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, 2024

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.)**

3100 Hanover Street
Palo Alto, California 94304
(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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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 $3.4 billion (based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2024 of $28.88 per share).

As of February 14, 2025, the registrant had 123,421,441 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 2025, or the 2025 Annual Meeting, to be filed with the Securities and Exchange Commission, or 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, 2024

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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.

RISK FACTOR SUMMARY

Our business is subject to numerous risk and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock, including the full discussion of risks included in this Annual Report on Form 10-K. The principal risks and uncertainties affecting our business include the following:

- 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 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.
- 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.
- If we continue to experience challenges attracting and retaining qualified personnel due to competitive labor markets, we may be unable to manage our future growth effectively, all of which could make it difficult to execute our business strategy.
- 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.

- 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 laboratory developed tests, or 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.
- Issued patents covering our products, services or technology 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.

PART I

Item 1. Business

Overview

We are a leading precision oncology company focused on guarding wellness and giving every person more time free from cancer. We are transforming patient care by providing critical insights into what drives disease through our advanced blood and tissue tests and real-world data. Our tests help improve outcomes across all stages of care, including screening to find cancer early, monitoring for recurrence in early-stage cancer, and helping doctors select the best treatment for patients with advanced cancer. For patients with advanced-stage cancer, we have commercially launched Guardant360 laboratory developed test, or LDT, and Guardant360 CDx, the first comprehensive liquid biopsy test approved by the U.S. Food and Drug Administration, or the FDA, to provide tumor mutation profiling with solid tumors and to be used as a companion diagnostic in connection with non-small cell lung cancer, or NSCLC, and breast cancer. We have also launched the Guardant360 TissueNext tissue test for advanced-stage cancer, Guardant Reveal blood test to detect residual and recurring disease in early-stage colorectal, breast and lung cancer patients, and Guardant360 Response blood test to predict patient response to immunotherapy or targeted therapy eight weeks earlier than current standard-of-care imaging.

We also collaborate with biopharmaceutical companies in clinical studies by providing the above-mentioned tests, as well as the GuardantOMNI blood test for advanced-stage cancer, and the GuardantINFINITY blood test, a next-generation Smart Liquid Biopsy that provides new, multi-dimensional insights into the complexities of tumor molecular profiles and immune response to advance cancer research and therapy development. Using data collected from our tests, we have also developed our GuardantINFORM platform to help biopharmaceutical companies accelerate precision oncology drug development through the use of this in-silico research platform to unlock further insights into tumor evolution and treatment resistance across various biomarker-driven cancers.

For early cancer detection, in May 2022, we launched the Shield LDT test to address the needs of individuals eligible for colorectal cancer screening. From a simple blood draw, Shield uses a novel multimodal approach to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors. In December 2022, we announced that the ECLIPSE study, a registrational study evaluating the performance of our Shield blood test for detecting colorectal cancer in average-risk adults, met co-primary endpoints. In addition, in March 2023, we submitted a premarket approval application, or PMA, for our Shield blood test to the FDA. In July 2024, we received FDA approval of our Shield blood test for colorectal cancer screening in adults age 45 and older who are at average risk for the disease, and in August 2024, our Shield blood test became commercially available in the U.S. as the first blood test approved by the FDA for primary colorectal cancer screening, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines. Shield is also the first blood test for colorectal cancer screening that meets coverage requirements by Medicare. We also expect to expand into lung cancer screening and multi-cancer detection with our Shield platform.

Our strategy

Our objective is to be the leading provider of therapy selection, minimal residual disease detection, and early cancer screening 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, key opinion leaders, or 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 and other regulatory approval internationally 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;
  - providing earlier insights into emerging clinically relevant biomarkers;
  - providing seamless customer experiences through collaborations with electronic medical record partners; and
  - expanding lab capabilities and services through partnerships.
- **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 for cancer management across all stages of the disease;
  - 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 partnerships with cancer centers, research organizations and laboratory companies in Europe and Asia, to drive global commercialization of our products.

Our products and development program

We have launched various products and programs using our digital sequencing technology, which is enabled by robust, high-efficiency biochemistry at the front-end, next-generation sequencing and a machine learning augmented bioinformatics pipeline. We believe our product portfolio could address the full continuum of cancer care for selected indications, and has utility in both the clinical and biopharmaceutical markets.

Therapy Selection

Guardant360 CDx Test

We believe our Guardant360 CDx test was the first comprehensive liquid biopsy test approved by the FDA, and is the market leading comprehensive liquid biopsy test, based on the number of tests ordered. Our Guardant360 CDx test is a 74-gene test to provide tumor mutation profiling to be used by qualified health professionals in accordance with professional guidelines in oncology for cancer patients with any solid malignant neoplasm. Our Guardant360 CDx test has also been approved by the FDA for use as a companion diagnostic to identify NSCLC patients who may benefit from treatment with TAGRISSO® (osimertinib), RYBREVANT® (amivantamab-vjmw), LUMAKRAS™ (sotorasib) and ENHERTU® (fam-trastuzumab deruxtecan-nxki), and breast cancer patients who may benefit from treatment with ORSERDU™ (elacestrant), marketed by biopharmaceutical companies. Additional gene content and immune-oncology biomarkers (e.g. microsatellite instability, or 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 LDT

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. Our Guardant360 LDT test measures 730+ genes and supports all guideline-recommended biomarkers, to help inform which therapy may be effective for advanced stage cancer patients with solid tumors, without the need to obtain archival tissue or subject the patient to another invasive biopsy. Our Guardant360 LDT test has been migrated to the Smart Liquid Biopsy platform which enables more sensitive epigenetic tumor fraction detection. Results are typically delivered within seven days following receipt of sample and delivered by a clinical report.

Guardant360 Response Test

Our Guardant360 Response test is the first blood-only liquid biopsy that enables doctors to view molecular response, or changes in circulating tumor DNA, or ctDNA, levels, from a simple blood draw to potentially gain early insight regarding patient response to treatment. For doctors, knowing early and confidently if a patient's treatment is working is critical in deciding whether to continue, stop, or explore other options. Studies across cancers and therapies show the Guardant360 Response test predicted treatment response eight weeks earlier than current standard-of-care radiological and imaging scans.

Guardant360 TissueNext Test

To complement our liquid biopsy-based products, Guardant360 TissueNext, our first tissue-based test with AI-powered PD-L1 detection, is designed to identify patients with advanced cancer who may benefit from biomarker-informed treatment. 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 believe our Guardant360 TissueNext test, together with our liquid biopsy-based products, have the potential to help address the challenges with tissue genotyping products currently in the market.

Minimal Residual Disease Detection and Recurrence Monitoring

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 expect to address this need, first in early-stage colorectal, breast and lung cancers, with our Guardant Reveal tissue-free blood test for residual disease and recurrence monitoring. We believe the Guardant Reveal test has the potential to 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 believe the Guardant Reveal test can improve turnaround by simultaneously interrogating both genomic and epigenomic signals from a single blood draw without the need for tissue. In addition, our Guardant Reveal test has been migrated to the Smart Liquid Biopsy platform which could maximize detection sensitivity without requiring tissue. Similar to our data development effort for our Guardant360 tests, we are investing heavily in establishing clinical validity and utility for the use of Guardant Reveal in adjuvant treatment and surveillance settings. We also believe our Guardant Reveal test may 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. Results are typically delivered within seven days following receipt of sample and delivered by a clinical report.

Screening

Shield Test

According to American Cancer Society: Colorectal Cancer Facts & Figures 2023-2025, it is estimated that only 59% of adults at 45 years and older are screened despite compelling evidence that routine cancer screening can reduce colorectal cancer mortality. Therefore, we believe that there is a critical need to develop products to expand precision oncology to earlier stage cancer settings. These products could enable clinicians to precisely detect, and intervene in the disease evolution when the disease is more likely to be curable, key to significantly improving patient clinical outcomes.

In order to systematically address this need, in May 2022, we launched the Shield LDT test to address the needs of individuals eligible for colorectal cancer screening. From a simple blood draw, Shield uses a novel multimodal approach to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors. 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 Shield assay in these settings. In December 2022, we announced that the ECLIPSE study, a registrational study evaluating the performance of our Shield blood test for detecting colorectal cancer in average-risk adults, met co-primary endpoints. The test demonstrated 83% sensitivity in detecting individuals with colorectal cancer. Specificity was 90% in both individuals without advanced neoplasia and in those who had a negative colonoscopy result. These results exceed the performance criteria set forth by the Centers for Medicare and Medicaid Services, or CMS, for reimbursement. This test also demonstrated 13% sensitivity in detecting advanced adenomas. Based on these study results, in March 2023, we submitted a PMA for our Shield blood test to the FDA. In July 2024, we received FDA approval of our Shield blood test for colorectal cancer screening in adults age 45 and older who are at average risk for the disease, and in August 2024, our Shield blood test became commercially available in the U.S. as the first blood test approved by the FDA for primary colorectal cancer screening, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines. Shield is also the first blood test for colorectal cancer screening that meets coverage requirements by Medicare.

We also expect to expand into lung cancer screening and multi-cancer detection, or MCD, with our Shield platform. To clinically validate the performance of our next-generation Shield blood test in lung cancer screening in high-risk individuals ages 50-80, in January 2022, we initiated a nearly 10,000-patient prospective, registrational study, which we refer to as the SHIELD LUNG study. In addition, in January 2025, our Shield MCD test was selected for the Vanguard study funded by the National Cancer Institute, part of the National Institutes of Health. The Vanguard study is a four-year pilot study which will enroll up to 24,000 people to inform the design of a randomized controlled trial evaluating the use of MCD tests for cancer 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.

Biopharmaceutical Offerings

GuardantINFINITY Test

Our GuardantINFINITY test is a next-generation Smart Liquid Biopsy test that provides new, multi-dimensional insights into the complexities of tumor molecular profiles and immune response to advance cancer research and therapy development. Our GuardantINFINITY assay provides a more comprehensive molecular profile of tumors than earlier assays, giving researchers access to novel genomic and epigenomic insights to provide a simultaneously deeper and more complete understanding of a tumor's biology, its system-wide interactions and the associated immune response in a range of applications, from therapy selection to molecular response and longitudinal monitoring. The assay's extensive methylome panel helps identify the unique methylation pattern that each tumor delivers, providing an important new dimension of research insights that has been largely unexplored in clinical development to date. GuardantINFINITY is available as a single modular assay with flexible configurations that can be tailored to fit a current application, along with the ability to unlock additional content modules at any time, without incurring the burden or delay of additional sample collection. The core module offers genotyping coverage

of more than 800 genes with sample-level methylation detection and tumor fraction score for biomarker discovery, clinical research, therapy selection and response monitoring.

GuardantOMNI Test

Our GuardantOMNI test 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. The test has a significantly larger genomic panel footprint than the Guardant360 LDT test and has achieved comparable analytical performance in clinical studies, with the 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 study 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 LDT 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 LDT test. In addition, the broad genomic footprint of our GuardantOMNI test enables accurate measurement of tumor mutational burden.

GuardantINFORM

GuardantINFORM complements our core diagnostic business with aggregated data obtained through real world genomic testing. This genomic and epigenetic data is first matched with clinically relevant information, and through AI-enabled analytical tools and expertise, unlocks important insights into disease progression and treatment impact that can be fed back into drug discovery and development, as well as clinical research and practice. Given the trend for oncologists to use liquid biopsy to monitor changes over time, our GuardantINFORM database uniquely provides longitudinal biological insight into tumor evolution alongside longitudinal clinical outcomes, which is particularly valuable for both resistance characterization of disease and as testing moves earlier in the cancer journey.

GuardantConnect

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

Smart Liquid Biopsy Platform

Our Smart Liquid Biopsy platform drives significant research and development efficiencies and operating leverage, which supports performance improvements, cross-development of new applications, cost savings and improved turnaround time. While products continue to evolve by leveraging commonality in equipment, reagents, and staffing, this platform also provides a foundation for future product evolutions and data integration. We believe our Smart Liquid Biopsy platform has the potential to unlock the power of the epigenome, broaden the view of what drives cancer biology, and provide industry leading high-sensitivity genomic and epigenomic detection at ultra-high specificity and low cost.

Clinical Studies and Publications

We are proactively pursuing studies to support the use of our tests as a preferred alternative or complementary to tissue testing to inform first line treatment right after diagnosis and at time of disease progression, with the goal to provide evidence that our tests detect genomic alterations at a similar rate compared to standard of care tissue testing and detects mutations that may not be detected by tissue based testing in the United States, Europe and Asia. Such a strategy is predicated on the tests' abilities 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. 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.

Commercialization

Successful commercial adoption of our tests by clinicians and biopharmaceutical companies is critical to our business. 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. We believe that our relationships

with key stakeholders across the oncology space have helped facilitate the use of our tests by clinicians and biopharmaceutical companies.

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, cancer centers and primary care physicians. Our sales representatives typically have extensive sales-related 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.

Biopharmaceutical commercial efforts

Our business development team is focused on enterprise selling to biopharmaceutical companies in the United States and internationally, and 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 study 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 and epigenomic data, which can be used in combination with clinical outcomes or claims data for multiple applications, including novel target identification.

International commercial efforts and 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 direct contacts with insurers and hospitals, distributor relationships, and laboratory partnerships. Specifically, we have demonstrated the ability to deploy our technology to partner laboratories such as cancer centers, research organizations and laboratory companies, for the development of test assays based on our technology platform. We believe that this capability will be important in accelerating adoption of our platform and the performance of our testing in certain countries. We are conducting studies in various jurisdictions, and have secured and will continue our efforts to secure reimbursement in several countries. In addition, we have established, and as these studies progress and we near commercial opportunities in these jurisdictions, will continue to seek to establish in-country laboratories and direct sales organizations.

In preparation for wider commercialization in the European Union, or the EU, we obtained a CE mark for our Guardant360 CDx test. In December 2020, we signed our first public private partnership agreement with Vall D'Hebron Institute of Oncology, or VHIO, one of Europe's leading cancer research institutions, and in May 2022, the first blood-based cancer testing services in Europe based on our digital sequencing platform became available at the VHIO testing facility in Spain. In October 2021, we signed a partnership agreement with The Royal Marsden NHS Foundation Trust, or Royal Marsden, a premier cancer center within the United Kingdom, or the UK, for patient care, research and teaching of all types of cancer, and in April 2023, the blood-based cancer testing services based on our digital sequencing platform became available at Royal Marsden testing facility in the UK. In September 2024, we signed a partnership agreement with the Agostino Gemelli University Polyclinic Foundation IRCCS, one of Italy's largest and most renowned hospitals known for its advanced oncology services, including diagnostics, treatment, and research, to establish an in-house liquid biopsy testing service within its hospital system.

In May 2018, we formed and capitalized Guardant Health AMEA, Inc., with SoftBank, which we refer to as Guardant AMEA, relating to the sale, marketing and distribution of our tests generally outside the Americas and Europe and to accelerate commercialization of our products in Asia, the Middle East and Africa. In June 2022, we

purchased all of the shares held by SoftBank and its affiliates, and upon completion of the transaction, we obtained full control over operations of Guardant AMEA throughout the Asia, Middle East and Africa region. In Japan, we have received regulatory approval of our Guardant360 CDx test as a companion diagnostic for identifying patients who may benefit from treatment with LUMAKRAS™ (sotorasib), Keytruda® (pembrolizumab), Opdivo® (nivolumab), and ENHERTU® (trastuzumab deruxtecan), from Japan's Ministry of Health, Labour and Welfare, or the MHLW. In addition, in July 2023, the MHLW granted national reimbursement approval for our Guardant360 CDx test for patients with advanced or metastatic solid tumor cancers in Japan.

In June 2022, we signed a strategic partnership agreement with Adicon Holdings Limited, or Adicon, a leading independent clinical laboratory company based in China, and in December 2023, the blood-based cancer testing services based on our digital sequencing platform became available at Adicon's testing facility, which offers our industry-leading comprehensive genomic profiling tests to biopharmaceutical companies to advance clinical research and the development of new cancer therapies in China.

Payer coverage and reimbursement

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, if at all, at a lower amount than participating providers. 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 tests 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, some of the time as a non-participating provider through 2023. 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, subject to statue of limitations.

Our tests are currently covered by various commercial payers and our reimbursement is directly impacted by their policies. 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.

In addition to our existing covered and contracted payers, various laboratory benefit managers and evidence review organizations working with commercial payers have endorsed coverage of Guardant360 CDx, Guardant360 LDT, Guardant360 TissueNext and Guardant Reveal.

