employment automatically will be forfeited and terminated as of the termination date without consideration therefor.

2.4 Settlement.

(a) PSUs will be paid in Shares within 15 days after the vesting of the applicable PSU (or, with respect to PSUs that become vested upon a termination of employment, within five days following the effective date of the Release); provided, however, that in the event that the Administrator reasonably determines in good faith that the Company (after expending commercially reasonable best efforts) shall not be able to effectuate a Net Settlement (as defined below) with respect to some or all of such PSUs due to insufficient cash at the Company, Participant agrees to cooperate in good faith with the Company to determine a mutually agreeable new payment date for any PSUs for which Net Settlement will not apply. Notwithstanding the foregoing, if the vesting and payment of a PSU is subject to execution of the Release, and such Release may be executed and/or revoked in a calendar year following the calendar year in which the payment event occurs, the payment shall be made in the calendar year in which the release revocation period ends, to the extent necessary to comply with Section 409A. In no event shall Shares be paid later than March 15 of the calendar year following the year in which the PSUs vest.

(b) Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulations Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this award of PSUs (the "***Award***") and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company shall withhold, or cause to be withheld, Shares otherwise vesting or issuable under this Award in satisfaction of any applicable tax withholding obligations (a "***Net Settlement***"). The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a fair market value on the date of withholding no greater than the aggregate amount of such liabilities based on the maximum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income. Notwithstanding the foregoing, if, with respect to the vesting of a PSU, the Administrator reasonably and in good faith determines that the Company (after expending commercially reasonable best efforts) is not able to fully satisfy the applicable tax withholding obligations by means of a Net Settlement due to insufficient cash at the Company, then to the extent a Net Settlement is unavailable, the Company shall instruct its designated broker to sell such number of Shares issuable under this Award as is necessary to satisfy the remaining tax withholding obligations (for the Shares for which Net Settlement will not apply), and such broker shall remit cash proceeds of such sale to the Company sufficient to satisfy such tax withholding obligations.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the PSUs, regardless of any action the Company or any Affiliate takes with respect to any tax withholding obligations that arise in connection with the PSUs. Neither the Company nor any Affiliate makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the PSUs or the subsequent sale of Shares. The Company and the Affiliates do not commit and are under no obligation to structure the PSUs to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the PSUs, the Shares subject to the PSUs and the Baseline Price and Price Per Share Goals are subject to adjustment, modification and/or termination in certain events as provided in this Agreement and the Plan. Notwithstanding any contrary provision of the Grant Notice, the Plan or the Agreement, the Administrator's actions in making such adjustments, including (without limitation) under Sections 3(a) and 8(a) – (c) or 8(g) of the Plan and Section 4.10 of the Agreement with respect to this Award at all times shall be intended to preserve the material economic and other material rights and interests of Participant under this Award. Further, for the avoidance of doubt

and without limiting the foregoing in this Section, the Baseline Price and Price Per Share Goals will be adjusted, in such manner to the extent necessary as is equitable, as determined by the Administrator in good faith, in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the PSUs, upon any dividend or other distribution affecting the Common Stock, whether ordinary or extraordinary and whether in the form of cash, stock, other securities, or other property, or upon any other event described in Section 8(b) of the Plan. For the avoidance of doubt, the occurrence of any event described in the foregoing sentence (including as described in Section 8(b) of the Plan, but excluding the issuance of compensatory equity awards granted to a member of the Board, an employee and/or a consultant, in each case, in the ordinary course of business and solely with respect to services provided to the Company or any of its Affiliates, and further excluding the issuance of any shares of Common Stock with respect to the vesting, exercise and/or settlement of any such compensatory equity awards) shall require the Administrator, acting reasonably and in good faith, to determine if an adjustment is necessary or appropriate to prevent the dilution or enlargement of the benefits or potential benefits or material rights intended to be made available under the PSUs, and such adjustment (if any) shall be made by the Administrator in an equitable manner, acting reasonably and in good faith. For purposes of the foregoing sentence, (i) a "consultant" shall mean any consultant or advisor of the Company or any Affiliate who qualifies as a consultant or advisor under the applicable rules of Form S-8 Registration Statement and (ii) if Participant believes that a compensatory equity award is granted outside the ordinary course of business, Participant must raise the issue with the Administrator within 60 days following Participant acquiring knowledge of such award.

4.2 Company Representations. As of the Grant Date, the number of Shares available for issuance under the Plan is equal to or exceeds the aggregate number of Shares issuable hereunder and under the PSU award granted to [Helmy Eltoukhy / AmirAli Talasaz] on even date herewith. The Company shall use its reasonable best efforts to maintain the effectiveness of one or more registration statement(s) on Form S-8 covering the Shares issuable hereunder for so long as the Award remains outstanding.

4.3 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.4 Transferability. Without limiting the generality of any other provision in this Agreement, the PSUs shall be subject to the restrictions on transferability set forth in Section 9(a) of the Plan. In addition, notwithstanding anything to the contrary contained herein, Participant shall not, without the consent of the Administrator (which shall not be unreasonably withheld), sell, pledge, assign, hypothecate, transfer or otherwise dispose of (collectively, "***Transfer***") any Shares delivered under this Agreement prior to the applicable dates set forth in **Exhibit C** (the "***Post-Vesting Transfer Restrictions***"). Notwithstanding the foregoing, the Post-Vesting Transfer Restrictions shall not apply to (i) any Transfer of Shares to the Company, (ii) any Transfer in satisfaction of any tax withholding obligations with respect to the PSUs, (iii) any Transfer following Participant's termination of employment due to death or Disability, including without limitation by will or pursuant to the laws of descent and distribution, or due

to a Qualifying Termination that occurs following a Change in Control, (iv) subject to the consent of the Administrator (which shall not be unreasonably withheld), any Transfer of the Shares to an estate planning vehicle of Participant or (v) any Transfer upon the occurrence of, and in connection with, a Change in Control (or such earlier time as is necessary in order for Participant to participate in such Change in Control transaction with respect to the Shares and receive the consideration payable with respect thereto in connection with such Change in Control). If any Shares are Transferred to an estate planning vehicle of Participant in accordance with the foregoing sentence, then the Shares shall continue to be subject to all terms and conditions set forth herein (including with respect to the Post-Vesting Transfer Restrictions) and Participant and the transferee shall execute any documents reasonably requested by the Administrator to (x) confirm the status of the transferee as an estate planning vehicle of Participant, (y) satisfy any requirements for the Transfer under Applicable Law and (z) evidence such Transfer.

4.5 Clawback. Notwithstanding Section 10(m) of the Plan, the Award and the Shares issuable hereunder shall be subject to any clawback or recoupment policy in effect on the Grant Date or as may be adopted or maintained by the Company to the limited extent required in order to comply with Applicable Law, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder. The Company and Participant acknowledge that neither this Section 4.5 nor Section 10(m) of the Plan are intended to limit any clawback and/or disgorgement of the Award and/or the Shares issuable hereunder pursuant to Section 304 of the Sarbanes-Oxley Act of 2002. For the avoidance of doubt, this Award shall not be subject to any clawback policy (or portion thereof) adopted after the Grant Date to the extent that it exceeds the minimum requirements of any Applicable Law with which the Company is required to comply.

4.6 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.7 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.8 Successors and Assigns. The Company may assign any of its rights under this Agreement to any successor or, in connection with any transaction or event described in Section 8(b) of the Plan, a Parent that is the issuer of the shares underlying the PSUs, and this Agreement will inure to the benefit of such Parent Affiliate or successor. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.9 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, and the PSUs will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.10 Entire Agreement; Amendment. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter

hereof. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however*, that no amendment, modification, suspension or termination of this Agreement shall materially and adversely affect the PSUs without the prior written consent of Participant.

4.11 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.12 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the PSUs, as and when settled pursuant to the terms of this Agreement.

4.13 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Affiliate or interferes with or restricts in any way the rights of the Company and its Affiliates, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or an Affiliate and Participant.

4.14 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

EXHIBIT B
VESTING SCHEDULE

The PSUs will be eligible to vest on each of three potential Vesting Dates during the Performance Period based on the achievement of the Price Per Share Goals set forth in the table below or such other Vesting Dates as specified in Sections 2.2 and 2.3 of the Agreement; provided that, except as set forth in Section 2.2 and 2.3 of the Agreement, Participant has been in continued employment with the Company or its Affiliates from the Grant Date through the applicable Vesting Date.

Price Per Share Goal	Number of PSUs that Vest
$120 per Share	565,192
$150 per Share	**565,191 (the "*Second Tranche PSUs*")**
$200 per Share	**565,191 (the "*Third Tranche PSUs*")**

For the avoidance of doubt, each Price Per Share Goal may be achieved only once during the Performance Period and more than one Price Per Share Goal may be achieved on a particular date. For example, if the first Price Per Share Goal of $120 per Share is determined by the Administrator to have been satisfied on January 1, 2021, the Price Per Share thereafter drops below such level and again reaches $120 per Share during the thirty consecutive calendar day period ending June 30, 2021, no additional PSUs shall vest as a result of reaching the same Price Per Share Goal for a second time. In no event may more than 1,695,574 PSUs vest pursuant to this Award.

"***CIC Price***" means the fair market value of the per Share consideration received by the Company's stockholders in such Change in Control (valued as of the date of the Change in Control). Notwithstanding the foregoing, in the event that consideration is not received by the Company's stockholders in a Change in Control (for example, pursuant to the Company's sale of new shares of its capital stock under Section 11(h)(iii) of the Plan), the CIC Price shall be the per Share consideration paid by the person or persons acting as the acquirer(s) in such Change in Control (valued as of the date of the Change in Control).

"***Performance Period***" means the period beginning on the Grant Date and ending on the Expiration Date.

"***Price Per Share***" means the Fair Market Value of a share of Common Stock; provided, however, that for purposes of determining whether any PSUs become vested in connection with a Change in Control during the Performance Period, then the Price Per Share shall mean the CIC Price.

"***Price Per Share Goal***" means a target Price Per Share as set forth in the table above, and that has been maintained for any 30 consecutive calendar day period during the Performance Period; provided, however, that for purposes of determining whether any PSUs become vested in connection with a Change in Control during the Performance Period, the Price Per Share Goal shall be evaluated, without regard to such 30 consecutive calendar day requirement, as compared to the CIC Price.