We are actively engaged to expand coverage among existing commercial 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 commercial payers to include additional tests, 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 CMS, with opportunities for public participation. Medicare's National Coverage Determination, or NCD, for Next Generation Sequencing, or NGS, 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 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. 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 Medicare's National Coverage Determination for Next Generation Sequencing established in March 2018. 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" (ADLTs)), 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. We are subject to reporting requirements under PAMA and the Medicare rate for our tests will be calculated based on our private payer rates. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which delayed the next data reporting period by one year and prevented any reduction in payment amounts from commercial payer rate implementation in 2022. On November 2, 2022, CMS published its final rule for the Medicare Physician Fee Schedule for calendar year (CY) 2023, including changes for clinical laboratories that took effect on January 1, 2023. Changes include updated regulatory definitions to specify the data collection period for the data reporting period of January 1, 2023 through March 31, 2023; revisions to indicate that data reporting is required every 3 years beginning January 2023; and to confirm that for CY 2022, payment may not be reduced by more than 0% as compared to CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15% as compared to the amount established for the preceding year. On December 29, 2022, Congress passed the Consolidated Appropriations Act, 2023, which prevented any reduction in payment amounts from commercial payor rate implementation for 2023; delayed by one year data reporting requirements for tests other than ADLTs; and extended the three-year period in which payment may not be reduced by more than 15%, to CYs 2024 through 2026.

Current Procedural Terminology, or CPT, coding plays a significant role in how our tests are 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 our molecular diagnostics tests. Changes to the codes used to report to payers may result in significant changes in reimbursement. If their policies were to change in the future to cover additional cancer indications, we anticipate that our total reimbursement would increase. In January 2021, a proprietary laboratory analyses, or PLA code was issued for our Guardant360 CDx test with an effective date in April 2021. Additionally, based on this new PLA code, we applied to the CMS for our Guardant360 CDx test to become an advanced diagnostic laboratory test, or ADLT. In March 2021, CMS approved ADLT status to the Guardant360 CDx test, based on which Medicare paid us at the lowest available commercial rate per test, from April 1, 2021 to December 31, 2021. Effective January 1, 2022, Medicare started to reimburse Guardant360 CDx services at the median rate of claims paid by commercial payers. In March 2022, Palmetto GBA, the Medicare administrative contractor for MolDX, conveyed coverage for our Guardant360 TissueNext test under the existing local coverage determination. The policy covers our Guardant360 TissueNext test for Medicare fee-for-service patients with advanced solid tumor cancers. In July 2022, Palmetto GBA conveyed coverage for our Guardant Reveal test for fee-for-service Medicare patients in the United States with stage II or III colorectal cancer whose testing is initiated within three months following curative intent therapy, with an effective date of December 2021. In April 2023, Palmetto GBA conveyed coverage for our Guardant360 Response test for fee-for-service Medicare patients in the U.S. with metastatic or inoperable solid tumors who are on an immune checkpoint inhibitor therapy, tested four to ten weeks from therapy initiation. Effective January 1, 2024, Medicare has increased the reimbursement rate for our Guardant360 LDT test to the same rate as our Guardant360 CDx test. In January 2025, Palmetto GBA granted coverage for our Guardant Reveal test to monitor disease recurrence in patients with colorectal cancer in the surveillance setting following curative intent therapy. This represents an expansion from the prior Medicare coverage of our Guardant Reveal test for colorectal cancer in the early post-surgical setting only.

In August 2024, following the FDA approval, our Shield blood test met the coverage requirements by Medicare based on the criteria established in its NCD for blood-based colorectal cancer screening tests. The test is covered once every three years for eligible Medicare beneficiaries.

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 healthcare 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

As of January 2025, 21 states, including California, have enacted laws that require biomarker testing to be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of disease or condition if the test is supported by medical and scientific evidence, and these enacted laws will mandate coverage for Guardant360 CDx, Guardant360 LDT, Guardant360 TissueNext, Guardant Response and Guardant Reveal when certain criteria are met. In addition, several more states have current legislation in progress. While we believe that additional states might enact similar laws in the future, we cannot predict how these changes, if any, will affect our business and financial condition.

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, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received differs from the revenue recorded. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. Additionally, if coding changes were to occur, payments for certain uses of our tests could be reduced, put on hold, or eliminated. 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 currently perform clinical, research use only, and investigation use only tests in our laboratory located in Redwood City, California. Our Redwood City 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. We also perform research use only tests in our laboratory located in San Diego, California. In addition, our Redwood City, San Diego and Palo Alto, California laboratories are currently operated as centers for our research and technology development.

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 sample collection, laboratory processing, analysis and reporting. All major processing steps utilize quality control to ensure consistent and reproducible results.

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 materials to our laboratories. 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 lot that has been previously qualified and released 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, minimal residual disease detection, and early cancer screening is leading to more companies offering services in genomic profiling. The promise of liquid biopsy testing 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 for therapy selection include Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in 2018; Caris Life Science; Tempus AI, Inc.; NeoGenomics Laboratories, Inc.; Exact Sciences Corp.; Myriad Genetics, Inc.; and Laboratory Corporation of America. In addition, Natera, Inc., Tempus AI, Inc., Exact Sciences Corp., Myriad Genetics, Inc., Caris Life Science, Foundation Medicine, Inc. and Quest Diagnostics, Inc., among others, are our competitors in minimal residual disease detection. Additionally, our competitors in the early screening testing space include GRAIL, Inc., Exact Sciences Corp., Freenome Holdings, Inc., and Delfi Diagnostics.

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., and most if not all of the competitors within the liquid biopsy space for therapy selection, that sell molecular diagnostic tests for cancer to physicians and have or may develop tests that compete with our tests. In addition, we are aware that certain of our customers are also developing their own tests and may decide to enter our market or otherwise stop using our tests.

In addition to developing kits, certain diagnostic companies also provide next-generation sequencing platforms that could be used for liquid biopsy testing. These include Illumina, Inc., Thermo Fisher Scientific Inc., Pacific Biosciences of California, Inc., Ultima Genomics, Inc., Oxford Nanopore Technologies Limited, and other companies developing next-generation sequencing platforms that are sold directly to biopharmaceutical companies, clinical laboratories and research centers. While many of the applications for these platforms are focused on research and development applications, each of these companies has launched and could continue to commercialize products focused on the clinical oncology market. These tests could include FDA-approved diagnostic kits, which can be sold to the clients who have purchased their platforms.

Furthermore, many companies are developing information technology-based tools to support the integration of next-generation sequencing testing into the clinical setting. These companies may also use their own tests or others to develop an integrated system which could limit 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 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 and obligations.

Our patent strategy is focused on seeking coverage for our core technology, our digital sequencing platform, and specific follow-on applications and implementations for screening, detecting and monitoring cancer or other diseases by determining genetic and/or epigenomic variations in patient samples. In addition, we file for patent protection in connection with our on-going research and development activities, particularly those related to early-stage cancer detection.

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

- issued patents and patent applications relating to our digital sequencing platform, including claims directed to methods for preparing and sequencing cell-free DNA, techniques for enriching nucleic acid samples, identifying CNVs, SNVs, indels and fusions in cell-free DNA, and detecting epigenomic variations (such DNA methylation) in biological samples;
- issued patents and patent applications relating to detecting residual disease and monitoring cancer and other diseases by determining genetic and epigenomic variations in biological samples; and
- issued patents and patent applications 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 2041.

We also bolster our proprietary technology by acquiring or in-licensing technologies developed by third parties. While we developed our digital sequencing platform internally, we believe the technologies we in-licensed from third parties, which mostly relate to improvements to next-generation sequencing technologies, are potentially valuable and of possible strategic importance to us or our competitors. Under some of our in-license agreements, we are obligated to pay low single-digit percentage running royalties on net sales of the product or service where the licensed technology is used in, subject to minimum annual royalties or fees for certain of the in-license 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 products globally, in the United States, Australia, South America, Europe and Asia.

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, however, we may not be successful and our intellectual property rights may be invalidated, circumvented or challenged and found unenforceable. 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, to protect our unpatented technology and other proprietary information, and 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 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 diagnostics, 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, advertising and promotion activities, sales, distribution and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA. 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 application. 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 typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical study data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. A PMA 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 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. FDA may issue a hold letter requesting additional information, which would stop the review clock for FDA. The applicant has 180 days to respond to such additional information request, after which the FDA review clock will resume. 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 or *de novo* request. 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 is obtained or a *de novo* request is granted. 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 September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintain a list device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible.

The PMA process

We currently market our Guardant360 CDx test and the Shield test pursuant to an approved PMA. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical studies. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, 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, 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 study data and clinical study sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA generally takes between one and three years but may take significantly longer.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval order, 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 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 studies are necessary, in which case the PMA approval may be delayed for several months or years while the studies 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.

In approving a PMA, 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 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 PMAs 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. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which could affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of

information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

The IDE process

Clinical studies are almost always required to support a PMA or a *de novo* request, and are sometimes required to support 510(k) submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical studies, but must still comply with abbreviated IDE requirements when conducting such studies. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical study to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical studies may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical study after obtaining approval for the study by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the studies support the safety and effectiveness of the device or warrant the continuation of clinical studies. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, study monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a study begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Expedited development and review programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and healthcare providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510(k) clearance and *de novo* classification. The program is available to medical devices that

meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of postmarket data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions.

FDA regulation of laboratory developed tests

Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics that are designed, manufactured, and used within a single laboratory for use only in that laboratory. We believe certain of our diagnostic testing products qualify as LDTs subject to the FDA's enforcement discretion.

Legislative and administrative proposals to clarify or amend FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals regarding the regulation of LDTs will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our LDTs or to develop and introduce new tests as LDTs. For example, in recent years, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents titled "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)," or the Reporting Guidance. The Framework Guidance stated that FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting Guidance would have further enabled FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT.

On November 18, 2016, the FDA announced that it would not finalize either guidance document 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, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017. In May 2024, the FDA finalized a rule requiring LDTs to undergo premarket review as medical devices. While the rule is set to be implemented in the spring of 2025, it has been challenged in two separate lawsuits in federal court. The FDA could ultimately subject LDTs to additional regulatory requirements. Moreover, legislative measures could result in a change to the approach to FDA's regulation over LDTs, including a requirement for premarket review of LDTs, among other things.

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 many 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.

FDA Regulation of Companion Diagnostics

If safe and effective use of drug or biologic depends on an *in vitro* diagnostic, then the FDA may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product for that indication, the FDA may will not approve the drug or new indication if the companion diagnostic device is not also approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population.

Our Guardant 360 CDx test has been approved by the FDA for use as a companion diagnostic to identify NSCLC and breast cancer patients who may respond to certain therapies marketed by our biopharmaceutical customers.

Pervasive and continuing FDA regulation

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

- establishment registration and device listing with the FDA;
- 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 (including in vitro diagnostic medical devices) are subject to extensive regulation, such as premarket review, marketing authorization or certification, by similar agencies or notified bodies in other countries. Regulatory requirements and approval or certification processes are not harmonized and vary from one country to another. International regulators and notified bodies are independent and not bound by the findings of the FDA.

Regulation of Medical Devices in the EU

The EU has adopted specific directives and regulations regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices (including in vitro diagnostic medical devices).

In the EU, there is currently no premarket government review of medical devices (including in vitro diagnostic medical devices). However, the EU requires that all in vitro diagnostic medical devices placed on the market in the EU must meet the essential requirements of the EU In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC), or IVDD, including the requirement that an in vitro diagnostic medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

Compliance with the essential requirements of the IVDD is a prerequisite for European conformity marking, or CE mark, without which in vitro diagnostic medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the essential requirements laid down in Annex I to the IVDD, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of in vitro diagnostic medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for (general) in vitro diagnostic medical devices (i.e., all in vitro diagnostic medical devices other than those covered by Annex II to the IVDD and in vitro diagnostic medical devices for self-testing), where the manufacturer can self-declare the conformity of its products with the essential requirements, a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. We have obtained CE mark for our Guardant360 CDx test and the non-CDx blood collection kit.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

All manufacturers placing in vitro diagnostic medical devices on the market in the EU must comply with the EU medical device vigilance system. Under this system, incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of an in vitro diagnostic medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through field safety notices.

The advertising and promotion of in vitro diagnostic medical devices is subject to some general principles set forth by EU directives. According to the IVDD, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at national level. EU member states laws related to the advertising and promotion of medical devices (including in vitro diagnostic medical devices), which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices (including in vitro diagnostic medical devices), in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

The EU regulatory landscape concerning medical devices is evolving. On April 5, 2017 Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, or IVDR, was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike the IVDD, the IVDR is directly applicable in all EU member states without the need for member states to implement into national law. This aims at reducing the risk of discrepancies in interpretation across the different European markets. On October 14, 2021, the European Commission proposed a "progressive" roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. Consequently, if the European Parliament and Council adopt the proposed regulation, the IVDR will fully apply on May 26, 2022 but there will be a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation.

The IVDR will become applicable five years after publication on May 26, 2022. Once applicable, the IVDR will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establish explicit provisions on importers' and distributors' obligations and responsibilities;
- impose an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- set up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices that may have to undergo an additional check by experts before they are placed on the market.

Regulation of Companion Diagnostics

In the EU, in vitro diagnostic medical devices are regulated by the IVDD which regulates the placing on the market, the CE marking, the essential requirements, the conformity assessment procedures, the registration obligations for manufactures and devices as well as the vigilance procedure. In vitro diagnostic medical devices must comply with the requirements provided for in the IVDD, and with further requirements implemented at national level (as the case may be).

The regulation of companion diagnostics will be subject to further requirements once the IVDR will become applicable on May 26, 2022. The IVDR introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue a CE certificate, the notified body must seek a scientific opinion from the European Medicines Agency, or EMA, on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a marketing authorization application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national competent authorities or the EMA.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Brexit

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency, or MHRA, has become the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA (but manufacturers were given a grace period of four to 12 months to comply with the new registration process) before being placed on Great Britain market. The MHRA only registers devices where the manufacturer or their United Kingdom, or UK, Responsible Person has a registered place of business in the UK. Manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA in line with the grace periods. Effective July 1, 2023, in Great Britain, all medical devices require a UKCA, or UK Conformity Assessed mark. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

An MHRA public consultation was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive 93/42/EEC and the IVDD), in particular to create a new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence, or AI, as medical devices, reform IVD regulation, and foster sustainability through the reuse and remanufacture of medical devices. The regime came into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicated that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

In addition, the Trade Deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization-related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

Under the terms of the Northern Ireland Protocol, Northern Ireland follows EU rules on medical devices and devices marketed in Northern Ireland require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark is required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK notified body conducts such assessment, a ‘UKNI’ mark is applied and the device may only be placed on the market in Northern Ireland and not the EU.

Other foreign regulations

In February 2021, Guardant Health Japan, an affiliate of Guardant AMEA, submitted an application to the MHLW, for regulatory approval of Guardant360 CDx. In December 2021, the MHLW granted regulatory approval of Guardant360 CDx in patients with advanced solid cancers. The Guardant360 CDx test was also granted approval as a companion diagnostic to identify patients with microsatellite instability-high (MSI-High) solid tumors who may benefit from Keytruda® (pembrolizumab) and patients with MSI-High advanced colorectal cancer who may benefit from Opdivo® (nivolumab). The MHLW additionally granted regulatory approval of the Guardant360 CDx liquid biopsy test as a companion diagnostic for identifying patients with metastatic NSCL cancer who may benefit from treatment with LUMAKRASTM (sotorasib), a *KRAS* G12C inhibitor developed and manufactured by Amgen.

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, or PAL. Oversight for medical devices is conducted with participation by the Pharmaceutical and Medical Devices Agency, or PMDA, a quasi-government organization performing many of the review functions for the 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. The 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.

In addition, the Physician Payments Sunshine Act imposes, among other things, reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by the statute) and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are currently exempt from these reporting requirements.

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.

In January 2022, we received a civil investigative demand, or CID, from the United States Attorney for the Northern District of California in connection with an investigation under the False Claims Act. The CID requests information and documents regarding billing government-funded programs for our panel of genetic tests known as Guardant360. We are fully cooperating with the investigation. At this time, we are unable to predict the outcome of this investigation. See "Commitments and Contingencies – Legal Proceedings" in this Annual Report on Form 10-K for more information.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, 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

Our Employees and Commitment to Diversity, Equity and Inclusion

As of December 31, 2024, we had 2,021 employees, 1,999 of which are full-time employees and approximately 1,849 of which are in the U.S., with the remainder in Asia, Europe and Canada. We have also engaged and may continue to engage independent contractors to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement, except as required by local laws such as in some European countries, and we have never experienced any employment-related work stoppages. We also track voluntary and involuntary turnover rates, conduct frequent employee engagement surveys, and consider relations with our employees to be good.

As part of our mission to conquer cancer, we continue to advance our environmental, social and governance efforts, including enhancing the diversity and inclusiveness of our workplace. We believe that diversity of backgrounds and ideas inspires creativity and helps us create the innovative technologies that patients need. We appreciate one another's differences and strengths and we are proud to be an equal opportunity employer. We do not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status or any other basis covered by applicable law. All employment is decided on the basis of qualifications, merit, and business need. Further, we have policies in place that prohibit harassment of all kinds. We maintain an inclusive culture where all employees feel empowered to be their authentic selves. We respect and appreciate each employee's unique perspective and experiences, and value their contribution to our mission. It is important that we celebrate, encourage and support similarities and differences to drive innovation for the benefit of our employees, patients and community.

We are proud to employ a diverse workforce that, as of December 31, 2024, was 55% racially/ethnically diverse and 54% female. For leadership positions across the company, which is defined as director level and above, 32% self-identified as racially/ethnically diverse and 40% self-identified as women. As of December 31, 2024, women held 30% of the independent director seats on our Board.

Culture, Compensation and Benefits

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 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. In order to ensure that we are meeting our human capital objectives, we regularly utilize employee engagement surveys to understand the effectiveness of our employee development and compensation programs and where we can improve across the company. We also regularly evaluate our compensation programs with an independent compensation consultant and utilize industry benchmarking in an effort to ensure they are competitive compared to similar biotechnology and biopharmaceutical companies with which we compete for talent, as well as fair and equitable across our workforce with respect to gender, race and other personal characteristics.

We are committed to rewarding, supporting, and developing the employees who make it possible to deliver on our strategy. To that end, we offer a comprehensive total rewards package that includes market-competitive fixed and/or variable pay, broad-based equity grants and bonuses, access to medical, dental, vision and life insurance benefits, disability coverage, fertility subsidies, retirement savings plans, paid time off and family leave, caregiving support, fitness, cellphone and internet reimbursements, and mental health and other wellness benefits.

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. We use the "Investors" portion of our website for purposes of compliance with Regulation FD and as a routine channel for distribution of important information to investors and interested parties, including new releases, analyst presentations, financial information and corporate governance practices. Accordingly, you should monitor the "Investors" portion of our website for the release of this information. 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

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. 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, 2024, 2023 and 2022, we incurred net losses of $436.4 million, $479.4 million and $654.6 million, respectively. As of December 31, 2024, we had an accumulated deficit of $2.6 billion. To date, we have financed our operations principally from the sale of stock or convertible securities, and revenue from precision oncology testing, and development services and other. We have devoted substantially all of our resources to the development and commercialization of our current products and to research and development activities related to our future products, including clinical and regulatory initiatives to obtain marketing approval and sales and marketing activities. We will need to generate substantial revenue to achieve and then sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

We may not be able to generate sufficient revenue to achieve and maintain profitability and our current or future products may not achieve or maintain sufficient commercial market acceptance.

We are currently not profitable. Even if we succeed in increasing adoption of our existing products and services by physicians, obtaining additional coverage decisions from commercial and government payers, maintaining and creating relationships with our existing and new biopharmaceutical partners, and developing and commercializing additional products and services, we may not be able to generate sufficient revenue to achieve or maintain profitability.

We believe our commercial success is dependent upon our ability to continue to successfully market and sell our current and future products, to continue to expand our current relationships and develop new relationships with clinicians and biopharmaceutical customers and to develop and commercialize new products. Our ability to achieve and maintain sufficient commercial market acceptance of our existing and future products will depend on a number of factors, including:

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

We cannot assure that we will be successful in addressing each of these criteria or other criteria that might affect the market acceptance of our products. If we are unsuccessful in achieving and maintaining market acceptance of our products, our business and results of operations will suffer.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

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

Additionally, it is difficult to predict the amount we are able to collect for our tests from commercial payers. We receive reimbursement for our tests from several commercial payers for whom we are not a participating provider. Because we are not contracted with these payers, they determine the amount they are willing to reimburse us for tests. We have provided testing services to patients with many cancer types and indications, some of the time as a non-participating provider through 2024. When we have received payment as a non-participating provider, the amounts, on average, were significantly lower than for participating providers. Even when these payers have paid a claim, they may elect at any time to review previously paid claims for overpayment against these claims. In the event of an overpayment determination, the payer may offset the amount they determine they overpaid against amounts they owe us on current claims. We have limited leverage to dispute these retroactive adjustments and we cannot predict when, or how often, a payer might engage in these reviews. A significant amount of these offsets by one or more payers in any given quarter could have a material effect on our results of operations and cause them to fall below expectations or guidance we may provide. Our efforts to become a participating provider of a number of commercial payers may not be successful. Even when we have obtained positive coverage decisions for our tests from commercial payers and entered into agreements with them, such agreements typically are standard form contracts and may allow payers to terminate coverage on short notice, impose significant obligations on us and create additional regulatory and compliance hurdles for us.

As part of our reimbursement operations, we appeal denials from payers, and if successful, we receive payments from these appeals. However, due to the inherent variability of the insurance landscape, we cannot guarantee future success of, or any payments from, appeals of reimbursement denials by payers. Historic success and payments are not indicative of future success of and payments from such appeals.

Due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our tests, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received for a test differs from the revenue recorded for the test. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly.

The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

We have historically provided guidance related to our annual revenue, non-GAAP gross margin, non-GAAP operating expense, and free cash flow. The variability and unpredictability could 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 such products for clinical use on a timely basis, or at all. For example, there can be no assurance that we will be able to produce commercial products for early detection of cancer. Before we can commercialize any new products, we will need to expend significant funds in order to:

- conduct substantial research and development, including validation studies and clinical studies;
- further develop and scale our laboratory processes to accommodate different products; and
- further develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including:

- failure of the product to perform as expected, including defects and errors;
- lack of validation data; or
- failure to demonstrate the clinical utility of the product.

Our development plan involves using data and analytical insights generated from our current products as a force multiplier of returns on research and development investment in our future products. However, if we are unable to generate additional or compatible data and insights, then we may not be able to advance our products under development as quickly, or at all, or without significant additional investment. In addition, we recently migrated some of our existing products to our Smart Liquid Biopsy platform. While we believe that this platform improves the tests and adds value, the tests may not perform as well as expected on the platform and the market might not accept the value proposition that we believe the platform provides.

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 93%, 91% and 87% of our revenue in the years ended December 31, 2024, 2023 and 2022, respectively. Continued adoption and use of our tests will depend on several factors, including the prices we charge for our tests, the scope of coverage and amount of reimbursement available from third-party payers for our tests, the availability of clinical data that supports the value of our tests and the inclusion of our tests in industry treatment guidelines. In addition, many biopharmaceutical companies have existing relationships with companies that develop molecular diagnostic tests, including our competitors, and may continue to use their tests instead of ours. Despite our business development efforts, it could be difficult, expensive and/or time-consuming for biopharmaceutical companies to switch diagnostic tests for their products, and our tests may not be widely accepted by biopharmaceutical companies, if at all, which could in turn hinder the growth of sales of our tests. If we are unable to achieve commercial success for our tests, our business, results of operations and financial condition would be materially and adversely affected. We cannot assure that our tests will continue to maintain or gain market acceptance, and any failure to do so would materially harm our business and results of operations.

If our products do not meet the expectations of patients and our customers, our operating results, reputation and business could suffer.

Our success depends on the market's confidence that we can provide reliable, high-quality precision oncology products that will improve clinical outcomes, lower healthcare costs and enable better biopharmaceutical development. We believe that patients, clinicians and biopharmaceutical companies are likely to be particularly

sensitive to product defects and errors in the use of our products, including if our products fail to detect genomic alterations with high accuracy from samples or if we fail to list or inaccurately include certain treatment options and available clinical studies in our test reports, and there can be no guarantee that our products will meet their expectations. Furthermore, if our competitors' products do not perform to expectations, it may result in lower confidence in our tests as well. As a result, the failure of our products to perform as expected could significantly impair our operating results and our reputation. In addition, we may be subject to legal claims arising from any defects or errors in our products.

If we are unable to support demand for our current and future products, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage our anticipated growth, our business could suffer.

As our volume of test sales grows, we will need to continue to increase our workflow capacity for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program and extend our platform to support comprehensive genomic analysis at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our precision oncology products. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities or process enhancements will be successfully implemented, if at all, or that we will have adequate space in our laboratory facility or be able to secure additional facility space to accommodate such required expansion.

As we commercialize additional products, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced.

Biopharmaceutical customers collaborate with us for analysis of whole blood or plasma samples for multiple applications primarily to support clinical studies, including patient identification, companion diagnostics, retrospective testing and data services. In addition, we generate revenue from licensing our digital sequencing technologies to our domestic biopharmaceutical customers and international laboratory partners. In the years ended December 31, 2024, 2023 and 2022, revenue from our top five biopharmaceutical customers, including their affiliated entities, accounted for 13%, 14% and 18% of our total revenue, respectively. The revenue attributable to our biopharmaceutical customers may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue. Adverse speculation about our existing or potential relationships with biopharmaceutical companies may be a catalyst for adverse speculation about us, our products and our technology, which can adversely affect our reputation and business.

Our future success depends in part on our ability to maintain relationships and to enter into new relationships with biopharmaceutical customers, including offering our platform to such customers for companion diagnostic development, novel target discovery and validation as well as clinical study enrollment, and growing into other business opportunities. This can be difficult due to many factors, including the type of biomarker support required and our ability to deliver it and our biopharmaceutical customers' satisfaction with our products or services, internal and external constraints placed on these organizations and other factors that may be beyond our control. Furthermore, our biopharmaceutical customers may decide to decrease or discontinue their use of our current products and tests, or our future products due to changes in their research and product development plans, failures in their clinical studies, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control. Continued usage of our tests by particular biopharmaceutical customers may also depend on whether the partner obtains positive data in its clinical studies, is able to successfully obtain regulatory approval and subsequently commercializes a therapy for which we have partnered with them to develop a companion diagnostic, or other administrative factors that are outside our control. Some of our biopharmaceutical customers have contracted with us to provide testing for large numbers of samples, which could strain our testing capacity and restrict our ability to perform tests for other customers. Furthermore, biopharmaceutical companies may decline to do business with us or decrease or discontinue their use of our tests

due to their broad strategic collaboration with any of our competitors. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to research and clinical studies that facilitate the collection and incorporation of new information into our platform and tests. We engage in conversations with biopharmaceutical companies regarding potential commercial opportunities on an ongoing basis. There is no assurance that any of these conversations will result in a commercial agreement, that the resulting relationship will be successful, or that clinical studies conducted as part of the engagement will produce successful outcomes. If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our product development could be delayed and revenue and results of operations could be adversely affected.

Our payer concentration may materially adversely affect our financial condition and results of operations.

We receive a substantial portion of our revenue from a limited number of third-party commercial payers, most of which have not contracted with us to be a participating provider. If one or more of these payers were to significantly reduce, or cease to pay, the amount such payer reimburses us for tests we perform, or if such payer does not reach or maintain favorable coverage and reimbursement decisions for our tests, it could have a material adverse effect on our business, financial condition and results of operations. We have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. If commercial payers were to decide not to include us as a participating provider, cease paying us altogether, drastically reduce the amount they were willing to pay us or attempt to recover any amounts they had already paid, it could cause significant fluctuations in our quarterly results and could harm our business and results of operations.

In September 2018, we began to receive reimbursement from Medicare for claims submitted with respect to our precision oncology tests. Precision oncology revenue from clinical tests for patients covered and administered by Medicare represented approximately 39%, 43% and 45% of our precision oncology revenue from clinical customers for the years ended December 31, 2024, 2023 and 2022, respectively. Revenue attributable to Medicare accounted for more than 10% of our total revenue in each of the years ended December 31, 2024, 2023 and 2022. 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 pathology 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 the 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, minimal residual disease detection, and early cancer screening is leading to more companies offering services in genomic profiling. The promise of liquid biopsy testing is also leading to more companies attempting to enter the space and compete with us. Over the last year, that has included new and accelerated development programs by a number of potential competitors, and increasing levels of merger and acquisition activity by both existing and new competitors. Currently, our main competition is from diagnostic companies with products and services to profile genes in cancers based on either single-marker or comprehensive genomic profile testing, based on next-generation sequencing in either blood or tissue. This may change over the next few years as a result of new competitors entering through investment and acquisition activity.

Our competitors within the liquid biopsy space for therapy selection include Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in 2018; Caris Life Science; Tempus AI, Inc.; NeoGenomics Laboratories, Inc.; Exact Sciences Corp.; Myriad Genetics, Inc.; and Laboratory Corporation of America. In addition, Natera, Inc., Tempus AI, Inc., Exact Sciences Corp., Myriad Genetics, Inc., Caris Life Science, Foundation Medicine, Inc. and Quest Diagnostics, Inc., among others, are our competitors in minimal residual disease detection. Additionally, our competitors in the early screening testing space include GRAIL, Inc., Exact Sciences Corp., Freenome Holdings, Inc., and Delfi Diagnostics.

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., and most if not all of the competitors within the liquid biopsy space for therapy selection, that sell molecular diagnostic tests for cancer to physicians and have or may develop tests that compete with our tests. In addition, we are aware that certain of our customers are also developing their own tests and may decide to enter our market or otherwise stop using our tests.

Some of our competitors and potential competitors may have longer operating histories; larger customer bases; greater brand recognition and market penetration; substantially greater financial, technological and research and development resources and selling and marketing capabilities; and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to product development than we can. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

In addition to developing kits, certain diagnostic companies also provide next-generation sequencing platforms that could be used for liquid biopsy testing. These include Illumina, Inc., Thermo Fisher Scientific Inc., Pacific Biosciences of California, Inc., Ultima Genomics, Inc., Oxford Nanopore Technologies Limited, and other companies developing next-generation sequencing platforms that are sold directly to biopharmaceutical companies, clinical laboratories and research centers. While many of the applications for these platforms are focused on research and development applications, each of these companies has launched and could continue to commercialize products focused on the clinical oncology market. These tests could include FDA-approved diagnostic kits, which can be sold to the clients who have purchased their platforms.

Furthermore, many companies are developing information technology-based tools to support the integration of next-generation sequencing testing into the clinical setting. These companies may also use their own tests or others to develop an integrated system which could limit access for us to certain networks.

The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients with late-stage, solid tumor cancer, the number of individuals who are at a higher risk for developing cancer, and the assumed prices at which we can sell tests for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell our products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

The precision oncology industry is subject to rapid change, which could make our current products and any future products we may develop, obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current and future products obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our platform and develop new products to keep pace with evolving standards of care. If we do not update our product offerings to reflect new scientific knowledge about cancer biology, information about new cancer therapies or relevant clinical studies, our products could become obsolete and sales of our current products and any new products we may develop could decline or fail to grow as expected.

If we continue to experience challenges attracting and retaining qualified personnel due to competitive labor markets, we may be unable to manage our future growth effectively, all of which could make it difficult to execute our business strategy.

Since our inception, we have experienced rapid growth and anticipate further growth in our business operations. Our future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue to increase headcount and to hire more specialized personnel as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, as well as sales and marketing staff, and improve and maintain our technology to properly manage our growth.

However, we have experienced challenges attracting and retaining qualified personnel due to competitive labor markets and may continue to do so. In this competitive environment, our business could be adversely impacted by increases in labor costs triggered by regulatory actions regarding wages, scheduling and benefits, and the need to attract and retain high quality employees with the requisite skill sets. In addition, if our new hires perform poorly, if we are unsuccessful in training, managing and integrating these new employees or if we are not successful in developing and retaining our existing employees, our business may be harmed.

In addition, we may not be able to maintain the quality or expected turnaround times of our products, or satisfy customer demand as it grows, and our business may be harmed. Our ability to manage our growth properly will also require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain and could be demanding, and failure to complete this in a timely and efficient manner could adversely affect our operations.

We may not be able to successfully market, sell or distribute our products, and if we are unable to expand our sales organization to adequately address our customers' needs, our business may be adversely affected.

We may not be able to market, sell or distribute our products and tests, and other products we may develop effectively enough to support our planned growth. We currently sell to clinicians in the United States through our own sales organization and to biopharmaceutical companies through our business development team.