"***Vesting Date***" means the first date occurring during the Performance Period in which a Price Per Share Goal is achieved, subject to certification by the Administrator that the applicable Price Per Share Goal has been achieved (provided that no such certification shall be required in the event one or more Price Per Share Goals are achieved as a result of the occurrence of a Change in Control). In the event a PSU vests upon a Change in Control or upon a Qualifying Termination or termination of employment due to death, the "Vesting Date" shall mean the date of such Change in Control, Qualifying Termination or termination of employment due to death, as applicable.

Examples:

1. General. The Fair Market Value of a share of Common Stock exceeds $120 starting on June 1, 2020 and remains in excess of $120 through and including June 30, 2020. The PSUs eligible to vest in accordance with the achievement of such Price Per Share Goal (565,192 PSUs) shall vest as of June 30, 2020, subject to certification by the Administrator.

2. Change in Control; No Prior Achievement of Price Per Share Goal. In connection with a Change in Control, the CIC Price equals $130 per Share. No PSUs have vested prior to the Change in Control. The number of PSUs that become vested in connection with the Change in Control shall equal 847,788 PSUs (which equals 565,192 PSUs that vest based on the achievement of the first Price Per Share Goal and 282,596 PSUs that vest (as set forth in the table in Section 2.2(b)). For the avoidance of doubt, any PSUs that are Assumed in the Change in Control and that do not vest under the preceding sentence (and are not otherwise vested as of the Change in Control) would remain eligible to vest in the future pursuant to the terms of this Agreement.

3. Change in Control; Prior Achievement of Price Per Share Goal. In connection with the first Change in Control to occur after the Grant Date, the CIC Price equals $130 per Share. Prior to the Change in Control, the first Price Per Share Goal ($120 per Share) was achieved and 565,192 PSUs previously vested. The number of PSUs that become vested in connection with the Change in Control shall equal 282,596 PSUs (as set forth in the table in Section 2.2(b)). For the avoidance of doubt, any PSUs that are Assumed in the Change in Control and that do not vest under the preceding sentence (and are not otherwise vested as of the Change in Control) would remain eligible to vest in the future pursuant to the terms of this Agreement.

EXHIBIT C
TRANSFERABILITY SCHEDULE

The Post-Vesting Transfer Restrictions under Section 4.3 of this Agreement shall lapse on the Post-Vesting Transfer Restrictions Lapse Date, as set forth in the table below.

Period in Which the Vesting Date Occurs with Respect to a PSU	**Post-Vesting Transfer Restrictions Lapse Date with Respect to such PSU**
Period beginning on the Grant Date and ending on the three-year anniversary of the Grant Date	One-year anniversary of the applicable Vesting Date
Period beginning on the first day following the three-year anniversary of the Grant Date and ending on the four-year anniversary of the Grant Date	On the later of: (i) the four-year anniversary of the Grant Date and (ii) the six-month anniversary of the applicable Vesting Date
Period beginning on the first day following the four-year anniversary of the Grant Date and ending on the Expiration Date	On the six-month anniversary of the applicable Vesting Date

EXHIBIT D
GENERAL RELEASE

1. Release. For valuable consideration, the receipt and adequacy of which are hereby acknowledged, the undersigned does hereby release and forever discharge the "***Releasees***" hereunder, consisting of Guardant Health, Inc. (the "***Company***"), and the Company's subsidiaries, affiliates, successors, assigns, agents, directors, officers, employees, representatives, lawyers, insurers, and all persons acting by, through, under or in concert with them, or any of them, of and from any and all manner of action or actions, cause or causes of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liability, claims, demands, damages, losses, costs, attorneys' fees or expenses, of any nature whatsoever, known or unknown, fixed or contingent (hereinafter called "***Claims***"), which the undersigned now has or may hereafter have against the Releasees, or any of them, arising from, based upon or relating to the undersigned's employment or termination of that employment from the beginning of the undersigned's employment with the Company, or by reason of any other matter, cause or thing whatsoever, in each case, to the date hereof. The Claims released herein include, without limiting the generality of the foregoing, any Claims with respect to any alleged breach of any express or implied contract of employment; any alleged torts or other alleged legal restrictions on Releasees' right to terminate the employment of the undersigned; and any alleged violation of any federal, state or local statute or ordinance including, without limitation, Title VII of the Civil Rights Act of 1964, the Age Discrimination In Employment Act ("***ADEA***"), the Americans With Disabilities Act.

2. Claims Not Released. Notwithstanding the foregoing, this general release (the "***Release***") shall not operate to release any rights or claims of the undersigned (i) to payments or benefits under that certain Performance-Based Restricted Stock Unit Grant Notice and Award Agreement dated as of May 26, 2020, between the Company and the undersigned, with respect to the payments and benefits provided in exchange for this Release or that previously vested but remain unpaid [or to payments and benefits provided under the Company's Executive Severance Plan in exchange for this Release][1], (ii) to payments or benefits under any other equity award agreement between the undersigned and the Company, (iii) to accrued or vested benefits the undersigned may have, if any, as of the date hereof under any applicable plan, policy, practice, program, contract or agreement with the Company, (iv) to any Claims, including claims for indemnification and/or advancement of expenses arising under any indemnification agreement between the undersigned and the Company or under the bylaws, certificate of incorporation or other similar governing document of the Company, (v) to any Claims which cannot be waived by an employee under applicable law, (vi) with respect to the undersigned's right to communicate directly with, cooperate with, or provide information to, any federal, state or local government regulator, or (vii) as a shareholder or similar of the Company or any affiliate.

3. Unknown Claims.

THE UNDERSIGNED ACKNOWLEDGES THAT THE UNDERSIGNED HAS BEEN ADVISED BY LEGAL COUNSEL AND IS FAMILIAR WITH THE PROVISIONS OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

> "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND

[1] Include if applicable.

THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

THE UNDERSIGNED, BEING AWARE OF SAID CODE SECTION, HEREBY EXPRESSLY WAIVES ANY RIGHTS THE UNDERSIGNED MAY HAVE THEREUNDER, AS WELL AS UNDER ANY OTHER STATUTES OR COMMON LAW PRINCIPLES OF SIMILAR EFFECT.

4. Exceptions. Notwithstanding anything in this Release to the contrary, nothing contained in this Release shall prohibit the undersigned from (i) filing a charge with, reporting possible violations of federal law or regulation to, participating in any investigation by, or cooperating with any governmental agency or entity or making other disclosures that are protected under the whistleblower provisions of applicable law or regulation and/or (ii) communicating directly with, cooperating with, or providing information (including trade secrets) in confidence to, any federal, state or local government agency or commission (including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, or the U.S. Department of Justice) for the purpose of reporting or investigating a suspected violation of law, or from providing trade secret information to the undersigned's attorney or in a sealed complaint or other document filed in a lawsuit or other governmental proceeding. Pursuant to 18 USC Section 1833(b), the undersigned will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (x) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (y) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

5. Representations. The undersigned represents and warrants that there has been no assignment or other transfer of any interest in any Claim which the undersigned may have against Releasees, or any of them.

6. No Action. The undersigned agrees that if the undersigned hereafter commences any suit arising out of, based upon, or relating to any of the Claims released hereunder or in any manner asserts against Releasees, or any of them, any of the Claims released hereunder, unless such suit or Claim constitutes a legal action by the undersigned challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA or the Older Worker's Benefit Protection Act and the Age Discrimination in Employment Act ("***OWBPA***"), if applicable, then the undersigned agrees that the Releasees may recover costs incurred by the Releasees in defending or otherwise responding to said suit or Claim, the Company may cease providing the consideration provided to the undersigned under this Release and/or the Releasees may obtain damages, except as provided by law.

7. No Admission. The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees, or any of them.

8. OWBPA. The undersigned agrees and acknowledges that this Release constitutes a knowing and voluntary waiver and release of all Claims the undersigned has or may have against the Company and/or any of the Releasees as set forth herein, including, but not limited to, all Claims arising under the OWBPA. In accordance with the Older Worker's Benefit Protection Act, the undersigned is hereby advised as follows:

(i) the undersigned has read the terms of this Release, and understands its terms and effects, including the fact that the undersigned agreed to release and forever discharge the Company and each of the Releasees, from any Claims released in this Release;

(ii) the undersigned understands that, by entering into this Release, the undersigned does not waive any Claims that may arise after the date of the undersigned's execution of this Release, including without limitation any rights or claims that the undersigned may have to secure enforcement of the terms and conditions of this Release;

(iii) the undersigned has signed this Release voluntarily and knowingly in exchange for the consideration described in this Release, which the undersigned acknowledges is adequate and satisfactory to the undersigned and which the undersigned acknowledges is in addition to any other benefits to which the undersigned is otherwise entitled;

(iv) the Company advises the undersigned to consult with an attorney prior to executing this Release;

(v) the undersigned has been given at least [21][2] days in which to review and consider this Release [and the accompanying OWBPA-required exhibits][3]. To the extent that the undersigned chooses to sign this Release prior to the expiration of such period, the undersigned acknowledges that the undersigned has done so voluntarily, had sufficient time to consider the Release, to consult with counsel and that the undersigned does not desire additional time and hereby waives the remainder of the [21]-day period; and

(vi) the undersigned may revoke this Release within seven days from the date the undersigned signs this Release and this Release will become effective upon the expiration of that revocation period. If the undersigned revokes this Release during such seven-day period, this Release will be null and void and of no force or effect on either the Company or the undersigned and the undersigned will not be entitled to any of the payments or benefits which are expressly conditioned upon the execution and non-revocation of this Release. Any revocation must be in writing and sent to [*name*], via electronic mail at [*email address*], on or before 5:00 p.m. Pacific time on the seventh day after this Release is executed by the undersigned.

9. Governing Law. This Release is deemed made and entered into in the State of California, and in all respects shall be interpreted, enforced and governed under the internal laws of the State of California, to the extent not preempted by federal law.

IN WITNESS WHEREOF, the undersigned has executed this Release this ____ day of _____, ____.

_____
[Helmy Eltoukhy / AmirAli Talasaz]

[2] Refer to 45 days in a group termination.

[3] To be included in a group termination.