Each of our target markets is large, distinctive and diverse. As a result, we believe it is necessary for our sales representatives and business development managers to have established oncology-focused expertise. Competition for such employees within the precision oncology industry is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales organization or business development team, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability.

Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our products, to increase our sales and to compete effectively will depend, in part, on our ability to manage this potential future growth effectively, without compromising quality.

Outside the United States, we established Guardant AMEA for sales of our products throughout Asia, the Middle East and Africa. If the sales and marketing efforts for our products in those regions are not successful, our business would be materially and adversely affected. In other territories, such as Europe, we sell our tests primarily through distributor relationships or direct contracts with hospitals. Locating, qualifying, engaging and maintaining relationships with distribution partners and hospitals with local industry experience and knowledge will be necessary to effectively market and sell our products outside the United States. We may not be successful in finding, attracting and retaining distribution partners or local hospitals, or we may not be able to enter into such arrangements on favorable terms. Sales practices utilized by any such parties that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our international sales and marketing efforts are not successful, we may not achieve market acceptance for our products outside the United States, which would materially and adversely impact our business.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or promptly transition to alternative suppliers.

We rely on a limited number of suppliers or, in some cases, sole suppliers, including Illumina Inc., or Illumina, for certain sequencers, reagents, blood tubes and other equipment, instruments and materials that we use in our laboratory operations. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing these laboratory equipment, instruments or materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly and adversely affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of the sequencers and as the sole provider of maintenance and repair services for these sequencers. Any disruption in operations of Illumina or other sole or limited suppliers or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations and thus our ability to conduct our business and generate revenue. These limited or sole suppliers could engage in diverse types of businesses, including selling products or providing services in competition with us, and there can be no assurance that we can continue to receive required equipment, instruments or materials from them.

We believe that there are only a limited number of other manufacturers that are capable of supplying and servicing the equipment and materials necessary for our laboratory operations, including sequencers and various associated reagents, and potentially replacing our current suppliers. The use of equipment or materials furnished by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. There can be no assurance that we will be able to secure alternative equipment, reagents and other materials, bring such equipment, reagents and materials online, and revalidate our tests without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, for example, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring or integrating the equipment and reagents we require for our products or in revalidating our products, our business, financial condition, results of operations and reputation could be materially and adversely affected.

If our existing laboratory facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to perform our tests and pursue our research and development efforts may be jeopardized.

We currently derive the majority of our revenue from tests performed at a single laboratory facility located in Redwood City, California. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for our laboratory operations. The inability to perform our tests or to reduce the backlog that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility, to locate and qualify a new facility or enable a third party to practice our proprietary technology, particularly in light of licensure and accreditation requirements. Even if we are able to find a third party with such qualifications to perform our tests, the parties may be unable to agree on commercially reasonable terms.

We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facility and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

We are dependent on third parties for the collection of blood samples for our tests.

We rely on third-party phlebotomy providers, including physician offices, to collect blood samples for our tests. Our current third-party phlebotomy providers may refuse to continue to collect samples for us in the future, in particular if they have agreements or arrangements with one of our competitors to collect samples for their tests, or if the phlebotomy provider is owned or controlled by a laboratory that offers tests that compete with ours. There has been a trend towards consolidation of independent phlebotomy providers. Independent phlebotomy providers, once acquired by our competitors, may terminate their relationships with us. If our patients are unable to readily access a phlebotomy provider to collect a blood sample for our tests, we may be unable to compete effectively with other laboratories that have greater access to phlebotomy providers and our business, financial condition and results of operations may be harmed.

In addition, if third-party phlebotomy providers fail to adequately and properly obtain and collect viable blood samples from patients and to properly package and ship the samples to us, our patients and their physicians may experience problems and delays in receiving test results, which could lead to dissatisfaction with our tests, therefore harming our reputation and adversely affecting our business, financial condition and results of operations. Similarly, our contracts with physician owned phlebotomy providers to collect blood could be scrutinized under federal and state healthcare laws such as the federal Anti-Kickback Statute, or AKS, and the federal law prohibiting physician self-referral, or Stark Law, to the extent these services to us are deemed to provide a financial benefit to or relieve a financial burden for a potential referral source, or are subsequently found not to be for fair market value. If our operations are found to be in violation of any of these laws and regulations, we may be subject to administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs or from coverage of commercial payers, refunding of payments received by us, and curtailment or cessation of our operations, any of which could harm our reputation and adversely affect our business, financial condition and results of operations.

We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed.

Our business depends on our ability to deliver test results quickly and reliably to our customers. Blood samples are typically received within days from the United States and outside the United States for analysis at our Redwood City, California facility. Disruptions in delivery services to transport samples to that facility, whether due to labor disruptions, bad weather, natural disaster, terrorist acts or threats or for other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner, delay our provision of test results to our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services to transport samples to us on commercially reasonable terms, our operating results may be adversely affected.

International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

We currently have limited international operations, but our business strategy incorporates potentially significant international expansion.

We plan to maintain distributor and partner relationships, to conduct physician and patient association outreach activities, to extend laboratory capabilities and to expand payer relationships, outside of the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us, our distributors, or our local partners to obtain regulatory approvals or certifications for the use of our products in various countries;
- presence of additional third-party patents or other intellectual property rights that may be relevant to our business and may potentially block our expansion;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payer reimbursement regimes, government payers, or patient self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to perform our tests locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations, currency controls and cash repatriation restrictions;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, boycotts, curtailment of trade and other business restrictions;
- public health or similar issues, such as epidemics or pandemics, that could cause business disruption for our offices in Japan and Singapore, and make it more difficult to sell our tests in the affected countries or regions, and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

We could be adversely affected by violations of the FCPA and other anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage, as a result of our international customers. Our reliance on independent distributors and third party partner laboratories to market, sell and/or perform our tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other U.S. companies in the medical device and biopharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, cause us to incur significant costs and expenses, including legal fees, and result in a material adverse effect on our business, prospects, financial condition and results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our highly regulated industry

We conduct business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition, and harm our business.

The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal, state and foreign laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and/or regulatory agencies enforcing those laws and regulations;
- federal, state and foreign healthcare fraud and abuse laws;
- federal, state and foreign laboratory anti-mark-up laws;
- coverage and reimbursement levels by Medicare, Medicaid, other governmental payers and private insurers;
- restrictions on coverage of and reimbursement for tests;

- federal, state and foreign laws governing laboratory testing, including CLIA, and state licensing laws;
- federal, state and foreign laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including laboratory developed tests, or LDTs;
- federal, state, local and foreign laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations;
- HIPAA, GDPR, APPI, CCPA, CPRA and similar state or foreign data privacy and security laws; and
- consumer protection laws.

In particular, the laws and regulations governing the marketing of clinical laboratory tests are complex, and there are often no sufficient regulatory or judicial interpretations of these laws and regulations. For example, some of our clinical laboratory tests are actively regulated by the FDA pursuant to the medical device provisions of the Federal Food, Drug and Cosmetic Act, or FDCA. The FDA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component, part or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. Our clinical laboratory tests are in vitro diagnostic products that are considered by the FDA to be medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, design, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices. If we do not comply with these requirements or fail to adequately comply, our business may be harmed.

Certain of our tests are currently marketed as LDTs, and future changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements.

We market some of our tests, Guardant360, Guardant360 Response, Guardant360 Tissue Next, Guardant Reveal and Shield, as LDTs. LDTs are in vitro diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although LDTs are classified as medical devices and the FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, the FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs. While we believe that we are in material compliance with applicable laws and regulations, we cannot assure that the FDA will agree with us. If there are changes in FDA policy, or if the FDA disagrees that we are marketing our tests as LDTs within the scope of its policy of enforcement discretion, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical studies or take other actions prior to continuing to market our tests. This could significantly increase the costs and expenses of conducting, or otherwise harm, our business.

Legislative and administrative proposals proposing to amend the FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our LDTs or to develop and introduce new tests as LDTs.

In addition, the FDA and Congress have, for over the past decade, considered a number of proposals to end the FDA's enforcement discretion policy for LDTs and subject LDTs to additional regulatory requirements.

Even if the FDA does not modify its policy of enforcement discretion, whether due to changes in FDA policy or legislative action, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements, including the requirement for premarket review and subsequent marketing authorization. We may also be required to conduct clinical studies to support our currently marketed products or planned product launches. If we are required to conduct such clinical studies delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any currently-marketed tests that we may be required to cease selling or the commercialization of any future tests that we may develop, which could harm our financial prospects.

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

In the event FDA rulemaking of oversight of LDTs were to be formalized, we may be required to obtain either 510(k) clearance or a premarket approval, or supplemental premarket approval, or respectively, PMA or PMA supplement, from the FDA, for some of our LDT products unless an exemption applies or FDA exercises its enforcement discretion and refrains from enforcing its medical device requirements. For example, the FDA has a policy of refraining from enforcing such requirements with respect to LDTs, which the FDA considers to be a type of *in vitro* diagnostic test that is designed, manufactured and used within a single laboratory.

The process of obtaining a PMA is a rigorous, costly, lengthy and uncertain process. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical study, manufacturing and labeling data. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support a substantial equivalence determination.

In order to sell our products in member states of the EU, our products must comply with the essential requirements of the new In Vitro Diagnostic Regulation (IVDR) 2017/746 issued and implemented by the European Union (EU) in May 2022.

These regulations introduced risk-based classification for IVDs and require notified body involvement for various high complexity devices including next generation sequencing tests such as Guardant360, Guardant360 Response, Guardant360 Tissue Next, and Guardant Reveal. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must fulfill the clinical evidence and post-market performance evidence requirements. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. To demonstrate compliance with the essential requirements we must demonstrate, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence.

The conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. The Notified Body would typically audit and examine the product's technical file and the manufacturer's quality system (notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

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

The FDA and foreign authorities or notified bodies can delay, limit or deny clearance or approval or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA, similar foreign authorities or notified bodies that our products are safe or effective for their intended uses;

- the disagreement of the FDA, similar foreign authorities or notified bodies with the design, conduct or implementation of our clinical studies or the analysis or interpretation of data from our pre-clinical or clinical studies;
- serious and unexpected adverse effects experienced by participants in our clinical studies;
- the data from our pre-clinical and clinical studies may be insufficient to support clearance or approval, or certification where required;
- our inability to demonstrate that the clinical and other benefits of any of our tests outweigh the risks;
- an advisory committee, if convened by the FDA, may recommend against approval of our PMA or other application for any of our tests or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the FDA may still not approve the test; Similar requirements may apply in foreign jurisdictions;
- the FDA, similar foreign authorities or notified bodies may identify deficiencies in our marketing application, or certification application and in our manufacturing processes, facilities or analytical methods or those of our third-party contract manufacturers;
- the potential for approval or certification policies or regulations of the FDA or similar foreign authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for the clearance or approval or certification; and
- the FDA, similar foreign authorities or notified bodies may audit our clinical study data and conclude that the data is not sufficiently reliable to support a PMA or other applications.

If we are unable to obtain clearance or approval or certification for any tests for which we plan to seek clearance or approval or certification, our business may be harmed.

Modifications to our FDA-cleared or approved products may require new 510(k) clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

For any product approved pursuant to a PMA, we are required to seek supplemental approval for many types of changes to the approved product, for which we will need to determine whether a PMA supplement or other regulatory filing is needed or whether the change may be reported via the PMA Annual Report. Similarly, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires new 510(k) clearance or, possibly, approval of a new PMA. The FDA requires us to make this determination in the first instance, but the FDA may review and may not agree with our determination. If the FDA disagrees with our determination and requires us to seek approvals or clearances for modifications to our previously approved or cleared products, for which we concluded that new approvals or clearances are unnecessary, we may be required to cease marketing or distribution of our products or to recall the modified product until we obtain the approval or clearance, and we may be subject to significant regulatory fines or penalties.

Similar requirements apply in foreign jurisdictions. For instance, in the EU, we must inform the notified body that carried out the conformity assessment of the devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our in vitro diagnostic medical devices that could affect compliance with the essential requirements or cause a substantial change to the intended use for which the device has been CE marked.

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 specifically covered indications or where prior approval has been obtained. Becoming a participating provider can result in higher reimbursement amounts for covered uses of our test and, potentially, no reimbursement for non-covered uses identified under the payer's policies or the contract.

Although we are a participating provider with some commercial payers, certain other large, national commercial payers, including Anthem, Aetna and Humana, have issued non-coverage policies that consider tissue and liquid CGP testing which are not FDA approved, including our Guardant360 and TissueNext test, as experimental or investigational. If we are not successful in obtaining coverage from such payers, or if other payers issue similar non-coverage policies, our business and results of operations could be materially and adversely affected.

Medicare's National Coverage Determination, or NCD, for Next Generation Sequencing, or NGS, first established in 2018 and subsequently updated in 2020 states that NGS tests, such as our Guardant360 test, are covered by Medicare nationally, when: (1) performed in a CLIA-certified laboratory, (2) ordered by a treating physician, (3) the patient meets certain clinical and treatment criteria, including having recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, (4) the test is approved or cleared by the FDA as a companion in vitro diagnostic for an FDA approved or cleared indication for use in that patient's cancer, and (5) results are provided to the treating physician for management of the patient using a report template to specify treatment options. Effective August 7, 2020, our Guardant360 CDx test obtained national coverage under the NGS NCD consistent with its FDA-approved indications.

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 clinical and treatment criteria required for either national coverage or MAC discretion to provide local coverage. In July 2018, Palmetto GBA, or Palmetto, the MAC responsible for administering Medicare's Molecular Diagnostic Services Program, or MolDX, issued a local coverage determination, or LCD, for our Guardant360 test for NSCLC patients who meet certain clinical and treatment criteria. Subsequently, in 2018, Noridian Healthcare Solutions, the MAC responsible for adjudicating claims in California, where our laboratory is located, and a participant in MolDX, finalized its LCD for our Guardant360 test. In September 2018, we began to receive reimbursement from Medicare for claims submitted with respect to Guardant360 clinical tests performed for NSCLC patients. In December 2019, replacing its prior NSCLC patient LCD, Palmetto GBA finalized its expanded LCD for our Guardant360 test that provides limited Medicare coverage for use of the Guardant360 test for qualifying patients diagnosed with solid cancers of non-central nervous system origin. In May 2019, Noridian also issued an expanded draft LCD for our Guardant360 test consistent with the expanded draft LCD issued by Palmetto in March 2019. In May 2020, Noridian issued a coverage article and confirmed limited Medicare coverage for our Guardant360 test for qualifying patients diagnosed with solid tumor cancers of non-central nervous system origin who meet the criteria of the NGS NCD. Noridian also retired the expanded draft LCD issued in May 2019 as being superseded by the coverage article. 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. In January 2022, Noridian issued a draft LCD with expanded coverage for our Guardant360 test consistent with the expanded draft LCD issued by Palmetto in March 2019 and finalized in December 2019, as well as the Noridian coverage article of May 2020. Noridian finalized this LCD in November 2022.

In March 2022, Palmetto GBA established coverage for our Guardant360 TissueNext test under an existing LCD. The coverage, which is also applicable to Noridian, covers our Guardant360 TissueNext test for Medicare fee-for-service patients with advanced solid tumor cancers. In July 2022, Palmetto GBA established coverage under an existing LCD for our Guardant Reveal test for fee-for-service Medicare patients in the United States with stage II or III colorectal cancer whose testing is initiated within three months following curative intent therapy. This coverage, which also applies to Noridian, has an effective date of December 2021. In April 2023, Palmetto GBA established coverage for Guardant360 Response under an existing LCD for tracking patient response to immunotherapy after an initial Guardant therapy selection test. This coverage also applies to Noridian.