GUARDANT HEALTH, INC.
2018 INCENTIVE AWARD PLAN

PERFORMANCE-BASED RESTRICTED STOCK UNIT GRANT NOTICE

Guardant Health, Inc., a Delaware corporation (the "***Company***"), has granted to the participant listed below ("***Participant***") the performance-based Restricted Stock Units (the "***PSUs***") described in this Performance-Based Restricted Stock Unit Grant Notice (this "***Grant Notice***"), subject to the terms and conditions of the 2018 Incentive Award Plan (as amended from time to time, the "***Plan***"), the Performance-Based Restricted Stock Unit Agreement attached as **Exhibit A** and the Vesting Schedule attached as **Exhibit B** (**Exhibits A** and **B** collectively, the "***Agreement***"), all of which are incorporated into this Grant Notice by reference. Capitalized terms not specifically defined in this Grant Notice or the Agreement have the meanings given to them in the Plan.

Participant:	[_____]
Grant Date:	[_____]
Number of PSUs:	[_____]
Vesting Schedule:	**Exhibit B**

By accepting (whether in writing, electronically or otherwise) the PSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Subject to the terms of this Grant Notice and the Agreement, Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

GUARDANT HEALTH, INC.	**PARTICIPANT**
By:	
Name:	[Participant Name]
Title:	

EXHIBIT A
PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Performance-Based Restricted Stock Unit Agreement have the meanings specified in the Grant Notice or the exhibits to the Grant Notice or, if not defined in the Grant Notice and its exhibits, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of PSUs and Dividend Equivalents.

(a) The Company has granted the PSUs to Participant effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"). Each PSU represents the right to receive one Share as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the PSUs have vested.

(b) The Company hereby grants to Participant, with respect to each PSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable PSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "***Dividend Equivalent Account***") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid. Any Dividend Equivalents granted in connection with the PSUs issued hereunder, and any amounts that may become distributable in respect thereof, shall be treated separately from such PSUs and the rights arising in connection therewith for purposes of the designation of time and form of payments required by Section 409A.

1.2 Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions set forth in the Grant Notice, this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The PSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 General Vesting; Forfeiture.

(a) The PSUs will vest based on the achievement of the Performance Goals as defined in and as set forth in **Exhibit B**, subject to the terms and conditions set forth on **Exhibit B**. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the PSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

(b) In no event will Participant vest in more than 100% of the total PSUs granted under this Award (as adjusted for stock dividends, etc.).

2.2 Notwithstanding anything to the contrary contained herein, except to the extent otherwise approved by the Administrator, the PSUs will be subject to automatic termination and forfeiture (i) if the Performance Goals have not been timely achieved in accordance with **Exhibit B** and (ii) upon Participant's Termination of Service other than a Qualifying Termination (as defined in **Exhibit B**).

2.3 Settlement.

(a) Vested PSUs and vested Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares as soon as administratively practicable after the applicable Payment Date, but in no event more than 30 days after such Payment Date. The exact payment date of PSUs and Dividend Equivalents shall be determined by the Company in its sole discretion and Participant shall not have a right to designate the time of payment.

(b) Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulations Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(c) If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this award of PSUs (the "***Award***") and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company shall withhold, or cause to be withheld, Shares otherwise vesting or issuable under this Award (including the PSUs or Dividend Equivalents) in satisfaction of any applicable tax withholding obligations. The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a fair market value on the date of withholding no greater than the aggregate amount of such liabilities based on the maximum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income. To the extent that any Federal Insurance Contributions Act tax withholding obligations arise in connection with the PSUs prior to the applicable settlement date, the payment of a portion of the award of PSUs shall be accelerated in an amount sufficient to satisfy (but not in excess of) such tax withholding obligations and any tax withholding obligations associated with any such accelerated payment, and the Company shall withhold such amounts in satisfaction of such withholding obligations.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the PSUs and the Dividend Equivalents, regardless of any action the

Company or any Affiliate takes with respect to any tax withholding obligations that arise in connection with the PSUs or Dividend Equivalents. Neither the Company nor any Affiliate makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the PSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Affiliates do not commit and are under no obligation to structure the PSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISION

4.1 Adjustments. Participant acknowledges that the PSUs, the Shares subject to the PSUs and the Dividend Equivalents are subject to adjustment, modification and/or termination in certain events as provided in this Agreement and the Plan.

4.2 Section 409A.

(a) To the extent applicable, this Agreement shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder ("***Section 409A***"), including without limitation any such regulations or other guidance that may be issued after the effective date of this Agreement. Notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the PSUs or Dividend Equivalents (or any portion thereof, respectively) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for the PSUs or Dividend Equivalents, as applicable, to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

(b) Notwithstanding anything to the contrary in this Agreement, no amounts shall be paid to Participant under this Agreement during the six (6)-month period following Participant's "separation from service" within the meaning of Section 409A (a "***Separation from Service***") to the extent that the Administrator determines that Participant is a "specified employee" (within the meaning of Section 409A) at the time of such Separation from Service and that paying such amounts at the time or times indicated in this Agreement would be a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code. If the payment of any such amounts is delayed as a result of the previous sentence, then on the first business day following the end of such six (6)-month period (or such earlier date upon which such amount can be paid under Section 409A without being subject to such additional taxes), the Company shall pay to Participant in a lump-sum all amounts that would have otherwise been payable to Participant during such six (6)-month period under this Agreement.

4.3 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post

office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.4 Clawback. The Award and the Shares issuable hereunder shall be subject to any clawback or recoupment policy in effect on the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder.

4.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.6 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.7 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.8 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the PSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.9 Entire Agreement; Amendment. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however*, that no amendment, modification, suspension or termination of this Agreement shall materially and adversely affect the PSUs without the prior written consent of Participant.

4.10 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.11 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the

Shares as a general unsecured creditor with respect to the PSUs and the Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.12 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Affiliate or interferes with or restricts in any way the rights of the Company and its Affiliates, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or an Affiliate and Participant.

4.13 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

EXHIBIT B
VESTING SCHEDULE

Lunar 2 Launch

50% of the PSUs shall become Performance-Vested PSUs upon the first date during the Performance Period that the *Lunar 2 Launch* Goal has been achieved, and following achievement of the *Lunar 2 Launch Goal*, 50% of the PSUs shall become Performance-Vested PSUs upon the date during the Performance Period that the Lunar 2 Launch Goal has been achieved (each such date, an "***Achievement Date***"), in either case, subject to certification by the Administrator of such achievement. Any Performance-Vested PSUs shall vest in full on the six month anniversary of the applicable Achievement Date (each, a "***Payment Date***"), subject to Participant's continued employment with the Company or its Affiliates through the applicable Payment Date. Notwithstanding the foregoing, if Participant experiences a Qualifying Termination following an Achievement Date but prior to the corresponding Payment Date, then, subject to Participant's (or Participant's estate's) execution and delivery of a general release of claims against the Company in a form acceptable to the Company that becomes effective and irrevocable within 60 days following such Qualifying Termination, the PSUs that became Performance-Vested PSUs on such Achievement Date shall vest in full upon the date of such Qualifying Termination and shall remain outstanding to be settled in accordance with Section 2.3(a) of the Agreement. If an Achievement Date does not occur on or prior to the last day of the Performance Period, except to the extent otherwise approved by the Administrator, the corresponding PSUs will automatically be forfeited and terminated as of last day of the Performance Period without consideration therefor.

"***Annual Revenue Run Rate***" means the Company's trailing four quarters' aggregate revenues as reported in its Form 10-Q or Form 10-K filed with Securities and Exchange Commission as reported in US Generally Accepted Account Principles, commencing with and including the fourth quarter of calendar year 2020, but excluding any revenue with respect to any four-quarter period that is attributable to Inorganic Growth Revenue to the extent such Inorganic Growth Revenue exceeds $50,000,000.

"***Cause***" means the occurrence of any one or more of the following events unless, to the extent capable of correction, Participant fully corrects the circumstances constituting Cause within 15 days after receipt of written notice thereof: (i) Participant's willful failure to substantially perform his or her duties with the Company (other than any such failure resulting from Participant's incapacity due to physical or mental illness or any such actual or anticipated failure after his or her issuance of a notice of termination for Good Reason), after a written demand for performance is delivered to Participant by the Administrator, which demand specifically identifies the manner in which the Administrator believes that Participant has not performed his or her duties; (ii) Participant's commission of an act of fraud or material dishonesty resulting in reputational, economic or financial injury to the Company; (iii) Participant's material misappropriation or embezzlement of the property of the Company or any of its affiliates; (iv) Participant's commission of, including any entry by Participant of a guilty or no contest plea to, a felony (other than a traffic violation) or other crime involving moral turpitude; (v) Participant's willful misconduct or gross negligence with respect to any material aspect of the Company's business or a material breach by Participant of his or her fiduciary duty to the Company, which willful misconduct, gross negligence or material breach has a material and demonstrable adverse effect on the Company; or (vi) Participant's material breach of Participant's obligations under a written agreement between the Company and Participant.

"***Good Reason***" means the occurrence of any one or more of the following events without Participant's prior written consent, unless the Company fully corrects the circumstances constituting Good Reason (provided such circumstances are capable of correction): (i) a material diminution in Participant's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities, excluding for this purpose any isolated, insubstantial or inadvertent actions not taken in bad faith and which are remedied by the Company promptly after receipt of notice thereof given by Participant; (ii) the Company's material reduction of Participant's annual base salary, as the same may be increased from time to time, other than as a result of a proportionate, across-the-board reduction of base compensation payable to similarly situated employees of Participant; or (iii) a material change in the geographic location at which Participant performs

his or her principal duties for the Company to a new location that is more than 30 miles from the location at which Participant performs his or her principal duties for the Company as of the Grant Date. Notwithstanding the foregoing, Participant will not be deemed to have resigned for Good Reason unless (1) Participant provides the Company with written notice setting forth in reasonable detail the facts and circumstances claimed by Participant to constitute Good Reason within 90 days after the date of the occurrence of any event that Participant knows or should reasonably have known to constitute Good Reason, (2) the Company fails to cure such acts or omissions within 30 days following its receipt of such notice, and (3) the effective date of Participant's termination for Good Reason occurs no later than 60 days after the expiration of the Company's cure period.

"***Inorganic Growth Revenue***" means revenue earned from the sale of products or services that were acquired, whether as a single asset or a whole company.

"***Lunar 2 Launch Goal***" means the Company's receipt of the first TRF for the Company's CRC IVD product.

"***Performance Goals***" shall mean the Lunar 2 Launch Goal and the Revenue Goal.