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 and its implementing regulations, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are generally required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests", or ADLTs), commercial payer payment rates and volumes for each test they perform. CMS uses this data to calculate a weighted median payment rate for each test, which is used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We are subject to reporting requirements under PAMA and the Medicare rate for our tests will be calculated in the future based on our private payer rates. For clinical diagnostic laboratory tests furnished on or after January 1, 2018, PAMA and its implementing regulations contemplate that their Medicare CLFS reimbursement rates are established upon these reported private payer rates. The second such reporting period (after 2017) was set for 2020. On December 20, 2019, Congress passed the Further Consolidated Appropriations Act of 2020, which delayed by one year the next data reporting period until 2021 and limited reduction in payment amounts in 2020 related to the implementation of pricing based on private payer rates reported in 2017. On March 27, 2020, Congress passed the CARES Act, which delayed by one year the next data reporting period until 2022 and prevented any reduction in payment amounts in 2021 related to the implementation of pricing based on private payer rates reported in 2017. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which delayed by one year the next data reporting period until 2023 and prevented any reduction in payment amounts in 2022 related to the implementation of pricing based on private payer rates reported in 2017. On November 2, 2022, CMS published its final rule for the Medicare Physician Fee Schedule for calendar year (CY) 2023, including changes for clinical laboratories that took effect on January 1, 2023. Changes include updated regulatory definitions to specify the data collection period for the data reporting period of January 1, 2023 through March 31, 2023; revisions to indicate that data reporting is required every 3 years beginning January 2023; and to confirm that for CY 2022, payment may not be reduced by more than 0% as compared to CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15% as compared to the amount established for the preceding year. On December 29, 2022, Congress passed the Consolidated Appropriations Act, 2023, which prevented any reduction in payment amounts in 2023 related to the implementation of pricing based on private payer rates reported in 2017; delayed by one year data the next data reporting period until 2024; and extended the three-year period in which payment may not be reduced by more than 15%, to CYs 2024 through 2026. On November 17, 2023, Congress passed the Further Continuing Appropriations and Other Extensions Act of 2024, which prevented any reduction in payment amounts in 2024 related to the implementation of pricing based on private payer rates reported in 2017; delayed by one year data the next data reporting period until 2025; and extended the three-year period in which payment may not be reduced by more than 15%, to CYs 2025 through 2027. On September 26, 2024, Congress passed the Continuing Appropriations and Extensions Act of 2025, which prevented any reduction in payment amounts in 2024 related to the implementation of pricing based on private payer rates reported in 2017; delayed by one year data the next data reporting period until 2026; and extended the three-year period in which payment may not be reduced by more than 15%, to CYs 2026 through 2028. None of these enactments have delayed annual reporting requirements for ADLTs like our Guardant360 CDx test. If we are unable to obtain and maintain favorable reimbursement rates from commercial payers for our tests, this may adversely affect the tests' Medicare reimbursement rates. It is unclear what impact new Medicare pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations or cash flows.

Some payers have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as us, of active laboratory benefit management by third parties is unclear, and we expect that it would have a negative impact on our revenue in the short term. Payers may resist reimbursement for our tests in favor of less expensive tests, require pre-authorization for our tests, or impose additional pricing pressure on and substantial administrative burden for reimbursement for our tests. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of payers for our tests. However, we cannot predict whether, under what circumstances, or at what price levels payers will cover and reimburse our tests. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our business and prospects could suffer.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious, adverse health consequences or death. We may also, on our own initiative, recall a product. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. In the case of our FDA-approved tests, a government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products could impair our ability to produce our products in a cost-effective and timely manner, which would have an adverse effect on our reputation, results of operations and financial condition. We may be subject to liability claims, may be required to bear costs or may take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, the FDA could require us to report those actions and take enforcement action for failing to report the recalls when they were conducted. Similar requirements apply in foreign jurisdictions. A future recall announcement could harm our reputation with customers and negatively affect our sales and financial condition.

If we initiate a correction or removal for one of our tests, issue a safety alert or undertake a field action or recall to reduce a risk to health imposed by the test, this could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our tests and to negative publicity, including FDA alerts, press releases or administrative or judicial actions. Furthermore, circulation of any such negative publicity could harm our reputation, be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and studies may not be predictive of future study results.

Our ongoing research and development and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad; and by notified bodies in some foreign jurisdictions. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The results of nonclinical and clinical studies of our products conducted to date, and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. The data and results from our clinical studies does not ensure that we will achieve similar results in future clinical studies. Failure can occur at any stage of clinical testing. Clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and nonclinical testing in addition to those we have planned before we are able to seek marketing authorizations or certifications for our products or product candidates.

We may experience delays in our clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of such clinical studies.

Patient enrollment in clinical studies and completion of patient follow up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available products. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study. In addition, the target enrollment for certain of our clinical studies, including our ECLIPSE study, is based upon our estimates that a given percentage of enrolled patients will have a specified disease or condition, and we cannot be certain that these estimates will prove correct, or that our clinical studies, even if fully enrolled, will produce data sufficient to support the submission of a PMA or other marketing application to the FDA or a comparable regulatory authority. If our clinical studies do not enroll a sufficient number of patients to support submission of a PMA or similar marketing application, or if the number of patients enrolled with the target disease or condition is lower than we estimated, we may be required to enroll additional patients in our clinical studies or conduct additional clinical studies before we are able to seek and/or obtain marketing authorizations for our product candidates, which may result in significant additional expenses for us and could delay or prevent us from bringing our product candidates to market.

In addition, we may find it necessary to engage CROs to perform data collection and analysis and other aspects of our clinical studies, which might increase the cost and complexity of our studies. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the studies, and would control only certain aspects of their activities. We would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties would not relieve us of our regulatory responsibilities. We and our third-party contractors are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA, and comparable regulations enforced by foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of study sponsors, principal investigators and study sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities or notified bodies may require us to perform additional clinical studies before clearing, or approving our marketing applications or certifying our products. A failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory clearance, approval or certification process.

If there are delays in testing or clearances, approvals or certifications as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance, approval, or certification for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, generate revenue or to achieve sustained profitability.

Interim, "topline" and preliminary data from our clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies or clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data at time of disclosure. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical and clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, such as the FDA, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our "research use only" and "investigational use only" products could become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

In the United States, some of our products 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 or policies 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 or certification of our products, we will continue to be subject to extensive regulatory oversight.

Medical devices are subject to extensive regulation by the FDA in the United States, the MHLW in Japan, the European authorities, EEA competent authorities, and comparable regulatory agencies in other territories where we do business. If any of our products are approved by the FDA, the MHLW, or other comparable foreign regulatory agencies or certified by notified bodies in foreign jurisdictions, we will be required to timely file various reports. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, as a condition of approving a PMA, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data from the post-approval study, become available. Failure to conduct or timely complete post-approval studies in compliance with applicable regulations, update the product labeling, or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business and revenue.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of medical devices to ensure that their promotional claims made are consistent with the applicable marketing authorizations, that there are adequate and reasonable data to substantiate the claims, and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our promotional claims are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions and we may be required to revise our promotional claims and make other corrections or restitutions. Similar requirements apply in foreign jurisdictions.

The FDA, state and foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;

- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for clearances or approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current clearances, approvals or certifications, resulting in prohibitions on sales of our products;
- refusal to issue certificates needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales of our products and have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our current or future products under development. For example, on February 23, 2022, the FDA issued a proposed rule to amend the Quality System Regulation, or QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization, or ISO, standards. This proposal was finalized on January 31, 2024. Additionally, in September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices similar to ours, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain marketing authorization or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any product candidates or make it more difficult to obtain marketing authorizations for, manufacture, market or distribute any product candidate we are developing. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to seeking marketing authorization, changes to manufacturing methods recalls, replacement or discontinuance of our products or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The EU regulatory landscape concerning medical devices (including in vitro diagnostic medical devices) has evolved in recent years. On April 5, 2017 Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, or the IVDR, was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different European markets.

Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies or notified bodies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new medical device products from being developed, authorized or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA, foreign regulatory authorities and notified bodies to review and authorize the sale or certify new products can be affected by a variety of factors, including government budget and funding levels; its ability to hire and retain key personnel and accept the payment of user fees; statutory, regulatory, and policy changes; and other events that may otherwise affect the FDA's foreign regulatory authorities' and notified bodies' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for new devices, including in vitro diagnostics to be reviewed and/or authorized or certified for marketing by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Other regulatory authorities may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In the EU, notified bodies must be officially designated to certify products and services in accordance with the IVDR. Only a few notified bodies have been designated to date. Without IVDR designation, notified bodies may not yet start certifying devices in accordance with the new Regulation. As only a few notified bodies has been IVDR-designated they are facing a heavy workload and their review times have lengthened. This situation could impact the way we are conducting or intend to conduct our business in the EU and the EEA.

Failure to comply with federal, state and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.

We are subject to the Clinical Laboratory Improvement Amendments, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. Any testing subject to CLIA regulation must be performed in a CLIA certified laboratory. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial payers, for our tests. We have a current CLIA certification to perform our tests at our laboratory in Redwood City, California. To maintain this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time.

We are also required to maintain a California clinical laboratory license to perform testing in California. California laboratory laws establish standards for day-to-day operation of our clinical laboratory in Redwood City, California, including the training and skills required of personnel and quality control. In addition, some other states require our California laboratory to be licensed in the state in order to test specimens from those states. In addition to California, our laboratory is licensed in Florida, Maryland, Pennsylvania, Rhode Island and New York. Although we have obtained licenses from states where we believe we are required to be licensed, it is possible that other states we are not aware of currently require out-of-state laboratories to obtain licensure in order to test specimens from the state, and that other states may adopt similar requirements in the future.

We may also be subject to regulations in foreign jurisdictions as we seek to expand international utilization of our tests or as such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of specimens necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with

licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA certification and/or state licenses, imposition of a directed plan of action, on-site monitoring, civil monetary penalties, criminal sanctions, inability to receive reimbursement from Medicare, Medicaid and commercial payers, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA certification, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In order to test specimens from New York, LDTs must be approved by the New York State Department of Health, or NYSDOH, on a product-by-product basis before they are offered, and our Guardant360 test has been approved by NYSDOH. We will need to seek NYSDOH approval of any future LDTs we develop and want to offer for clinical testing to New York residents, and there can be no assurance that we will be able to obtain such approval. As a result, we are subject to periodic inspection by the NYSDOH and are required to demonstrate ongoing compliance with NYSDOH regulations and standards. To the extent NYSDOH identified any non-compliance and we are unable to implement satisfactory corrective actions to remedy such non-compliance, the State of New York could withdraw approval for our tests.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have obtained CAP accreditation for our laboratories in Redwood City and San Diego, California, and Japan, and in order to maintain such accreditation, we are subject to survey for compliance with CAP standards every two years. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

We are subject to numerous federal and state healthcare statutes and regulations; complying with such laws pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties and a material adverse effect to our business and results of operations.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations may include, among others:

- the AKS, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind (e.g. provision of free or discounted goods, services or items), in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value, such as phlebotomy kits. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce referrals, purchases or recommendations of covered items or services may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct *per se* illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have held that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. Moreover, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the EKRA, which prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory. The EKRA applies to all payers including commercial payers and government payers;

- the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- federal and state "Anti-Markup" rules, which, among other things, typically prohibit a physician or supplier billing for clinical or diagnostic tests (with certain exceptions) from marking up the price of a purchased test performed by another physician or supplier that does not "share a practice" with the billing physician or supplier;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, biologicals, and kits, medical devices or supplies that require premarket approval by or notification to the FDA, and for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to (i) payments and other transfers of value to physicians (as defined by statute), certain other healthcare professionals such as physician assistants and nurse practitioners, and teaching hospitals, and (ii) ownership and investment interests in such manufacturers held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties for any payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- the federal government may bring a lawsuit under the False Claims Act, or the FCA, against any party whom it believes has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim for payment approved. The federal government and a number of courts have taken the position that claims presented in violation of certain other statutes, including the AKS or the Stark Law, can also be considered a violation of the FCA based on the theory that a provider impliedly certifies compliance with all applicable laws, regulations, and other rules when submitting claims for reimbursement. An FCA violation may provide the basis for the imposition of administrative penalties as well as exclusion from participation in governmental healthcare programs, including Medicare and Medicaid. A number of states including California have enacted laws that are similar to the federal FCA. Private individuals can bring FCA "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in federal healthcare programs. In January 2022, we received a civil investigative demand, or CID, from the United States Attorney for the Northern District of California in connection with an investigation under the False Claims Act. The CID requests information and documents regarding billing government-funded programs for the Company's panel of genetic tests known as Guardant360. We are fully cooperating with the investigation. At this time, we are unable to predict the outcome of this investigation. See "Commitments and Contingencies – Legal Proceedings" in this Annual Report on Form 10-K for more information;

- the HIPAA fraud and abuse provisions, which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private insurers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal and state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, unlawful trade practices, insurance fraud, kickbacks, patient inducement and statutory or common law fraud restrict the provision of products, services or items for free or at reduced charge to government or non-government healthcare program beneficiaries. These laws and regulations relating to the provision of items or services for free are complex and are subject to interpretation by the courts and by government agencies;

- other federal and state fraud and abuse laws, such as state anti-kickback, self-referrals, false claims and anti-markup laws, any of which may extend to services reimbursable by any payer, including private insurers;
- the federal No Surprises Act, which prohibits an out-of-network provider from billing a patient at an amount in excess of the in-network cost sharing for services furnished with respect to a visit at certain in-network healthcare facilities, as well as state laws restricting balance billing of patients;
- state laws that prohibit other specified practices, such as billing physicians for tests that they order; providing tests at no or discounted cost to induce adoption; waiving co-insurance, co-payments, deductibles or other amounts owed by patients; billing a state healthcare program at a price that is higher than what is charged to other payers; or employing, exercising control over or splitting fees with licensed medical professionals; and
- similar foreign laws and regulations in the countries in which we operate or may operate in the future.

As a clinical laboratory, our business practices may face additional scrutiny from various government agencies such as the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory and the decision to order laboratory tests typically are made or strongly influenced by the physician, with little or no patient input. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an exception. The government has been active in enforcement of these laws against clinical laboratories.

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and from employing or engaging physicians and other medical professionals (generally referred to as the prohibition against the corporate practice of medicine), which could include physician laboratory directors. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed medical professional. For example, California's Medical Board has indicated that determining the appropriate diagnostic tests for a particular condition and taking responsibility for the ultimate overall care of a patient, including making treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these laws may result in sanctions and civil or criminal penalties. It is possible that governmental authorities may conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for services provided, do not comply with current or future corporate practice of medicine or healthcare fraud and abuse statutes, regulations, agency guidance or case law.

The growth and international expansion of our business may increase the potential of violating applicable laws and regulations. The risk is further increased by the fact that many such laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our internal operations and business arrangements with third parties comply with applicable laws and regulations will involve substantial costs. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Any of the foregoing consequences could seriously harm our business and our financial results. To the extent our business operations are found to be in violation of any of these laws or regulations, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the healthcare providers or other parties with whom we interact or may interact in the future, are found not to be in compliance with applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in various healthcare programs, which could also negatively affect our business or revenue.

If the validity of an informed consent from patients regarding our test was challenged, we could be forced to stop offering our products or using our resources, our business and results of operations will be negatively affected.

We offer our tests to physicians and to biopharmaceutical companies in connection with clinical studies. We have implemented measures to ensure that data and biological samples that we receive have been collected from subjects who have provided appropriate informed consent. We also act as a sponsor of clinical studies in connection with the

development of our tests, which are frequently conducted in collaboration with different parties. We seek to receive approval from an ethical review board, or institutional review board, or IRB, or other reviewing bodies for projects that meet the definition of "human subjects research," which includes review and approval of processes for subject informed consent and authorization for use of personal information or waivers thereof. We and our biopharmaceutical partners could conduct clinical studies in a number of different countries. When we are acting as a vendor in connection with a clinical study sponsored by our biopharmaceutical partners, we rely upon them to comply with the requirements to obtain the subject's informed consent and to comply with applicable laws and regulations. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. Those informed consents could be challenged and prove invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our biopharmaceutical partners, could force us to stop accessing or using data and samples or servicing or conducting clinical studies, which would hinder our product offerings or development. We could also become involved in legal actions, which could consume our management and financial resources.

We may be subject to fines, penalties, licensure requirements, or legal liability, if it is determined that through our test reports we are practicing medicine without a license.

Our test reports delivered to physicians provide information regarding FDA or foreign regulatory authorities-approved therapies and clinical studies that oncologists may use in making treatment decisions for their patients. We make members of our organization available to discuss the information provided in the reports. Certain state laws prohibit the practice of medicine without a license. Our customer service representatives and medical affairs team provide support to our customers, including assistance in interpreting the test report results. A governmental authority or other parties could allege that the identification of available therapies and clinical studies in our reports and the related customer service we provide constitute the practice of medicine. A state may seek to have us discontinue the inclusion of certain aspects of our test reports or the related services we provide, or subject us to fines, penalties, or licensure requirements. Any determination that we are practicing medicine without a license may result in significant liability to us, and our business and reputation would be harmed.