"***Performance Period***" means the period commencing on the Grant Date and ending on the fourth anniversary of the Grant Date.

"***Performance-Vested PSUs***" means PSUs for which [a Performance Goal has] been achieved.

"***Qualifying Termination***" shall mean Participant's Separation from Service by reason of a termination of employment by the Company without Cause, by Participant for Good Reason or due to Participant's death.

"***Revenue Goal***" shall mean the Company's Annual Revenue Run Rate equaling or exceeding $600,000,000.

GUARDANT HEALTH, INC.
2018 INCENTIVE AWARD PLAN

PERFORMANCE-BASED RESTRICTED STOCK UNIT GRANT NOTICE

Guardant Health, Inc., a Delaware corporation (the "***Company***"), has granted to the participant listed below ("***Participant***") the performance-based Restricted Stock Units (the "***PSUs***") described in this Performance-Based Restricted Stock Unit Grant Notice (this "***Grant Notice***"), subject to the terms and conditions of the 2018 Incentive Award Plan (as amended from time to time, the "***Plan***"), the Performance-Based Restricted Stock Unit Agreement attached as **Exhibit A** and the Vesting Schedule attached as **Exhibit B** (**Exhibits A** and **B** collectively, the "***Agreement***"), all of which are incorporated into this Grant Notice by reference. Capitalized terms not specifically defined in this Grant Notice or the Agreement have the meanings given to them in the Plan.

Participant:	[_____]
Grant Date:	[_____]
Number of PSUs:	[_____]
Vesting Schedule:	**Exhibit B**

By accepting (whether in writing, electronically or otherwise) the PSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Subject to the terms of this Grant Notice and the Agreement, Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

GUARDANT HEALTH, INC.	**PARTICIPANT**
By:	
Name:	[Participant Name]
Title:	

EXHIBIT A
PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Performance-Based Restricted Stock Unit Agreement have the meanings specified in the Grant Notice or the exhibits to the Grant Notice or, if not defined in the Grant Notice and its exhibits, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of PSUs and Dividend Equivalents.

(a) The Company has granted the PSUs to Participant effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"). Each PSU represents the right to receive one Share as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the PSUs have vested.

(b) The Company hereby grants to Participant, with respect to each PSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable PSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "***Dividend Equivalent Account***") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid. Any Dividend Equivalents granted in connection with the PSUs issued hereunder, and any amounts that may become distributable in respect thereof, shall be treated separately from such PSUs and the rights arising in connection therewith for purposes of the designation of time and form of payments required by Section 409A.

1.2 Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions set forth in the Grant Notice, this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The PSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 General Vesting; Forfeiture.

(a) The PSUs will vest based on the achievement of the Performance Goals as defined in and as set forth in **Exhibit B**, subject to the terms and conditions set forth on **Exhibit B**. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the PSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

(b) In no event will Participant vest in more than 100% of the total PSUs granted under this Award (as adjusted for stock dividends, etc.).

2.2 Notwithstanding anything to the contrary contained herein, except to the extent otherwise approved by the Administrator, the PSUs will be subject to automatic termination and forfeiture (i) if the Performance Goals have not been timely achieved in accordance with **Exhibit B** and (ii) upon Participant's Termination of Service other than a Qualifying Termination (as defined in **Exhibit B**).

2.3 Settlement.

(a) Vested PSUs and vested Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares as soon as administratively practicable after the applicable Payment Date, but in no event more than 30 days after such Payment Date. The exact payment date of PSUs and Dividend Equivalents shall be determined by the Company in its sole discretion and Participant shall not have a right to designate the time of payment.

(b) Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulations Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(c) If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this award of PSUs (the "***Award***") and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company shall withhold, or cause to be withheld, Shares otherwise vesting or issuable under this Award (including the PSUs or Dividend Equivalents) in satisfaction of any applicable tax withholding obligations. The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a fair market value on the date of withholding no greater than the aggregate amount of such liabilities based on the maximum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income. To the extent that any Federal Insurance Contributions Act tax withholding obligations arise in connection with the PSUs prior to the applicable settlement date, the payment of a portion of the award of PSUs shall be accelerated in an amount sufficient to satisfy (but not in excess of) such tax withholding obligations and any tax

withholding obligations associated with any such accelerated payment, and the Company shall withhold such amounts in satisfaction of such withholding obligations.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the PSUs and the Dividend Equivalents, regardless of any action the Company or any Affiliate takes with respect to any tax withholding obligations that arise in connection with the PSUs or Dividend Equivalents. Neither the Company nor any Affiliate makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the PSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Affiliates do not commit and are under no obligation to structure the PSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the PSUs, the Shares subject to the PSUs and the Dividend Equivalents are subject to adjustment, modification and/or termination in certain events as provided in this Agreement and the Plan.

4.2 Section 409A.

(a) To the extent applicable, this Agreement shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder ("***Section 409A***"), including without limitation any such regulations or other guidance that may be issued after the effective date of this Agreement. Notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the PSUs or Dividend Equivalents (or any portion thereof, respectively) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for the PSUs or Dividend Equivalents, as applicable, to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

(b) Notwithstanding anything to the contrary in this Agreement, no amounts shall be paid to Participant under this Agreement during the six (6)-month period following Participant's "separation from service" within the meaning of Section 409A (a "***Separation from Service***") to the extent that the Administrator determines that Participant is a "specified employee" (within the meaning of Section 409A) at the time of such Separation from Service and that paying such amounts at the time or times indicated in this Agreement would be a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code. If the payment of any such amounts is delayed as a result of the previous sentence, then on the first business day following the end of such six (6)-month period (or such earlier date upon which such amount can be paid under Section 409A without being subject to such additional taxes), the Company shall pay to Participant in a lump-sum all amounts that would have otherwise been payable to Participant during such six (6)-month period under this Agreement.

4.3 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.4 Clawback. The Award and the Shares issuable hereunder shall be subject to any clawback or recoupment policy in effect on the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder.

4.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.6 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.7 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.8 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the PSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.9 Entire Agreement; Amendment. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however*, that no amendment, modification, suspension or termination of this Agreement shall materially and adversely affect the PSUs without the prior written consent of Participant.

4.10 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.11 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the PSUs and the Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.12 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Affiliate or interferes with or restricts in any way the rights of the Company and its Affiliates, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or an Affiliate and Participant.

4.13 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

EXHIBIT B
VESTESTING SCHEDULE

Revenue Goal

50% of the PSUs shall become Performance-Vested PSUs upon the first date during the Performance Period that the Revenue Goal has been achieved, and following achievement of the Revenue Goal, 50% of the PSUs shall become Performance-Vested PSUs upon the date during the Performance Period that the Lunar 2 Launch Goal has been achieved (each such date, an "***Achievement Date***"), in either case, subject to certification by the Administrator of such achievement. Any Performance-Vested PSUs shall vest in full on the six month anniversary of the applicable Achievement Date (each, a "***Payment Date***"), subject to Participant's continued employment with the Company or its Affiliates through the applicable Payment Date. Notwithstanding the foregoing, if Participant experiences a Qualifying Termination following an Achievement Date but prior to the corresponding Payment Date, then, subject to Participant's (or Participant's estate's) execution and delivery of a general release of claims against the Company in a form acceptable to the Company that becomes effective and irrevocable within 60 days following such Qualifying Termination, the PSUs that became Performance-Vested PSUs on such Achievement Date shall vest in full upon the date of such Qualifying Termination and shall remain outstanding to be settled in accordance with Section 2.3(a) of the Agreement. If an Achievement Date does not occur on or prior to the last day of the Performance Period, except to the extent otherwise approved by the Administrator, the corresponding PSUs will automatically be forfeited and terminated as of last day of the Performance Period without consideration therefor.

"***Annual Revenue Run Rate***" means the Company's trailing four quarters' aggregate revenues as reported in its Form 10-Q or Form 10-K filed with Securities and Exchange Commission as reported in US Generally Accepted Account Principles, commencing with and including the fourth quarter of calendar year 2020, but excluding any revenue with respect to any four-quarter period that is attributable to Inorganic Growth Revenue to the extent such Inorganic Growth Revenue exceeds $50,000,000.

"***Cause***" means the occurrence of any one or more of the following events unless, to the extent capable of correction, Participant fully corrects the circumstances constituting Cause within 15 days after receipt of written notice thereof: (i) Participant's willful failure to substantially perform his or her duties with the Company (other than any such failure resulting from Participant's incapacity due to physical or mental illness or any such actual or anticipated failure after his or her issuance of a notice of termination for Good Reason), after a written demand for performance is delivered to Participant by the Administrator, which demand specifically identifies the manner in which the Administrator believes that Participant has not performed his or her duties; (ii) Participant's commission of an act of fraud or material dishonesty resulting in reputational, economic or financial injury to the Company; (iii) Participant's material misappropriation or embezzlement of the property of the Company or any of its affiliates; (iv) Participant's commission of, including any entry by Participant of a guilty or no contest plea to, a felony (other than a traffic violation) or other crime involving moral turpitude; (v) Participant's willful misconduct or gross negligence with respect to any material aspect of the Company's business or a material breach by Participant of his or her fiduciary duty to the Company, which willful misconduct, gross negligence or material breach has a material and demonstrable adverse effect on the Company; or (vi) Participant's material breach of Participant's obligations under a written agreement between the Company and Participant.

"***Good Reason***" means the occurrence of any one or more of the following events without Participant's prior written consent, unless the Company fully corrects the circumstances constituting Good Reason (provided such circumstances are capable of correction): (i) a material diminution in Participant's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities, excluding for this purpose any isolated, insubstantial or inadvertent actions not taken in bad faith and which are remedied by the Company promptly after receipt of notice thereof given by Participant; (ii) the Company's material reduction of Participant's annual base salary, as the same may be increased from time to time, other than as a

result of a proportionate, across-the-board reduction of base compensation payable to similarly situated employees of Participant; or (iii) a material change in the geographic location at which Participant performs his or her principal duties for the Company to a new location that is more than 30 miles from the location at which Participant performs his or her principal duties for the Company as of the Grant Date. Notwithstanding the foregoing, Participant will not be deemed to have resigned for Good Reason unless (1) Participant provides the Company with written notice setting forth in reasonable detail the facts and circumstances claimed by Participant to constitute Good Reason within 90 days after the date of the occurrence of any event that Participant knows or should reasonably have known to constitute Good Reason, (2) the Company fails to cure such acts or omissions within 30 days following its receipt of such notice, and (3) the effective date of Participant's termination for Good Reason occurs no later than 60 days after the expiration of the Company's cure period.