Our billing and claim processing are complex and time-consuming, and any delay in submitting claims or failure to comply with applicable billing requirements could hinder collection and have an adverse effect on our revenue.

Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, such as Medicare, Medicaid, health plans, insurance companies and patients, all of which may have different billing requirements. Several factors make the billing process complex, including:

- differences between the list prices for our tests and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid, to the extent our tests are covered by such programs;
- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information, pre-authorization and other billing requirements among payers;
- changes to codes and coding instructions governing our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claim appeals process.

These billing complexities and the related uncertainty in obtaining payment for our tests could negatively affect our revenue and cash flow, our ability to achieve profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payers on a timely basis, or if we fail to comply with applicable billing requirements, it could have an adverse effect on our revenue and our business.

In addition, the coding procedure used by third-party payers to identify various procedures, including our test, during the billing process is complex, does not adapt well to our tests and may not enable coverage and adequate reimbursement rates. Third-party payers usually require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology, or the CPT code. CPT coding plays a significant role in how our Guardant360 test is reimbursed both from commercial and governmental payers. The CPT code set is maintained by the American Medical Association, or AMA. In cases where there is not a specific CPT code to describe a test, 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 "Category I" codes are issued annually and new PLA and level II HCPCS codes are issued as frequently as quarterly. Payers' acceptance of the new code could be delayed, and transition to the new code could result in a decrease in reimbursement for our tests, both of which could potentially reduce revenue from commercial and government payers. In addition, Z-Code Identifiers are used by certain payers, including under Medicare's Molecular Diagnostic Services Program, or MolDx, to supplement CPT codes for molecular diagnostics tests such as our Guardant360 test. Following the FDA approval of our Guardant360 CDx test, a new Z-Code Identifier was issued in August 2020. In January 2021, a CPT PLA code was issued for our Guardant360 CDx test with an effective date in April 2021. Additionally, based on this new PLA code, we applied to the CMS for our Guardant360 CDx test to become an advanced diagnostic laboratory test, or ADLT. In March 2021, CMS approved ADLT status for the Guardant360 CDx test, based on which Medicare paid us at the actual list charge per test, from April 1, 2021 to December 31, 2021. Effective January 1, 2022, Medicare started to reimburse Guardant360 CDx services at the median rate of claims paid by commercial payers and this rate will update annually based on the previous year's private payer data submission. In April 2022, a CPT PLA code was issued for Guardant360 with an effective date in July 2022. In July 2022, a CPT PLA code was issued for Guardant360 TissueNext with an effective date in October 2022. In October 2023, a CPT PLA code was issued for Guardant360 Response with an effective date in January 2024. Effective January 1, 2024, Medicare has increased the reimbursement rate for our Guardant360 LDT test to the same rate as our Guardant360 CDx test. Due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our tests, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received for a test differs from the revenue recorded for the test. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. Additionally, if coding changes were to occur, payments for certain uses of our tests could be reduced, put on hold, or eliminated.

Use of coding for billing our products that does not describe a specific test, requires the claim to be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. Because billing third-party payers for our tests is an unpredictable, challenging, time-consuming and costly process, we may face long collection cycles and the risk that we may never collect at all, either of which could adversely affect our business, results of operations and financial condition, and we may have to increase collection efforts and incur additional costs.

Changes in healthcare laws, regulations and policies could increase our costs, decrease our sales and revenues and negatively impact reimbursement for our tests.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA, became law. This law substantially changed the way healthcare 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 healthcare programs or result in the development of new programs, including those governing enrollments in state and federal healthcare programs, reimbursement changes and fraud and abuse. Our business and operations could be affected by the ACA, including in ways we cannot currently predict.

Since its enactment, there have been efforts to repeal all or part of the ACA. On June 17, 2021 the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that efforts to repeal or modify all or part of the ACA will continue under the Trump administration.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels and in foreign jurisdictions, regulators and commercial and government payers to reduce healthcare costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from commercial and government payers.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our current practices are challenged under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

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

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. We collect, process, maintain, retain, evaluate, utilize and distribute large amounts of personal health and financial information and other confidential and sensitive data about our customers and others in the ordinary course of our business. Concerns about and claims challenging our practices with regard to the collection, use, retention, disclosure or security of personally identifiable information or other privacy-related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business.

Numerous federal, state and foreign laws and regulations govern collection, dissemination, use and confidentiality of personally identifiable information and protected health information, or PHI, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA; state privacy and confidentiality laws (including state laws requiring disclosure of breaches); federal and state consumer protection and employment laws; and European and other foreign data protection laws. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

HIPAA establishes a set of national privacy and security standards for the protection of PHI, by health plans, certain healthcare providers that submit certain covered transactions electronically and healthcare clearinghouses, or ‘‘covered entities,’’ and their ‘‘business associates,’’ which are persons or entities that perform certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. We are a covered entity under HIPAA and therefore must comply with its requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. If we engage a business associate to help us carry out healthcare activities and functions, we must have a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with certain safeguards and other requirements under HIPAA.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face additional fines and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. In addition, responding to government investigations regarding alleged violations of these and other laws and regulations, even if ultimately concluded with no findings of violations or no penalties imposed, can consume company resources and impact our business and, if public, harm our reputation.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Laws in all 50 states require businesses to provide notice to individuals whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, and creating new data privacy and security laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act, or CCPA went into effect on January 1, 2020, and creates certain data privacy rights for California residents. The CCPA increases the privacy and security obligations of entities handling certain personal information, and provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect in January 2023, and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It has also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut, and Utah and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we may have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients, and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as PHI, or personally identifiable information along with increased demands for enhanced data security infrastructure, could greatly increase our costs of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional risks.

Furthermore, the Federal Trade Commission, or the FTC, and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In addition, the interpretation and application of consumer, health-related, and data protection laws, especially with respect to genetic samples and data, in the United States, European Economic Area, or EEA, and elsewhere are often uncertain, contradictory, and in flux. We operate or may operate in a number of countries outside of the United States whose laws may in some cases be more stringent than the requirements in the United States. For example, EEA member states have specific requirements relating to cross-border transfers of personal data to certain jurisdictions, including to the United States where our laboratory resides. In addition, some countries have stricter consumer notice and/or consent requirements relating to personal data collection, use or sharing, more stringent

requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, international privacy and data security regulations may become more complex and have greater consequences. For instance, the General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes stringent data protection requirements for the processing of personal data of persons within the EEA. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR imposes strict data protection compliance requirements including: providing detailed disclosures about how personal data is collected and processed; demonstrating that an appropriate legal basis is in place or otherwise exists to justify data processing activities; granting rights for data subjects in regard to their personal data; introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; defining pseudonymized (i.e., key-coded) data; imposing limitations on retention of personal data; maintaining a record of data processing; and complying with the principal of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EEA member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Failure to comply with the GDPR and other applicable privacy or data security-related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with client contracts and have an adverse effect on our business, financial condition and results of operations.

European data protection law also imposes strict rules on the transfer of personal data out of the EU to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, in July 2020, the Court of Justice of the EU, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses, or SCCs. In March 2022, the United States and EU announced a new regulatory regime intended to replace the invalidated regulations; In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the Privacy Shield. The European Commission adopted the adequacy decision on July 10, 2023. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover.

We are also subject to evolving EU privacy laws on cookies and e-marketing. In the EEA, informed consent is required for the placement of a cookie or similar technologies on a user's device and for direct electronic marketing. The GDPR also imposes conditions on obtaining valid consent, such as a prohibition on pre-checked consents and a requirement to ensure separate consents are sought for each type of cookie or similar technology. Any of these changes to EU data protection law or its interpretation could disrupt and harm our business. We rely on a mixture of safeguards to transfer personal data from our EU business to the U.S., and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators or current challenges to these mechanisms in the European courts.

In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or reinterpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other

obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products. If so, in addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results of operations.

We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Risks related to our intellectual property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop, manufacture and commercialize products, services or technology similar or identical to ours, and our ability to successfully develop, manufacture or commercialize our products, services or technology may be impaired.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to obtain, maintain and/or protect our intellectual property rights, third parties may be able to compete more effectively against us. In addition, we have incurred and may continue to incur substantial litigation costs in our attempts to enforce or restrict the use of our intellectual property rights against third parties or defend ourselves against third parties claiming that we are infringing upon such third parties' intellectual property rights.

To the extent our intellectual property rights offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property rights do not provide adequate coverage of our products, services or technology, our competitive position could be adversely affected, as could our business.

As is the case with other biotechnology companies, our success depends in large part on our ability to obtain, maintain and protect the intellectual property we own or we have licensed from others. We apply for patents covering our products, services and technologies and uses thereof, as we deem appropriate. However, obtaining, maintaining and enforcing biotechnology patents is costly, time-consuming and complex. We may fail to apply for patents on important products, services or technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain or enforce patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Patent prosecution process can be time-consuming and expensive. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to us by third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We own or license numerous U.S. patents and pending U.S. patent applications, with international counterparts in certain countries. It is possible that our or our licensors' pending patent applications will not result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, services or technologies, may not provide us with any competitive advantages, or may be challenged by third parties and be invalidated or found unenforceable. It is possible that others will design around our current or future patented products, services or technologies. Some of such patent rights are being challenged, including at the United States Patent and Trademark Office, or USPTO, in post-grant proceedings, at the European Patent Office, or EPO, in opposition proceedings, and some of such patent rights may be challenged in the future. We may not be successful in defending any such challenges made against our owned or licensed patents or patent applications. Any successful third-party challenge to such patent rights could result in their unenforceability or invalidity and increased competition to our business. We have challenged and may choose to challenge the patents or patent applications of third parties. The outcome of patent disputes or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA sequences.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like our current products and tests, and our future products, are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving legal and administrative standards around the world, including in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many foreign jurisdictions do not favor the enforcement of patent rights and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patent rights and other intellectual property rights thereunder. Proceedings to enforce our patent rights and other intellectual property protection in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property rights. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, services, methods and technologies that are patentable.

Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 16, 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution or post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings, to attack the validity of a patent. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence might not be sufficient to invalidate the claim if presented in a district court action. Accordingly, third parties have used and may continue to use the USPTO proceedings to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding our or our licensors' prosecution of patent applications and enforcement or defense of issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering our products, services or technology could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our owned or licensed patent rights have been, are being or may be challenged at a future point in time in opposition, derivation, re-examination, *inter partes* review, post-grant review or interference. Any successful third-party challenge to our patent rights in this or any other proceeding could result in the unenforceability or invalidity of such patent rights, which may lead to increased competition to our business, which could harm our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, manufacture or commercialize our current or future products, services or technology.

We may not be aware of all third-party intellectual property rights potentially relating to our products, services or technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We, or our licensors, might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and we, or our licensors, might not have been the first to file patent applications for these inventions. To determine the priority of our inventions, we have participated and may continue to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our or our licensors' patent applications. In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Our licensors may also license patent rights to others, and we may not be aware of such licenses before they are granted or such licenses may be subject to disputes or uncertainties that affect patent rights licensed by us or could limit our ability to enforce such patent rights. If third parties bring actions against our owned or licensed patent rights, we could experience significant costs and management distraction.

In patent litigation in the United States or abroad, defendant counterclaims alleging invalidity or unenforceability of plaintiff's patents are common. Grounds for a validity challenge for invalidity could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the patent office or made a misleading statement during prosecution. Similar claims may also be raised before patent offices in the United States or abroad, even outside the context of litigation, through mechanisms including re-examination, post-grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patent rights in such a way that they no longer cover our products. The outcome of patent litigation or patent office proceedings following assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the relevant patent that protects our products, service or technology. Such a loss of patent protection could have a material adverse impact on our business.

We and some of our licensors have initiated, are currently involved in, and may in the future initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our products, services or technology.

Defendants in such proceedings could counterclaim that the patents covering our products, services or technology are invalid or unenforceable and could institute legal proceedings to challenge such patents both in court and before patent offices. Any assertion of invalidity and/or unenforceability against the patents covering our products, services or technology, even if not successful, could be time-consuming and expensive to defend, damage our reputation in the marketplace and the prospects for our business, and divert our management's attention.

We rely on licenses from third parties, and if we lose these licenses then we may be subjected to future litigation. If we cannot license and maintain rights to use third-party intellectual property rights on reasonable terms, we may not be able to successfully develop, manufacture and/or commercialize our products, services or technology. Our licensed intellectual property rights may lose value or utility over time.

From time to time, we may identify third-party technology we may need, including those related to develop, manufacture or commercialize new products, services or technology. We may also need to negotiate agreements to in-license patents or other intellectual property rights from third parties before or after introducing a commercial products, service of technology, and we may not be able to obtain necessary licenses to such patents or other intellectual property rights. We are a party to various license agreements, including royalty-bearing agreements, that grant us rights to use and practice certain intellectual property of third parties, including claims included in issued patents, typically in certain specified fields of use. We may need to obtain additional licenses from others to advance our research, development, manufacture and commercialization activities. We may be unable to enter into the necessary license agreements on acceptable terms or at all, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. In return for the use of a third party's intellectual property rights, we may agree to pay the licensor royalties based on sales of our products, services or technology. Royalties are a component of cost of products, services or technology and affect the margins on our products, services or technology. If we are unable to negotiate reasonable royalties or if we have to pay royalties on technology that becomes less useful for us or ceases to provide value to us, our profit margin will be reduced and we may suffer losses.

Our license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us, including obligations to making payments to our licensors upon achievement of milestones.

In spite of our efforts, our licensors have asserted and may in the future assert that we have materially breached our obligations under such license agreements and could therefore seek or threaten to terminate the license agreements. If these licenses are terminated, or if the underlying patent rights fail to provide the intended exclusivity, our ability to develop, manufacture and commercialize products, services and technology covered by these license agreements would be limited or lost, and our competitors or other third parties might have the freedom to develop, produce, manufacture, seek regulatory approval of, or to market, products, services or technology identical or similar to ours and we may be required to cease our development, manufacture and/or commercialization activities in connection with our products, services and/or technology. Our actual or potential licensors could take action with respect to our licensed intellectual property that may decrease the value of such licensed intellectual property. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Moreover, disputes could arise with respect to any aspect of our license agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our products or product candidates, services, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the licensing of patent and other rights controlled by our licensors or developed under our collaborative development relationships to others;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how licensed to us or resulting from the joint creation or use of intellectual property by our licensors, us and/or our partners;
- the validity, enforceability or priority of licensed patent rights; and
- the amount of royalties and other payments we are obligated to pay under the license agreement.

If we do not prevail in such disputes, we may lose the rights under any of such license agreements, the license agreements may not be meaningful for our business and operations, and we may be subject to unnecessary or additional payment obligations.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements could be susceptible to multiple interpretations. The resolution of any such contract interpretation disagreement could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over licensed intellectual property impair our ability to enforce licensed intellectual property against third parties or use it to defend ourselves in litigation, the value of such licensed intellectual property may be diminished.

If we fail to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, manufacture and commercialize the affected product, product candidate, service or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. If any of these license agreements is terminated, if the licensor fails to abide by the terms of the license agreement, if the licensor fails to enforce its intellectual property rights licensed to us against third parties that infringe upon such intellectual property rights, or if the licensed patent or other rights are found to be invalid or unenforceable, we may be unable to achieve our business goals and our results of operations and financial condition could be adversely affected. Absent the license agreements, we could infringe patents and other intellectual property rights of the licensors subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products, services or technology, including our tests, which could adversely affect our ability to offer products, services or technology, our ability to continue operations and our financial condition.

Any intellectual property rights licensed by us may lose value or utility, including as a result of a change of in the industry, in our business objectives, others' technology, our dispute with the licensor, and other circumstances outside our control.

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

Filing, prosecuting and defending patents and other intellectual property rights covering our products, services and technology in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some territories outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries and regions do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling, making or importing products, services or technology by practicing our intellectual property rights. Competitors may practice our intellectual property rights in jurisdictions where we have not obtained patent protection to develop, manufacture, sell or import their own products, services or technology and may also export products, services or technology that infringe upon our intellectual property rights to territories where we have patent protection that do not provide strong intellectual property or enforcement rights as strong as that in the United States. These products, services or technology may compete with our products, services or technology. Our patents or other intellectual property rights existing outside the United States may not be effective or sufficient to prevent third parties from competing with us. Similarly, intellectual property rights may be exhausted in certain situations, and others could import our products sold abroad and compete with us domestically.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries and regions do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents and other intellectual property rights in such jurisdictions. Proceedings to enforce our patent rights and other intellectual property rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to pursuing patents covering our products, services and technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality and non-disclosure agreements with those that have access to our confidential and proprietary information including employees, independent contractors, academic institutions, corporate partners and our advisers, and invention assignment agreements with our employees and independent contractors, and when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized use or disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized use or disclosure is difficult, and we do not know whether the steps we have taken to prevent such use or disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed trade secrets of their former employers.