"***Inorganic Growth Revenue***" means revenue earned from the sale of products or services that were acquired, whether as a single asset or a whole company.

"***Lunar 2 Launch Goal***" means the Company's receipt of the first TRF for the Company's CRC IVD product.

"***Performance Goals***" shall mean the Lunar 2 Launch Goal and the Revenue Goal.

"***Performance Period***" means the period commencing on the Grant Date and ending on the fourth anniversary of the Grant Date.

"***Performance-Vested PSUs***" means PSUs for which a Performance Goal has been achieved.

"***Qualifying Termination***" shall mean Participant's Separation from Service by reason of a termination of employment by the Company without Cause, by Participant for Good Reason or due to Participant's death.

"***Revenue Goal***" shall mean the Company's Annual Revenue Run Rate equaling or exceeding $600,000,000.

GUARDANT HEALTH, INC.
2018 INCENTIVE AWARD PLAN

PERFORMANCE-based restricted STOCK Unit Grant Notice

Guardant Health, Inc., a Delaware corporation (the "***Company***"), has granted to the participant listed below ("***Participant***") the performance-based Restricted Stock Units (the "***PSUs***") described in this Performance-Based Restricted Stock Unit Grant Notice (this "***Grant Notice***"), subject to the terms and conditions of the 2018 Incentive Award Plan (as amended from time to time, the "***Plan***"), the Performance-Based Restricted Stock Unit Agreement attached as **Exhibit A** and the Vesting Schedule attached as **Exhibit B** (**Exhibits A** and **B** collectively, the "***Agreement***"), all of which are incorporated into this Grant Notice by reference. Capitalized terms not specifically defined in this Grant Notice or the Agreement have the meanings given to them in the Plan.

Participant:	[_____]
Grant Date:	[_____]
Number of PSUs:	[_____]
Vesting Schedule:	**Exhibit B**

By accepting (whether in writing, electronically or otherwise) the PSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Subject to the terms of this Grant Notice and the Agreement, Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

GUARDANT HEALTH, INC.	**PARTICIPANT**
By:	
Name:	[Participant Name]
Title:	

EXHIBIT A
Performance-BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Performance-Based Restricted Stock Unit Agreement have the meanings specified in the Grant Notice or the exhibits to the Grant Notice or, if not defined in the Grant Notice and its exhibits, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of PSUs and Dividend Equivalents.

(a) The Company has granted the PSUs to Participant effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"). Each PSU represents the right to receive one Share as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the PSUs have vested.

(b) The Company hereby grants to Participant, with respect to each PSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable PSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "***Dividend Equivalent Account***") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid. Any Dividend Equivalents granted in connection with the PSUs issued hereunder, and any amounts that may become distributable in respect thereof, shall be treated separately from such PSUs and the rights arising in connection therewith for purposes of the designation of time and form of payments required by Section 409A.

1.2 Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions set forth in the Grant Notice, this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The PSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.
VESTING; forfeiture AND SETTLEMENT

2.1 General Vesting; Forfeiture.

(a) The PSUs will vest based on the achievement of the Performance Goals as defined in and as set forth in **Exhibit B**, subject to the terms and conditions set forth on **Exhibit B**. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the PSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

(b) In no event will Participant vest in more than 100% of the total PSUs granted under this Award (as adjusted for stock dividends, etc.).

2.2 Notwithstanding anything to the contrary contained herein, except to the extent otherwise approved by the Administrator, the PSUs will be subject to automatic termination and forfeiture (i) if the Performance Goals have not been timely achieved in accordance with **Exhibit B** and (ii) upon Participant's Termination of Service other than a Qualifying Termination (as defined in **Exhibit B**).

2.3 Settlement.

(a) Vested PSUs and vested Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares as soon as administratively practicable after the applicable Payment Date, but in no event more than 30 days after such Payment Date. The exact payment date of PSUs and Dividend Equivalents shall be determined by the Company in its sole discretion and Participant shall not have a right to designate the time of payment.

(b) Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulations Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(c) If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this award of PSUs (the "***Award***") and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company shall withhold, or cause to be withheld, Shares otherwise vesting or issuable under this Award (including the PSUs or Dividend Equivalents) in satisfaction of any applicable tax withholding obligations. The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a fair market value on the date of withholding no greater than the aggregate amount of such liabilities based on the maximum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income. To the extent that any Federal Insurance Contributions Act tax withholding obligations arise in connection with the PSUs prior to the applicable settlement date, the payment of a portion of the award of PSUs shall be accelerated in an amount sufficient to satisfy (but not in excess of) such tax withholding obligations and any tax withholding obligations associated with any such accelerated payment, and the Company shall withhold such amounts in satisfaction of such withholding obligations.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the PSUs and the Dividend Equivalents, regardless of any action the Company or any Affiliate takes with respect to any tax withholding obligations that arise in connection with the PSUs or Dividend Equivalents. Neither the Company nor any Affiliate makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the PSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Affiliates do not commit and are under no obligation to structure the PSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the PSUs, the Shares subject to the PSUs and the Dividend Equivalents are subject to adjustment, modification and/or termination in certain events as provided in this Agreement and the Plan.

4.2 Section 409A.

(a) To the extent applicable, this Agreement shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder ("***Section 409A***"), including without limitation any such regulations or other guidance that may be issued after the effective date of this Agreement. Notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the PSUs or Dividend Equivalents (or any portion thereof, respectively) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for the PSUs or Dividend Equivalents, as applicable, to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

(b) Notwithstanding anything to the contrary in this Agreement, no amounts shall be paid to Participant under this Agreement during the six (6)-month period following Participant's "separation from service" within the meaning of Section 409A (a "***Separation from Service***") to the extent that the Administrator determines that Participant is a "specified employee" (within the meaning of Section 409A) at the time of such Separation from Service and that paying such amounts at the time or times indicated in this Agreement would be a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code. If the payment of any such amounts is delayed as a result of the previous sentence, then on the first business day following the end of such six (6)-month period (or such earlier date upon which such amount can be paid under Section 409A without being subject to such additional taxes), the Company shall pay to Participant in a lump-sum all amounts that would have otherwise been payable to Participant during such six (6)-month period under this Agreement.

4.3 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at

Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.4 Clawback. The Award and the Shares issuable hereunder shall be subject to any clawback or recoupment policy in effect on the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder.

4.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.6 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.7 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.8 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the PSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.9 Entire Agreement; Amendment. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however*, that no amendment, modification, suspension or termination of this Agreement shall materially and adversely affect the PSUs without the prior written consent of Participant.

4.10 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.11 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any

underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the PSUs and the Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.12 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Affiliate or interferes with or restricts in any way the rights of the Company and its Affiliates, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or an Affiliate and Participant.

4.13 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

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EXHIBIT B
VESTING SCHEDULE

Revenue Goal + Lunar 2 Launch

The PSUs shall become Performance-Vested PSUs upon the first date during the Performance Period that both the Revenue Goal and the Lunar 2 Launch Goal have been achieved (the "***Achievement Date***"), subject to certification by the Administrator of such achievement. Any Performance-Vested PSUs shall vest in full on the six month anniversary of the Achievement Date (the "***Payment Date***"), subject to Participant's continued employment with the Company or its Affiliates through the Payment Date. Notwithstanding the foregoing, if Participant experiences a Qualifying Termination on or following the Achievement Date but prior to the Payment Date, then, subject to Participant's (or Participant's estate's) execution and delivery of a general release of claims against the Company in a form acceptable to the Company that becomes effective and irrevocable within 60 days following such Qualifying Termination, the PSUs shall vest in full upon the date of such Qualifying Termination and shall remain outstanding to be settled after the Payment Date in accordance with Section 2.3(a) of the Agreement. If the Achievement Date does not occur on or prior to the last day of the Performance Period, except to the extent otherwise approved by the Administrator, the PSUs will automatically be forfeited and terminated as of the last day of the Performance Period without consideration therefor.

"***Annual Revenue Run Rate***" means the Company's trailing four quarters' aggregate revenues as reported in its Form 10-Q or Form 10-K filed with Securities and Exchange Commission as reported in US Generally Accepted Account Principles, commencing with and including the fourth quarter of calendar year 2020, but excluding any revenue with respect to any four-quarter period that is attributable to Inorganic Growth Revenue to the extent such Inorganic Growth Revenue exceeds $50,000,000.

"***Cause***" means the occurrence of any one or more of the following events unless, to the extent capable of correction, Participant fully corrects the circumstances constituting Cause within 15 days after receipt of written notice thereof: (i) Participant's willful failure to substantially perform his or her duties with the Company (other than any such failure resulting from Participant's incapacity due to physical or mental illness or any such actual or anticipated failure after his or her issuance of a notice of termination for Good Reason), after a written demand for performance is delivered to Participant by the Administrator, which demand specifically identifies the manner in which the Administrator believes that Participant has not performed his or her duties; (ii) Participant's commission of an act of fraud or material dishonesty resulting in reputational, economic or financial injury to the Company; (iii) Participant's material misappropriation or embezzlement of the property of the Company or any of its affiliates; (iv) Participant's commission of, including any entry by Participant of a guilty or no contest plea to, a felony (other than a traffic violation) or other crime involving moral turpitude; (v) Participant's willful misconduct or gross negligence with respect to any material aspect of the Company's business or a material breach by Participant of his or her fiduciary duty to the Company, which willful misconduct, gross negligence or material breach has a material and demonstrable adverse effect on the Company; or (vi) Participant's material breach of Participant's obligations under a written agreement between the Company and Participant.

"***Good Reason***" means the occurrence of any one or more of the following events without Participant's prior written consent, unless the Company fully corrects the circumstances constituting Good Reason (provided such circumstances are capable of correction): (i) a material diminution in Participant's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities, excluding for this purpose any isolated, insubstantial or inadvertent actions not taken in bad faith and which are remedied by the Company promptly after receipt of notice thereof given by Participant; (ii) the Company's material reduction of Participant's annual base salary, as the same may be increased from time to time, other than as a result of a proportionate, across-the-board reduction of base compensation payable to similarly situated employees of Participant; or (iii) a material change in the geographic location at which Participant performs his or her principal duties for the Company to a new location that is more than 30 miles from the location at

which Participant performs his or her principal duties for the Company as of the Grant Date. Notwithstanding the foregoing, Participant will not be deemed to have resigned for Good Reason unless (1) Participant provides the Company with written notice setting forth in reasonable detail the facts and circumstances claimed by Participant to constitute Good Reason within 90 days after the date of the occurrence of any event that Participant knows or should reasonably have known to constitute Good Reason, (2) the Company fails to cure such acts or omissions within 30 days following its receipt of such notice, and (3) the effective date of Participant's termination for Good Reason occurs no later than 60 days after the expiration of the Company's cure period.

"***Inorganic Growth Revenue***" means revenue earned from the sale of products or services that were acquired, whether as a single asset or a whole company.

"***Lunar 2 Launch Goal***" means the Company's [receipt of the first TRF for the Company's CRC IVD product.

"***Performance Goals***" shall mean the Lunar 2 Launch Goal and the Revenue Goal.

"***Performance Period***" means the period commencing on the Grant Date and ending on the fourth anniversary of the Grant Date.

"***Performance-Vested PSUs***" means PSUs for which the Performance Goals have been achieved.

"***Qualifying Termination***" shall mean Participant's Separation from Service by reason of a termination of employment by the Company without Cause, by Participant for Good Reason or due to Participant's death.

"***Revenue Goal***" shall mean the Company's Annual Revenue Run Rate equaling or exceeding $600,000,000.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

AMENDMENT #5 TO SUPPLY AGREEMENT

Illumina, Inc., a Delaware corporation having a place of business at 5200 Illumina Way, San Diego, CA 92122 ("**Illumina**") and Guardant Health, Inc., a Delaware corporation having a place of business at 505 Penobscot Drive, Redwood City CA 94063 ("**Customer**"), entered into that certain Supply Agreement dated September 15, 2014, as amended ("**Agreement**"). Customer and Illumina may be referred to herein as "**Party**" or "**Parties**." Illumina and Customer desire to amend the Agreement by entering into this Amendment #5 ("**Amendment #5**") as of the date of last signature below ("**Amendment #5 Effective Date**").

The Parties hereby agree as follows:

1. The definitions set forth below are hereby deleted in their entirety and replaced as follows:

   "**Clinical Service Laboratory**" means a high-throughput commercial laboratory entity, that is (i) similarly situated to Customer (primary factors to be considered are [***]; and (ii) in the business of marketing, performing, and delivering results of high-complexity screening or diagnostic tests on human samples received from, and delivered to unaffiliated health care professionals or health care organizations for [***] purposes.

   "**Clinical Use**" means testing of human samples and specimens with Customer's or its Affiliates' own Laboratory Developed Tests in a clinical laboratory in the [***], specifically excluding [***].

   "**Collection Territory**" means the country or countries from which samples and specimens may be collected for testing by Customer and its Affiliates for Clinical Use. The Collection Territory is worldwide.

   "**Core Consumables**" means (i) with respect to the NextSeq Sequencing System (500/550/1000/2000), those Consumables commercialized as of the Effective Date and future Consumables, in each case that are intended by Illumina to be used to perform a sequencing process on the NextSeq Sequencing System (500/550/1000/2000), (ii) with respect to the NovaSeq 6000 Sequencing System, the NovaSeq 6000 Reagent Kits v1.5 and future Consumables that are intended by Illumina to be used to perform a sequencing process on the NovaSeq 6000 Sequencing System, and (iii) with respect to Illumina sequencing systems and system upgrades launched after the Amendment #5 Effective Date, those Consumables used to perform a sequencing process on such systems. Non-limiting examples of Core Consumables are kits used to perform clustering and sequencing on Illumina Hardware. Kits used for sample and library preparation are not Core Consumables unless such kits are necessary (i.e., no reasonable technological alternative) for use with Supplied Products.

   "**Direct Countries**" means those countries where Illumina customarily makes Supplied Products available for purchase directly by end user customers (e.g., without involvement of a channel partner, distributor, or reseller).

   "**Excluded Activities**" means any and all uses of a Supplied Product that (A) is not in accordance with the Supplied Product's Specifications or Documentation, (B) is a reuse of a previously used Consumable except to the extent the Specifications or Documentation for the applicable Consumable expressly states otherwise, (C) is the disassembling, reverse-engineering, reverse-compiling, or reverse-assembling of the Supplied Product, (D) is the separation, extraction, or isolation of components of Consumables or other unauthorized analysis of the Consumables, (E) gains access to or determines the methods of operation of the Supplied Product, (F) is the use of third party On-Hardware Consumables with Hardware (unless the Specifications or Documentation state otherwise), (G) is the transfer to a third-party of, or sub-licensing of, Software or third-party software, or (H) is the use of the Supplied Products in a facility not owned by, leased by, or otherwise under the contractual control of Customer.

   "**Pre-Release Sequencing Product**" means (i) a sequencing instrument, or (ii) reagents or consumable items that are used to perform a process on an Illumina sequencing instrument, and in both the case of (i) and (ii), are not available for purchase in Illumina's product catalogue. Kits used for sample and library preparation would not meet

the definition of a Pre-Release Sequencing Product unless such kits are necessary (i.e., no reasonable technological alternative) for use with Supplied Products.

"**Special Project**" means a project or circumstance giving rise to a discrete purchase outside of the ordinary course of purchases made by the applicable Illumina customer in a particular country (e.g., large-scale population health project, large-scale public health project, research project, clinical test validation, or clinical trial, or a circumstance requiring purchase of replacement Core Consumables).

"**Territory**" means worldwide; provided, however, Illumina shall only be obligated to ship Supplied Products into countries that are Direct Countries. Illumina shall not provide warranty support in countries that are not Direct Countries.

2. The original last sentence of Section 2.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"Without limiting any use rights with respect to Supplied Products that may be granted to Affiliates of Customer under this Agreement, this Agreement is personal to Customer and the rights and obligations regarding purchase and supply do not extend to Affiliates of Customer."

3. The following sentence is hereby added at the end of Section 2.1:

"In addition to the obligation in Section 14(d) of the Fifth Amendment, to the extent (i) Customer requests a specific development arrangement relating to a potential Pre-Release Sequencing Product, or (ii) Illumina has existing Pre-Release Sequencing Products, Illumina shall in good faith consider partnering with Customer under a separate agreement, taking into account any similar activities undertaken with other Clinical Service Laboratories."

4. The penultimate sentence of Section 6.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

> "Illumina shall accept all Purchase Orders that are submitted in accordance with this Agreement and the applicable quotation (if any), it being agreed that Illumina shall, when requested by Customer, promptly issue quotations that are consistent with the terms and conditions of this Agreement and Exhibit A. In the event of a conflict between the terms of this Agreement and the applicable quotation, the terms of this Agreement shall prevail."

5. The following language is hereby added to Section 6.1 of the Agreement:

"In the event Illumina does not provide a quote or other reference for a particular Supplied Product, then it shall be sufficient for Customer's Purchase Order to include the Illumina catalogue number in lieu of such quote or other reference. In the event Illumina is experiencing a supply shortage of the applicable Supplied Product (or components therein), including due to Force Majeure, Illumina will allocate the existing supply in an equitable manner among its customers (including affiliates) in proportion to their order date, confirmed order volumes, date of scheduled delivery, and customary practices in effect and applicable to all customers, and which practices shall not favor Affiliates over other customers in the event of a supply shortage."

6. The following new Section 9.6 is hereby added to the Agreement:

"9.6 **Certain Firewalling Obligations**. Contingent upon the close of the acquisition of GRAIL by Illumina, and in addition to the confidentiality obligations set forth in Section 9.1 of the Agreement, Illumina shall in no event share Confidential Information of Customer with GRAIL or any subsidiary of GRAIL, or any employees of Illumina who work within the division of Illumina of which GRAIL will become a part following the close of Illumina's acquisition of GRAIL. Any Confidential Information shall be used by Illumina only in connection with and as reasonably necessary to perform Illumina's product supply, service or other commitments to Customer, and shall not

be used for any other purpose. All such employees who may receive Confidential Information will be advised of these confidentiality obligations and use restrictions. Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products. Upon written request from Customer, which request shall be made not more than once per quarter, Illumina shall provide a written certification signed by an executive officer of Illumina that Illumina is in compliance with its firewalling obligation described in the preceding sentence."

7. Section 10.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

"10.2 **Customer Representations and Warranties**. Customer is not an authorized dealer, representative, reseller, or distributor, of Illumina's, or any of its Affiliates', products or services. Customer represents and warrants, that (a) it or an Affiliate owns, leases, or otherwise contractually controls the facilities in which Supplied Products will be used for Customer Use, (b) it has the right and authority to enter into this Agreement without violating the terms of any other agreement; (c) to its knowledge, as of the Amendment #5 Effective Date, it and its Affiliates (where applicable) have all rights and licenses necessary to purchase and use the Supplied Products for Customer Use; and (d) the person(s) signing this Agreement on its behalf has the right and authority to bind Customer and its Affiliates (where applicable) to the terms and conditions of this Agreement."

8. Section 12.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"12.1 **Term.** This Agreement shall commence on the Effective Date and expire twelve (12) years following the Amendment #5 Effective Date ("**Initial Term**"). Upon expiration of the Initial Term, this Agreement will automatically renew for successive one year periods (each such period, a "**Renewal Term**"), unless (i) earlier terminated as provided hereunder, or (ii) either Party provides notice of non-renewal to the other Party not less than 12 months prior to the date such renewal would otherwise take effect. The Initial Term and any Renewal Terms shall be collectively referred to as the "**Term**."

9. The following language is hereby added to Section 12.2(a) of the Agreement:

"Notwithstanding the foregoing, if a material breach by Customer relates to any infringement of any Intellectual Property Rights (alleged or adjudicated) of Illumina , then Illumina may not terminate this Agreement pursuant to this Section 12.2 solely on the basis of such alleged material breach."

10. A new subsection (d) is hereby added at the end of Section 12.2:

"d. **Termination for Convenience**. Customer may terminate this Agreement for convenience and without termination liability at any time upon ninety (90) days' prior written notice to Illumina, provided, however, that Customer shall honor all invoices, which invoices shall be issued upon shipment, for Supplied Products ordered under a Purchase Order that was accepted by Illumina prior to the termination date. Illumina may not terminate this Agreement for convenience prior to the end of the Initial Term, provided, however, Illumina may provide a notice of non-renewal of the Agreement as set forth in Section 12.1."