We have employed or engaged and expect to employ or engage individuals who were previously employed at or associated with universities or other companies, including our competitors or potential competitors. Although we try to ensure that our employees and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we lose, in addition to paying monetary damages, we may be deprived of valuable intellectual property and face increased competition. A loss of key research personnel or work product could hamper or prevent our ability to develop, manufacture and/or commercialize products, services or technology, which could materially adversely affect our business. Even if we are successful in defending against these claims, litigation could result in damage to our reputation and substantial costs and be a distraction to management and affected individuals.

We may not be able to protect and enforce our trademarks and we could infringe others' trademarks.

We have not yet registered trademarks in all of our potential markets, although we have registered Guardant Health and Guardant360 in the United States. If we apply to register additional trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not timely register and enforce marks used in connection with our products, services or technology, we may encounter difficulty in enforcing them against third parties, and if these marks are registered by others, we could infringe such trademarks and may have to defend ourselves to continue the use of our trademarks, which may be time consuming and costly, and we may be unsuccessful.

We may be subject to claims challenging the inventorship or ownership of our owned or licensed intellectual property.

We or our licensors may be subject to claims that former employees, independent contractors, collaborators or other third parties have an interest in or right to our owned or licensed patents, trade secrets or other intellectual property. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, independent contractors or others who are involved in developing such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending against any such claims, we may lose exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in damage to our reputation and substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are and may continue to be involved in litigation and other legal proceedings related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We have been, are currently in, and may also in the future be, involved with litigation or USPTO actions with various third parties. We expect that the number of such claims may increase as the number of our products or services grows, and the level of competition in our industry segments increases. Any infringement claim, regardless of its validity, could harm our business by, among other things, resulting in time-consuming and costly litigation, diverting management's time and attention from the development of our business, or requiring the payment of monetary damages (including treble damages, attorneys' fees, costs and expenses if we are found to have willfully infringed) and ongoing royalties.

Litigation may be necessary for us to enforce our intellectual property and proprietary rights or to determine the scope, coverage and validity of the intellectual property and proprietary rights of others. We are currently engaged in lawsuits and in proceedings before the USPTO in relation to certain such patents. The outcome of such lawsuits, as well as any other litigation or proceeding, is inherently uncertain and might not be favorable to us. Further, we could encounter delays in introductions or interruptions in the development, manufacture or sale of products, services or technologies, as we develop alternative products, services or technologies. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. If we do not prevail in such legal proceedings, we may be required to pay damages, and we may lose significant intellectual property protection for our products, services or technologies, such that competitors could copy our products, services or technologies. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, services or technologies, incumbent participants in such markets may assert their patents and other intellectual property or proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. As our business matures and our public profile grows, we may also be subject to an increased number of allegations of patent or other intellectual property infringement, whether by our competitors or other third parties, both in the United States and throughout the world wherever we seek to manufacture, commercialize or import our products, services or technologies. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In addition, while we can assert our own patents or other intellectual property rights during litigation, our own patents or other intellectual property rights may provide little or no deterrence or protection against third parties. Therefore, our commercial success may depend in part on our non-infringement of the patents or other intellectual property rights of third parties and on our success in defending ourselves in litigation.

However, our research, development, manufacture and commercialization activities are currently and may in the future be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other patent challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, and corresponding proceedings before foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing, manufacturing and/or commercializing products, services or technologies. As the precision oncology industry expands and more patents are issued, the risk increases that our products, services or technologies may be subject to claims of infringement of the patent rights of third parties. Numerous significant intellectual property issues have

been litigated, are being litigated and will likely continue to be litigated, between existing and new participants in our existing and targeted markets, and our competitors have asserted and may in the future assert that our products or services infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets, and we may enforce our owned or licensed intellectual property rights against our competitors and other parties.

Third parties have asserted and may in the future assert that we are employing their proprietary technology or trade secrets without authorization. For instance, TwinStrand Biosciences, Inc. and the University of Washington filed a lawsuit for patent infringement against us in August 2021 and a jury verdict was entered against us in November 2023. We are also aware of issued U.S. patents and patent applications with claims related to our products and services, and there may be other related third-party patents or patent applications of which we are not aware. By interacting with us, our licensors may learn more about our business or technology and could assert additional patent rights against us, such as patent rights that are not currently licensed to us or patent rights that may be obtained by any such licensors in the future, which may occur if such patent rights are not available for licensing or if they are not offered on acceptable or commercially reasonable terms. Because patent applications can take many years to issue and are not publicly available until a certain period of time passes from filing, there may be currently pending patent applications which may later result in issued patents that our current or future products, services or technologies may infringe. In addition, similar to what other companies in our industry have experienced, we expect our competitors and others may develop or obtain patents with our products, services or technologies in mind and claim that making, having made, using, selling, offering to sell or importing our products, services or technologies infringes these patents.

We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can, for example, because they have substantially greater resources.

Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, manufacture, commercialize, sell and import certain products, services or technologies, and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from developing, manufacturing, commercializing, selling and importing certain products, services or technologies. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in product, service or technologies introductions while we attempt to develop alternative products, services or technologies to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from developing, manufacturing or commercializing products, services or technologies and the prohibition of developing, manufacturing or commercializing of any of our products, services or technologies could materially affect our business and our ability to gain market acceptance for our products, services or technologies.

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

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

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to

pay these fees, and we rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or forfeiture of the patent or patent application and thus loss of patent rights in the relevant jurisdiction. Such an event would allow our competitors to enter the unprotected market and have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or services are obtained, once the patent life has expired, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of our new products, services or technologies, patents protecting them might expire before or shortly after they are commercialized. As a result, our owned and licensed patent portfolio may not provide us with a sufficient exclusivity period to exclude others from commercializing products or services similar or identical to ours.

Risks related to our common stock and indebtedness

The price of our common stock has fluctuated substantially and may do so in the future, and you may not be able to resell shares of our common stock at or above the price at which you purchased them.

The market price of our common stock has been volatile and may fluctuate substantially in the future due to many factors, including:

- volume and customer mix for our precision oncology testing;
- 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
- the effects of high inflation or other general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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. In February 2025, we issued $600 million aggregate principal amount of 1.25% convertible senior notes due 2031, or the 2031 Notes (together with the 2027 Notes, the Notes) in exchange for the retirement of approximately $659.3 million aggregate principal amount of the 2027 Notes, or the Note Exchange. 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;
- the accrual and payment of interest on the 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 Notes or any additional indebtedness that we may incur. In addition, 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 Notes, if triggered, may adversely affect our financial condition. Conversion of the Notes, to the extent the 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 features of the Notes are triggered, holders of the Notes will be entitled to convert their Notes into shares of our common stock upon the occurrence of certain events. If one or more holders of the Notes elect to convert their 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 Notes is triggered, the conversion of some or all of the 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 and the 2031 Notes may become in the future convertible at the option of the holders thereof prior to August 15, 2027 and November 15, 2030, respectively, under certain circumstances as provided in the respective indentures. 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 Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, and even anticipated conversion of the Notes into shares of our common stock could depress the price of our common stock.

The convertible note hedge may affect the value of the 2027 Notes and our common stock.

In connection with the sale of the 2027 Notes, we entered into convertible note hedge, the 2027 Note Hedge, transactions with certain financial institutions, or option counterparties, certain of which are expected to be cancelled in connection with the Note Exchange. The 2027 Note Hedge transactions are expected generally to reduce the potential dilution upon any conversion of the 2027 Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted 2027 Notes.

The option counterparties and/or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock in secondary market transactions prior to the maturity of the 2027 Notes (and are likely to do so during any observation period related to a conversion of the Notes, or following any repurchase of the 2027 Notes by us on any fundamental change repurchase date (as provided in the indenture governing the 2027 Notes) or otherwise). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2027 Notes, which could affect note holders' ability to convert the 2027 Notes and, to the extent the activity occurs during any observation period related to a conversion of the 2027 Notes, it could affect the amount and value of the consideration that note holders will receive upon conversion of the 2027 Notes.

The potential effect, if any, of these transactions and activities on the market price of our common stock or the 2027 Notes will depend in part on market conditions and cannot be ascertained at this time. Any of these activities could adversely affect the value of our common stock and the value of the 2027 Notes (and as a result, the value of the consideration, the amount of cash and/or the number of shares, if any, that note holders would receive upon the conversion of the 2027 Notes) and, under certain circumstances, the ability of the note holders to convert the 2027 Notes.

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the 2027 Notes or our common stock. In addition, we do not make any representation that the option counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

We are subject to counterparty risk with respect to the 2027 Note Hedge transactions.

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the 2027 Note Hedge transactions. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with that option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties.

Provisions in our corporate charter documents and under Delaware law could make a change in control of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may make it more difficult for our stockholders to replace current members of our board of directors or add new members thereto. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempts by our stockholders to change our management team. Among others, these provisions include that:

- our board of directors has the exclusive right to expand its size and to elect directors to fill a vacancy created by the expansion of the board or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- a special meeting of stockholders may be called only by our board of directors, its chairman, or our co-chief executive officers, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- our amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect their director candidates;
- our board of directors may alter our bylaws without obtaining stockholder approval;
- approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors is required to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- stockholders must provide advance notice and additional disclosures in order to nominate candidates for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law by Delaware courts, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits brought against us and our directors and officers by our stockholders. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. However, a Delaware court held that such an exclusive forum provision relating to federal courts was unenforceable under Delaware law, and unless and until the Delaware court decision is reversed on appeal or otherwise abrogated, we do not intend to enforce such a provision in the event of a complaint asserting a cause of action arising under the Securities Act against us or any of our directors, officers, employees or agents.

General Risk Factors

We may acquire businesses, form joint ventures or make investments in companies or technologies that could negatively affect our operating results, distract management's attention from other business concerns, dilute our stockholders' ownership, and significantly increase our debt, costs, expenses, liabilities and risks.

We have made acquisitions of businesses, technologies and assets and may pursue additional acquisitions in the future. We also may pursue strategic alliances and additional joint ventures that leverage our industry experience to expand our product offerings or distribution. We have limited experience with acquisitions and forming strategic partnerships. We compete for those opportunities with others including our competitors, some of which have greater financial or operational resources than we do. We may not be able to identify suitable acquisition candidates or strategic partners, we may have inadequate access to information or insufficient time to complete due diligence, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Difficulties in assimilating acquired businesses include redeployment or loss of key employees and their severance, combination of teams and processes in various functional areas, reorganization or closures of facilities, relocation or disposition of excess equipment, and increased litigation, regulatory and compliance risks, any of which could be expensive and time consuming and adversely affect us. Integration of an acquired business also may disrupt our ongoing operations and require management resources that we would otherwise focus on developing our existing business. In addition, any acquisition could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We may also experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, joint ventures or investments, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

We may need to raise additional capital to fund our existing operations, develop our platform, commercialize new products or expand our operations.

We may consider raising additional capital in the future to expand our business, to meet existing obligations, to pursue acquisitions or strategic investments, to take advantage of financing opportunities or for other reasons, including to:

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

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

- our ability to achieve revenue growth;
- our rate of progress in establishing payer coverage and reimbursement arrangements with domestic and international commercial payers and government payers;
- the cost of expanding our laboratory operations and product offerings, including our sales and marketing efforts;
- our rate of progress in, and costs of our sales and marketing activities associated with, establishing adoption of and reimbursement for our current products, including our tests;
- our rate of progress in, and costs of our research and development activities associated with, products in research and early development;

- the effect of competing technological and market developments;
- costs related to our international expansion; and
- the potential costs of and delays in product development as a result of any existing or new regulatory oversight applicable to our products.

We may seek to sell equity or convertible securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity or convertible securities, dilution to our stockholders could result. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products or grant licenses on terms that are not favorable to us. These alternatives of raising additional capital may not be available to us on acceptable or commercially reasonable terms, if at all, or in amounts sufficient to meet our needs. The failure to obtain any required future financing may require us to reduce or curtail existing operations and could contribute to negative market perceptions about us or our securities.

As a result of adverse geopolitical and macroeconomic developments, including economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions and there has been increasing uncertainty about economic stability. If the equity and credit markets remain depressed or further deteriorate as a result of this global uncertainty, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since our inception and we may never achieve or sustain profitability. Under the Tax Cuts and Jobs Act, federal net operating loss, or NOL, carryforwards we generated in tax years through December 31, 2017 may be carried forward for 20 years and may fully offset taxable income in the year utilized, and federal NOLs we generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not completed a study to assess whether an ownership change for purposes of Section 382 or 383 has occurred, or whether there have been multiple ownership changes since our inception. For purposes of Section 382 or 383, we may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. Therefore, if we attain profitability, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Changes in tax laws or regulations could harm our financial condition and results of operations.

Changes in tax laws or regulations, or changes in interpretations of existing laws and regulations, could materially affect our financial condition and results of operations. For example, the Trump administration, members of Congress, and future U.S. presidential administrations may propose, various U.S. federal tax law changes, which if enacted could have a material impact on our business operations and financial performance. In addition, many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws, including as a result of the base erosion and profit shifting, or BEPS, project that is being led by the Organization for Economic Co-operation and Development, or OECD, and other initiatives led by the OECD or the European Commission. Due to the expanding scale of our international business activities, these types of changes to the taxation of our activities could increase the amount of taxes imposed on our business. Any of these outcomes could harm our financial position and results of operations.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. In connection with adopting and implementing a new revenue recognition standard, FASB ASC Topic 606, *Revenue from Contracts with Customers*, management has made and will continue to make judgments and assumptions based on our interpretation of the new standard. The new revenue recognition standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. We also adopted a new lease accounting standard, FASB ASC Topic 842, *Leases*, which involved significant judgment and assumptions, including the estimation of incremental borrowing rate used to discount our lease liabilities and the assessment of risks associated with the specific economic environment of our leased assets. It is possible that interpretation, industry practice and guidance may evolve as we work toward implementing these new accounting standards. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of analysts and investors, resulting in a decline in the market price of our common stock.

The loss of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians, sales representatives and business development managers could adversely affect our business.

Our success depends on the skills, experience and performance of key members of our senior management team, including Helmy Eltoukhy and AmirAli Talasaz, our Co-Chief Executive Officers. The individual and collective efforts of these employees will be important as we continue to develop our platform and additional products, and as we expand our commercial activities. The loss or incapacity of existing members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers signed offer letters when first joining our company, but do not have employment agreements, and we cannot guarantee their retention for any period of time. We do not maintain "key person" insurance on any of our employees.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our headquarters in Palo Alto, California. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, we may have difficulties locating, recruiting or retaining qualified sales representatives and business development managers. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a result of being a public company, we are required, under Section 404 of the Sarbanes-Oxley Act, to furnish annual reports by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;

- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

Pursuant to the Sarbanes-Oxley Act and the rules and regulations promulgated by the SEC, we are required to furnish in this Annual Report on Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we believe our internal control over financial reporting is currently effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and would increase our costs of doing business.

In addition, under the federal securities laws, our auditors are required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated, communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, CMS and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations, lawsuits or other actions stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or from coverage of commercial payers, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, which could have a significantly adverse impact on our business. Whether or not we are successful in

defending against such actions, we could incur substantial costs and expenses, including legal fees, and divert the attention of management from the operation of our business.

If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products could lead to the filing of product liability claims were someone to allege that our products identified inaccurate or incomplete information regarding the genomic alterations of the tumor or malignancy analyzed, reported inaccurate or incomplete information concerning the available therapies for a certain type of cancer, or otherwise failed to perform as designed. We may also be subject to professional liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could damage our reputation or cause current clinical customers to terminate existing agreements with us and potential clinical customers to seek other partners, any of which could adversely impact our results of operations.

Cybersecurity incidents such as security breaches, loss of data and other disruptions in relation to our information technology systems, as well as those of our third-party service providers, could compromise sensitive information related to our business, prevent us from accessing it and expose us to substantial liability, which could adversely affect our business and reputation.