11. Section 12.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

"12.3 **Right to Cease Delivery**. In addition to any other remedies available to Illumina under this Agreement or at Law, Illumina reserves the right to cease shipping Supplied Product to Customer immediately if Customer (a) uses the Supplied Product outside the scope of Customer Use, (b) fails to pay invoices when due, provided that Illumina shall work with Customer in good faith to address invoices that are not paid when due, so long as Customer has not purposefully withheld payment on any one invoice and has a good record of paying invoices when due, (c) breaches any term in Article III (Use Rights for Supplied Products), (d) breaches any Customer representation or warranty made hereunder or (e) provides notice to Illumina in accordance with Section 12.2(c). Notwithstanding the foregoing, (i) in no event will Illumina have the right to cease shipping of the Supplied Product solely on the basis of any alleged claim of infringement of any Intellectual Property Rights of Illumina, and (ii) with respect to (a), (c), and

(d), in no event will Illumina have the right to cease shipping of the Supplied Product until the applicable matter has been resolved in a final adjudication pursuant to Section 13."

12. Section 13.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"13.1 **Governing Law; Jurisdiction**. This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation shall be governed and construed in accordance with the laws of the State of California, U.S.A., without regard to provisions on the conflicts of laws. The Parties agree that the United Nations Convention on Contracts for the International Sale of goods shall not apply to this Agreement, including any terms in Documentation. In either Party's discretion (except with respect to claims based on patent infringement, validity, or unenforceability, all of which shall be adjudicated in a court of law), any dispute, claim or controversy arising out of or relating to the breach, termination, enforcement, interpretation or validity of these terms and conditions, shall be determined by confidential binding arbitration conducted in the English language to be held in San Mateo, California before one arbitrator who has at least 10 years of experience in handling disputes similar to the dispute to be arbitrated hereunder and administered by JAMS pursuant to the JAMS Comprehensive Arbitration Rules. In all cases of arbitration hereunder each Party shall bear its own costs and expenses and an equal share of the arbitrator's and administrator's fees of arbitration; neither Party nor an arbitrator may disclose the existence, content, or results of any arbitration without the prior written consent of both Parties, unless required by law; the decision of the arbitrator shall be final and binding on the Parties, provided that, the arbitrator shall not have the authority to alter any explicit provision of these terms and conditions; judgment on the award may be entered in any court having jurisdiction. This clause shall not preclude the Parties from seeking provisional remedies in aid of arbitration from a court of appropriate jurisdiction. Notwithstanding anything herein to the contrary, any claims or causes of action involving infringement, validity, or enforceability of a Party or its Affiliate's Intellectual Property rights are not subject to this arbitration clause."

13. The heading and first sentence of Section 13.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

"13.2 **Affiliates; Rights of Third Parties**. Customer agrees that (i) Illumina may delegate or subcontract any or all of its rights and obligations under this Agreement to one or more of its Affiliates, and (ii) Affiliates of Customer may use the Supplied Products in accordance with the terms and conditions of this Agreement and applicable law, and references to "Customer" in Article III hereof shall be construed to include Affiliates of Customer, provided in each case (of (i) and (ii)) that such Affiliates (where applicable) are bound to comply with the terms and conditions of this Agreement. With respect to the occurrence of (i) or (ii) in the preceding sentence, a Party shall be solely responsible, and jointly and severally liable, for any acts and omissions of its Affiliates under this Agreement, including but not limited to any breach of this Agreement by its Affiliates. Illumina invoices and other documentation may come from an Illumina Affiliate and Customer shall honor those just as if they came directly from Illumina. Except as expressly set forth in this Section 13.2, there are no third party beneficiaries to this Agreement. The Parties to this Agreement may rescind or terminate this Agreement or vary any of its terms in accordance with their rights under this Agreement and by law, without the consent of any third party."

14. To the extent permitted under applicable law, Customer shall:

    a. have access to overall [***]. Without limiting the foregoing, [***], Customer shall have access to [***], for such testing in the relevant country and Illumina agrees to [***] for all relevant [***] at the time of offering such [***] to [***]. Notwithstanding the foregoing, in the event Illumina and Customer partner on a project that Illumina and Customer acknowledge in writing is a Special Project between Illumina and Customer using Core Consumables, Illumina will [***].

    b. have access to Illumina sequencing platforms (e.g., NextSeq, NovaSeq, and future platforms) for purchase in accordance with Illumina's customary practices.

    c. have access to product service and support services in accordance with Illumina's customary practices (e.g., included with instrument purchase or purchased separately).

d. have access to [***]; provided, however, this obligation to offer access to Customer shall not be triggered if [***]; and

e. have access to [***]. Notwithstanding the foregoing, in the event Illumina and Customer partner on a project that Illumina and Customer acknowledge in writing is a Special Project between Illumina and Customer using Core Consumables, Customer shall have access to [***].

In the case of Section 14(d) and Section 14(e) above, any obligation to provide access is contingent [***]. Further, in the case of both Section 14(a) and Section 14(e) above, the triggering pricing to [***] must be for purchases in the ordinary course for clinical or research-use testing performed in a particular country. Purchases for Special Projects made by [***], shall be governed by express language regarding such Special Projects, as set forth in subparts (a) and (e). Illumina shall identify Special Projects as such in its internal documentation.

In the event of a triggering event under this Section 14, then Illumina will [***].

For clarity, any Purchase Orders accepted before the date of the triggering purchase, regardless of whether or not the relevant Supplied Products have shipped, will be [***].

15. Exhibit A is hereby deleted in its entirety and replaced with the attached **Exhibit A**.

Except as expressly modified herein, the Agreement shall remain in full force and effect in accordance with its terms. All capitalized terms not defined in this Amendment #5 shall have the meaning ascribed to them in the Agreement. This Amendment #5 may be executed in one or more counterparts, and each of which shall be deemed to be an original, and all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment #5 to be executed by their respective duly authorized representatives.

Guardant Health, Inc.:		**Illumina, Inc.:**	
By:	/s/ AmirAli Talasaz	By:	/s/ Nicole Berry
Name:	AmirAli Talasaz	Name:	Nicole Berry
Title:	President and Chief Operating Officer	Title:	SVP & GM, Americas Region
Date:	12/30/2020	Date:	1/1/2021

EXHIBIT A - Part 1 of 2 - HARDWARE PRICING

The following tables list the Hardware subject to purchase under this Agreement. Any additional Hardware offered for sale pursuant to Illumina's catalog found available at https://www.illumina.com/products/all-products.html will be automatically added to this list and shall be subject to the terms under this Agreement; provided, however, with respect to any products not expressly set forth in the first table of this Exhibit A – Part 1 of 2, discounts (if any) shall be determined at the time of purchase and otherwise subject to the terms under this Agreement, including Section 14. Any applicable discounts shall apply to the then-current list price in the country to which the applicable Supplied Products will be shipped by Illumina. Any applicable discounts associated with a certain number of systems installed shall be applied on a Customer-specific or Affiliate-specific basis, as applicable (i.e., shipments to Customer Facilities and Affiliate Facilities shall not be aggregated).

For example purposes only:

Example 1: Customer places a Purchase Order for one NovaSeq System to be shipped Customer's Facility in the United States where Customer already has five NovaSeq Systems which were purchased and installed during the Term. Customer shall receive a [***] discount off the NovaSeq System to be shipped to and installed at Customer's Facility in the United States.

Example 2: Customer places a Purchase Order for one NovaSeq System to be shipped Customer's Affiliate's Facility in France where such Affiliate already has three NovaSeq Systems which were purchased and installed during the Term. Customer shall receive a discount [***] discount off the NovaSeq System to be shipped to and installed at the Affiliate's Facility in France.

Catalog #	**Description**
SY-410-1003	MiSeq® System MiSeq System Integrated system for automated generation of DNA clonal clusters by bridge amplification, sequencing, primary and secondary analysis. System includes embedded touchscreen monitor and on-instrument computer, dual surface imaging capability, MiSeq Software Suite, installation kits and standards, installation and training, and 12 months warranty (including parts and labor).
SY-415-1002	NextSeq® 550 Sequencing System llumina NextSeq™ 550 Sequencing System is an integrated system for automated generation of DNA clonal clusters by bridge amplification, sequencing, and primary analysis. System includes embedded touchscreen monitor and on-instrument computer, NextSeq Control Software, installation and training, and 12 months warranty (including parts and labor).
SY-420-1001	MiniSeq System Illumina MiniSeq Sequencing System is an integrated system for automated generation of DNA clonal clusters by bridge amplification, sequencing, and analysis. System includes embedded touch screen monitor and on- instrument computer, MiniSeq Control Software, Local Run Manager analysis and management software, installation and training, and 12 months warranty (including parts and labor).HiSeq® 4000 Sequencing System The Illumina HiSeq 4000 Sequencing System is a dual flow cell sequencing instrument. System includes workstation computer, touch screen monitor, HiSeq Control Software, installation kits and standards, installation and training, and 12 months warranty (including parts and labor).

SY-101-1001	iScan System The Illumina iScan System is a bench-top reader that utilizes Illumina's BeadArray technology and includes the iScan Reader, isolation table, computer, installation, and a 1 year warranty.
20012850	NovaSeq™ 6000 Sequencing System The NovaSeq 6000 Sequencing System is an integrated ultrahigh throughput system performing onboard cluster generation and sequencing. This system includes installation and training and 12 months warranty (including parts and labor).

Hardware Discounts and Service Contract Discounts

For the avoidance of doubt, Customer shall not be entitled to a credit or refund for the amount of discount which would apply under this Agreement for units of Existing Hardware purchased prior to the Effective Date or for Hardware purchased outside of this Agreement after the Effective Date. Discounts on HiSeqs and NextSeqs are calculated separately. For the further avoidance of doubt, the discounts specified below with respect to purchases by Customer of NovaSeq 6000 Instruments are based on Customer's cumulative purchases of NovaSeq 6000 Instruments during the Term and not based on any one particular purchase by Customer of NovaSeq 6000 Instruments. So, by way of example:

> If Customer purchases three (3) NovaSeq 6000 Instruments in the third quarter of 2017 and then Customer purchases an additional two (2) NovaSeq 6000 Instruments in the fourth quarter of 2017, then Customer has qualified for and is entitled to a [***] discount on the first four NovaSeq 6000 Instruments and a [***] discount with respect to Customer's purchase of the fifth NovaSeq 6000 Instrument and the [***] discount shall also apply to additional four (4) NovaSeq 6000 Instruments purchased during the Term.
> If Customer purchases any additional NovaSeq 6000 Instruments subsequent to Customer's purchase of the nine (9) NovaSeq 6000 Instruments, in the aggregate, then Customer has qualified for and is entitled to the [***] discount with respect to Customer's purchase of such additional NovaSeq 6000 Instruments during the Term.

Product (Instruments)	**Discount off of NextSeq 550 Instruments**
Discount	[***]%

Number of NovaSeq 6000 Instruments*	[***]	[***]	[***]
Discount off of NovaSeq 6000 Instruments	[***]	[***]	[***]

*[***].

NovaSeq Service Contract Discount:

Number of NovaSeq Instruments**	Discount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

** [***].

NextSeq Service Contract Discount:

Number of NextSeq Instruments**	Discount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

** [***]

Instrument Services (On Site Service and Parts Only Contract) Discount: [***]
An extra [***] discount is available with a 2 year service contract renewal, or an extra [***] discount is available with a [***] service contract renewal. The extra [***] or [***] discount may not be stacked with one another (i.e., the [***] discount and [***] discount may not be combined).

Catalogue Number	Description
20016099	NovaSeq 6000 OQ Coverage Add-On
20016086	NovaSeq 5000 OQ Coverage Add-On
20016100	NovaSeq 6000 IQ/OQ
20016087	NovaSeq 5000 IQ/OQ
20016102	ILMN PC NovaSeq 6000 Prev Maint
20016101	ILMN PC NovaSeq 6000 Sys Health Check
20016098	NovaSeq 6000 OQ
20016332	NovaSeq 6000 PQ
20016088	ILMN PC NovaSeq 5000 Sys Health Check
15072327	NextSeq® 550 OQ Coverage Add-On
20023558	NextSeq 550 Dx OQ Coverage AddOn
15057044	PROD Care NSQ® 500 IPVCoverage Add-On
15067681	NextSeq® 500 IQ/OQ
15067965	NextSeq® 550 IQ/OQ
20023559	NextSeq 550 Dx IQ/OQ
15067736	NextSeq® Proof of Concept
20023957	NSQ 550Dx Preventative Maintenance
15067967	NextSeq® 550 PQ
15054362	NextSeq® 500 PQ
15054364	NextSeq® 500 Operational Qualification
20023610	NextSeq 550 Dx (OQ)
20025872	NextSeq 550 Dx PQ
20038659	NSQ Control SW v4 / Win 10 no contract
20023958	NSQ 550Dx System Health Check
15057273	PROD Care NSQ® 500 PREVative MAIN
15071377	Product Care N-Sq® 550 sys Health Check
15057274	PROD Care NSQ® 500 SYS Health CHK

EXHIBIT A – Part 2 of 2 – CONSUMABLES PRICING

The following tables list the Consumables subject to purchase under this Agreement and any applicable discounts off the then-current list price in the country to which the applicable Consumables will be shipped by Illumina. Any additional Consumables offered for sale pursuant to Illumina's catalog available at https://www.illumina.com/products/all-products.html will be automatically added to this list and shall be subject to the terms under this Agreement; provided, however, with respect to any products not expressly set forth in the first table of this Exhibit A – Part 2 of 2, discounts (if any) shall be determined at the time of purchase and otherwise subject to the terms under this Agreement, including Section 14. Any applicable discounts associated with amounts invoiced by Illumina for shipments of Consumables or systems installed shall be applied on a Customer-specific or Affiliate-specific basis, as applicable (i.e., shipments to Customer Facilities and Affiliate Facilities shall not be aggregated).

For example purposes only:

Example 1: Customer places a Purchase Order for one NovaSeq 6000 S4 Reagent Kit v1.5 to be shipped Customer's Facility in the United States. Customer already has ten NovaSeq Systems which were purchased and installed during the Term, and Customer's NovaSeq 6000 Core Consumables Spend is $21,000,000. Customer shall receive a [***] discount off NovaSeq 6000 S4 Reagent Kit v1.5 to be shipped to Customer's Facility in the United States.

Example 2: Customer places a Purchase Order for one NovaSeq 6000 S4 Reagent Kit v1.5 to be shipped Customer's Affiliate's Facility in France where such Affiliate already has ten NovaSeq Systems which were purchased and installed during the Term, and such Affiliate's NovaSeq 6000 Core Consumables Spend is $15,000,000. Customer shall receive a discount [***] discount off the NovaSeq 6000 S4 Reagent Kit v1.5 to be shipped to the Affiliate's Facility in France.

Catalog #	**Description**
20028318	NovaSeq 6000 S1 Rgt Kit v1.5 (200 cycles)
20028402	NovaSeq 6000 SP Rgt Kit v1.5 (500 cycles)
20028319	NovaSeq 6000 S1 Rgt Kit v1.5 (100 cycles)
20028400	NovaSeq 6000 SP Rgt Kit v1.5 (300 cycles)
20040719	NovaSeq 6000 SP Rgt Kit v1.5 (200 cycles)
20028401	NovaSeq 6000 SP Rgt Kit v1.5 (100 cycles)
20021663	NovaSeq Xp Flow Cell Dock
20021665	NovaSeq Xp 4-Lane Kit
20043131	NovaSeq XP 4-Lane Kit v1.5
20021664	NovaSeq Xp 2-Lane Kit
20043130	NovaSeq XP 2-Lane Kit v1.5
20040830	NovaSeq 6000 S4 Rgt Kit v1.5 (300 cycles)-10pk
20040831	NovaSeq 6000 S4 Rgt Kit v1.5 (300 cycles)-20pk
20040832	NovaSeq 6000 S4 Rgt Kit v1.5 (300 cycles)-40pk
20039123	TG NextSeq™ 500/550 HO v2 75 cycle - 60pkg
20024913	TG NextSeq 500/550 Hi Output v2.5 (300 cycles)
20024908	NextSeq 500/550 Hi Output KT v2.5 (300 cycles)
20024912	TG NextSeq 500/550 Hi Output v2.5 (150 cycles)
20024907	NextSeq 500/550 Hi Output KT v2.5 (150 cycles)
20024910	TG NextSeq 500/550 Mid Output v2.5 (300 cycles)
20024905	NextSeq 500/550 Mid Output KT v2.5 (300 cycles)
20024911	TG NextSeq 500/550 Hi Output v2.5 (75 cycles)
20024906	NextSeq 500/550 Hi Output KT v2.5 (75 cycles)
20024909	TG NextSeq 500/550 Mid Output v2.5 (150 cycles)

20024904	NextSeq 500/550 Mid Output KT v2.5 (150 cycles)
20027466*	NovaSeq 6000 S4 Reagent Kit (200 cycles)
20012860*	NovaSeq 5000/6000 S2 Rgt Kit (300 cyc)
20012861*	NovaSeq 5000/6000 S2 Rgt Kit (200 cyc)
20012862*	NovaSeq 5000/6000 S2 Rgt Kit (100 cyc)
20012863*	NovaSeq 5000/6000 S1 Rgt Kit (300 cyc)
20012864*	NovaSeq 5000/6000 S1 Rgt Kit (200 cyc)
20029137*	NovaSeq 6000 SP Reagent Kit (500 cycles)
20012865*	NovaSeq 5000/6000 S1 Rgt Kit (100 cyc)
20027465*	NovaSeq 6000 SP Reagent Kit (300 cycles)
20040326*	NovaSeq 6000 SP Reagent Kit (200 cycles)
20027464*	NovaSeq 6000 SP Reagent Kit (100 cycles)
20012866*	NovaSeq 6000 S4 Rgt Kit (300 cyc)

*[***].

Purchase Periods
Following the Amendment #5 Effective Date, and no later than February 15 of each year thereafter, Illumina will [***].

Consumables Purchase Price

"**Consumable Spend**" equals [***].

Consumable Volume Discount Applicable to NextSeq Consumables

The following discounts off the then-current list price shall apply to NextSeq Consumables purchased by Customer:

Consumable Spend	Non-TG	TG Consumables
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Discount Applicable to NovaSeq 5000/6000 Reagent Kits v1 through December 31, 2020:

Product	Discount
[***]	[***]

Discount Applicable to NovaSeq 6000 S4 Reagent Kits v1, through December 31, 2020:

NovaSeq 6000 Core Consumable Spend	Discount
[***]	[***]
[***]	[***]
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Discount Applicable to NovaSeq 6000 S4 Reagent Kits v1.5:

The following discounts off the then-current list price shall apply to NovaSeq 5000/6000 S4 Reagent Kits v1.5 purchased by Customer:

NovaSeq 6000 Core Consumable Spend	8-9 NovaSeq installed instruments	10-11 NovaSeq installed instruments	12-13 NovaSeq installed instruments	14-15 NovaSeq installed instruments	16+ NovaSeq installed instruments
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

Any applicable discounts associated with a certain number of systems being installed shall be applied [***].

"**NovaSeq 6000 Core Consumables Spend**" equals [***].

Exhibit 21.1

Subsidiaries of Guardant Health, Inc.

Name	Jurisdiction of Incorporation
Guardant Health AMEA, Inc.	Delaware
Guardant Health Pte. Ltd.	Singapore
Guardant Health Japan Corp.	Japan
Guardant Holdings (Switzerland) GmbH	Switzerland
Bellwether Bio, Inc.	Washington

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-227762 and 333-236807) of Guardant Health, Inc. of our reports dated February 25, 2021, with respect to the consolidated financial statements of Guardant Health, Inc. and the effectiveness of internal control over financial reporting of Guardant Health Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
February 25, 2021

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Helmy Eltoukhy, certify that:

1. I have reviewed this Annual Report on Form 10-K of Guardant Health, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ Helmy Eltoukhy
Helmy Eltoukhy
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Bell, certify that:

1. I have reviewed this Annual Report on Form 10-K of Guardant Health, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ Michael Bell
Michael Bell
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Guardant Health, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 25, 2021

/s/ Helmy Eltoukhy
Helmy Eltoukhy
Chief Executive Officer and Director
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Guardant Health, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 25, 2021

/s/ Michael Bell
Michael Bell
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.