In the ordinary course of our business, we collect and store sensitive data, including credit card and other financial information, other personal information, intellectual property and proprietary business information owned or controlled by us or other parties such as customers and payers. We also communicate sensitive data, including patient data, through phone, Internet, facsimile, multiple third-party vendors and their subcontractors. We depend on information technology systems for significant elements of our operations, including our laboratory information management system, our computational biology system, our knowledge management system, our customer reporting and our GuardantConnect software platform. Our information technology systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. Our information technology systems store a wide variety of information critical to our business, including research and development information, patient data, commercial information and business and financial information. We face a number of risks related to protecting this critical information, including loss of access, inappropriate use or disclosure, unauthorized access, inappropriate modification and our being unable to adequately monitor, audit or modify our controls over such critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf.

Cybersecurity incidents such as security breaches, computer viruses, malware and other incidents could cause misappropriation, loss or other unauthorized disclosure of confidential data, materials or information, including those concerning our customers and employees. Increasingly complex methods have been used in cyberattacks, including ransomware, phishing, structured query language injections, social engineering schemes, insider threats, AI tool supported attacks, and distributed denial-of-service attacks conducted by actors including computer attackers, foreign governments and cyber terrorists. A cyberattack can also be in the form of unauthorized access or a blocking of authorized access. The risk of a cybersecurity incident has generally increased as the number, intensity and sophistication of attempted attacks has increased. As a result of the continued hybrid working environment, we and our third party service providers and partners may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience cybersecurity incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We can provide no assurance that we or our vendors will be able to detect, prevent or contain the effects of such attacks or other information security risks or threats in the future.

The costs of attempting to protect against the foregoing risks and the costs of responding to a cybersecurity incident are significant. Large scale cybersecurity incidents 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 cybersecurity incident, our and/or our vendors' remediation efforts may not be successful, and a cybersecurity incident could result in interruptions, delays or cessation of service, and loss of existing or potential customers. In addition, cybersecurity incidents 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 such as PHI, or if our statements or practices are found to be deceptive or misrepresentative, we could face regulatory actions, fines and other liability.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use, modification or disclosure, no security measures can be perfect. We and certain of our service providers are from time to time subject to cybersecurity incidents. For example, in the past year, we identified cybersecurity incidents involving an unauthorized actor obtaining access to our email system and sending phishing messages. Despite the precautionary measures we have taken in response to such incidents and to prevent other unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from performing our comprehensive genomic analysis, preparing and providing reports to pathologists and oncologists, billing payers, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. While we do not believe that we have experienced any material cybersecurity incidents as of the date of this Annual Report on Form 10-K, as described above we have experienced prior cybersecurity incidents. Any cybersecurity incident could result in legal claims or proceedings, and liability under federal, state or foreign laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Notice of cybersecurity incidents may be required to be made to affected individuals, the Secretary of the HHS or other state, federal or foreign regulators, to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. 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.

It could be difficult to predict the ultimate resolution of any such cybersecurity incidents or to estimate the amounts or ranges of potential loss, if any, that could result therefrom. If we cannot successfully resolve a cybersecurity incident, it could materially impact our ability to operate our business as well as our results of operations and financial position. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

The security of our sensitive business-related information and the personal information we collect, as well as our information systems, is important for our business. In the normal course of business, we may collect and store personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information regarding study participants in connection with clinical studies, sensitive third-party information and employee information. 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. To protect this information, we have implemented a cybersecurity program, and have established oversight mechanisms designed to provide effective cybersecurity governance, risk management, and timely incident response. Our cybersecurity program takes into account recognized cybersecurity industry frameworks and standards including NIST-CSF, ISO 27001/27002 as well as HIPAA.

Our cybersecurity policies require that we implement and maintain monitoring and detection programs, network security precautions, encryption of critical data, and management of third-party risk. We maintain various protections designed to safeguard against cyberattacks, including but not limited to attack surface management, anti-phishing secure email gateways, log monitoring and analysis, cloud security posture management, endpoint detection and response, and network intrusion detection and prevention systems. We also have processes in place to prevent unauthorized access to data processing systems and facilities, including two-factor authentication, tiered approval processes and password complexity, and our employees and applicable contractors undergo mandatory privacy and security trainings annually. We have established and periodically test our disaster recovery plan and we protect against business interruption by backing up our major systems. In addition, we periodically scan our environment for any vulnerabilities, perform penetration testing and engage third parties to assess the effectiveness of our data security practices and compliance with applicable practices and standards. In addition, we maintain a third-party risk register to identify, prioritize and track risks, including those associated with our use of third-party service providers. We also maintain cybersecurity insurance coverage though it may not be sufficient to cover all costs of a cybersecurity incident.

Governance

Our cybersecurity program is led by a team of cybersecurity professionals. The program incorporates aspects of industry-standard frameworks, policies and practices designed to protect the privacy and security of our sensitive information. Senior members of our management, including our Chief Information Security Officer and Chief Information Officer, each of whom has over 10 years of experience in various roles involving information technology, including security, auditing, compliance, systems and programming, are responsible for assessing cybersecurity risk. Cybersecurity risk management is performed by the senior leadership of the cybersecurity team as well as members of our legal and privacy teams where relevant. These individuals are informed about, and monitor the prevention, mitigation, detection and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management processes described above, including the operation and testing of our incident response plan. Additionally, our threat intelligence program issues a semi-annual report briefing to inform the security team about relevant cybersecurity events, significant vulnerabilities and vendor-related incidents.

Our Chief Information Security Officer reports to the full Board of Directors and the Nominating and Corporate Governance Committee on two occasions per year on information security and cybersecurity matters, or more frequently as needed. These reports generally cover various topics, which may include summaries of recent industry events or notable topics that may influence our cybersecurity risk perspective and security priorities; any actions taken in response to such events or topics; and a review of our top cybersecurity concerns and priorities. Our Nominating and Corporate Governance Committee has oversight responsibility for our data security practices and we believe the committee has the requisite skills and visibility into the design and operation of our data security practices to fulfill this responsibility effectively.

Despite the implementation of our cybersecurity program, our security measures cannot guarantee that a significant cyberattack will not occur. A successful attack on our information technology systems could have significant consequences to the business. As of the date of this Annual Report on Form 10-K, we are not aware of any material cybersecurity incidents or threats that have impacted our business. However, we and our customers have

experienced cybersecurity incidents and routinely face risks of cybersecurity incidents, wholly or partially beyond our control, as we rely heavily on our information technology systems. While we devote resources to our security measures to protect our systems and information, these measures cannot provide absolute security. See Part I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K for additional information about the risks to our business associated with a cybersecurity incident affecting our information technology systems.

Item 2. Properties

Our headquarters are located in Palo Alto, California, where we lease approximately 249,500 square feet of office and lab space. The lease for the Palo Alto office was entered into in July 2020 and has a term of 12 years with an option to renew the lease term for an additional 10 years. In addition, we have approximately 200,000 square feet of additional office and lab space in Redwood City and San Diego, California, with current lease expiration dates ranging from 2025 to 2029. We also maintain domestic leased office spaces in Dallas and Spring, Texas; Seattle, Washington; Long Island City, New York; and Washington, D.C.; and warehouse space in Union City, California. In addition, for international locations, we maintain leased office space in Japan, Singapore and India. 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 9 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 14, 2025, there were 47 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

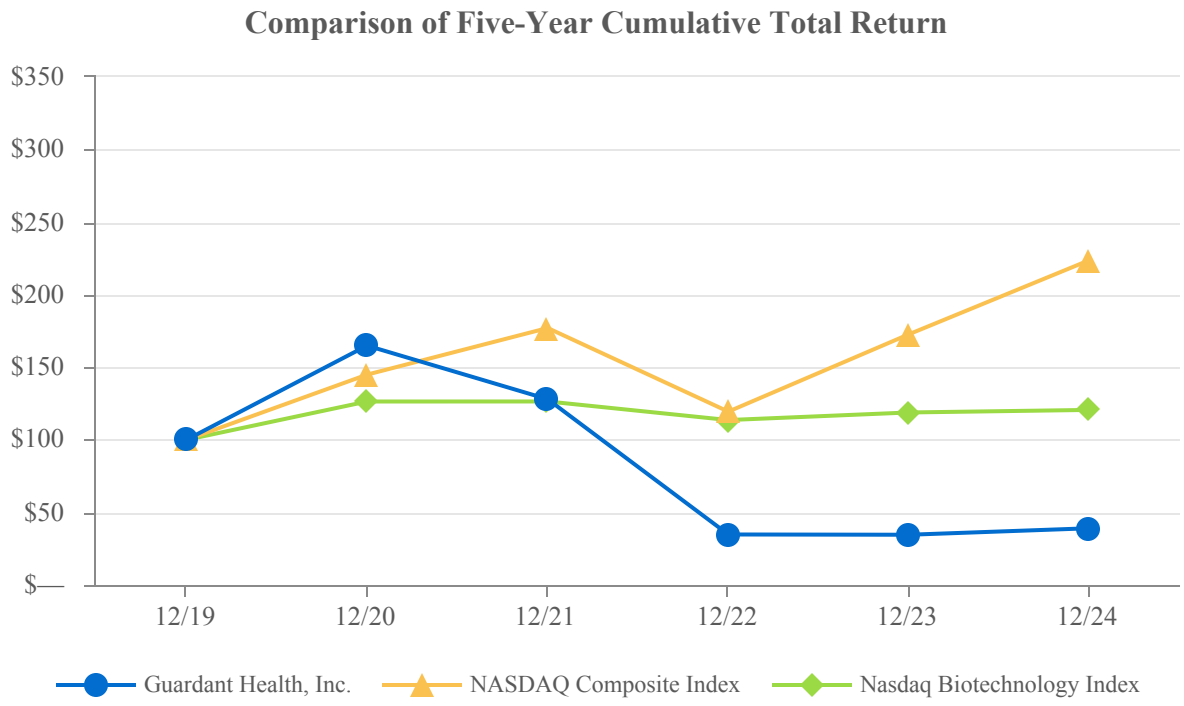
None.

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 2025 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, or the 2025 Proxy Statement.

Stock performance graph

The graph below shows a comparison of five-year cumulative total return to stockholders of our common stock relative to the Nasdaq Composite Index and the Nasdaq Biotechnology Index through December 31, 2024. 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 December 31, 2019 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. [Reserved]

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, 2024 and 2023. A detailed discussion comparing our results of operations for the years ended December 31, 2023 and 2022 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, 2023.

Overview

We are a leading precision oncology company focused on guarding wellness and giving every person more time free from cancer. We are transforming patient care by providing critical insights into what drives disease through our advanced blood and tissue tests, and real-world data. Our tests help improve outcomes across all stages of care, including screening to find cancer early, monitoring for recurrence in early-stage cancer, and helping doctors select the best treatment for patients with advanced cancer. For patients with advanced-stage cancer, we have commercially launched Guardant360 laboratory developed test, or LDT, and Guardant360 CDx, the first comprehensive liquid biopsy test approved by the U.S. Food and Drug Administration, or the FDA, to provide tumor mutation profiling with solid tumors and to be used as a companion diagnostic in connection with non-small cell lung cancer, or NSCLC, and breast cancer. We have also launched the Guardant360 TissueNext tissue test for advanced-stage cancer, Guardant Reveal blood test to detect residual and recurring disease in early-stage colorectal, breast and lung cancer patients, and Guardant360 Response blood test to predict patient response to immunotherapy or targeted therapy eight weeks earlier than current standard-of-care imaging.

We also collaborate with biopharmaceutical companies in clinical studies by providing the above-mentioned tests, as well as the GuardantOMNI blood test for advanced-stage cancer, and the GuardantINFINITY blood test, a next-generation Smart Liquid Biopsy that provides new, multi-dimensional insights into the complexities of tumor molecular profiles and immune response to advance cancer research and therapy development. Using data collected from our tests, we have also developed our GuardantINFORM platform to help biopharmaceutical companies accelerate precision oncology drug development through the use of this in-silico research platform to unlock further insights into tumor evolution and treatment resistance across various biomarker-driven cancers.

For early cancer detection, in May 2022, we launched the Shield LDT test to address the needs of individuals eligible for colorectal cancer screening. From a simple blood draw, Shield uses a novel multimodal approach to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors. In December 2022, we announced that the ECLIPSE study, a registrational study evaluating the performance of our Shield blood test for detecting colorectal cancer in average-risk adults, met co-primary endpoints. In addition, in March 2023, we submitted a premarket approval application, or PMA, for our Shield blood test to the FDA. In July 2024, we received FDA approval of our Shield blood test for colorectal cancer screening in adults age 45 and older who are at average risk for the disease, and in August 2024, our Shield blood test became commercially available in the U.S. as the first blood test approved by the FDA for primary colorectal cancer screening, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines. Shield is also the first blood test for colorectal cancer screening that meets coverage requirements by Medicare. We also expect to expand into lung cancer screening and multi-cancer detection with our Shield platform.

We currently perform clinical, research use only, and investigation use only tests in our laboratory located in Redwood City, California. Our Redwood City 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. We also perform research use only tests in our laboratory located in San Diego, California. In addition, our Redwood City, San Diego and Palo Alto, California laboratories are currently operated as centers for our research and technology development.

We generated total revenue of $739.0 million, $563.9 million and $449.5 million for the years ended December 31, 2024, 2023 and 2022, respectively. We also incurred net losses of $436.4 million, $479.4 million and $654.6 million in the years ended December 31, 2024, 2023 and 2022, respectively. We have funded our operations to date

principally from the sale of our stock, convertible senior notes, and revenue from our precision oncology testing and development services and other. In May 2023, we completed a follow-on underwritten public offering, in which we issued and sold 14,375,000 shares of our common stock at a price of $28.00 per share, and received net proceeds of $381.4 million after deducting underwriting discounts and commissions and other offering costs of $21.1 million. In December 2023, we completed a registered direct offering with an investment management firm, in which we issued and sold 3,387,446 shares of our common stock at a price of $26.77 per share, and received net proceeds of $90.6 million. As of December 31, 2024, we had cash, cash equivalents, restricted cash and marketable debt securities of approximately $944.2 million.

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. Precision oncology revenue from clinical tests for patients covered and administered by Medicare represented approximately 39%, 43% and 45% of our precision oncology revenue from clinical customers for the years ended December 31, 2024, 2023 and 2022, respectively.

- ***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 payers' 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 are 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 tests 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 tests are 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 our molecular diagnostics tests. Changes to the codes used to report to payers may result in significant changes in its reimbursement. If their policies were to change in the future to cover additional cancer indications, we anticipate that our total reimbursement would increase.

  In March 2021, the Centers for Medicare and Medicaid Services, or CMS, approved advanced diagnostic laboratory test, or ADLT, status to our Guardant360 CDx test, based on which Medicare paid us at the lowest available commercial rate per test, from April 1, 2021 to December 31, 2021. Effective January 1, 2022, Medicare started to reimburse Guardant360 CDx services at the median rate of claims paid by commercial payers. In March 2022, Palmetto GBA, the Medicare administrative contractor for MolDX, conveyed coverage for our Guardant360 TissueNext test under the existing local coverage determination. The policy covers our Guardant360 TissueNext test for Medicare fee-for-service patients with advanced solid tumor cancers. In July

2022, Palmetto GBA conveyed coverage for our Guardant Reveal test for fee-for-service Medicare patients in the United States with stage II or III colorectal cancer whose testing is initiated within three months following curative intent therapy, with an effective date of December 2021. In April 2023, Palmetto GBA conveyed coverage for our Guardant360 Response test for fee-for-service Medicare patients in the U.S. with metastatic or inoperable solid tumors who are on an immune checkpoint inhibitor therapy, tested four to ten weeks from therapy initiation. Effective January 1, 2024, Medicare has increased the reimbursement rate for our Guardant360 LDT test to the same rate as our Guardant360 CDx test. In January 2025, Palmetto GBA granted coverage for our Guardant Reveal test to monitor disease recurrence in patients with colorectal cancer in the surveillance setting following curative intent therapy. This represents an expansion from the prior Medicare coverage of our Guardant Reveal test for colorectal cancer in the early post-surgical setting only.

In August 2024, following the FDA approval, our Shield blood test met the coverage requirements by Medicare based on the criteria established in its National Coverage Determination for blood-based colorectal cancer screening tests. The test is covered once every three years for eligible Medicare beneficiaries.

Due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our tests, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received differs from the revenue recorded. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. Additionally, if coding changes were to occur, payments for certain uses of our tests could be reduced, put on hold, or eliminated. 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 studies 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 study enrollment. For example, our tests are being developed as companion diagnostics under collaborations with biopharmaceutical companies.

- ***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 Guardant Reveal, in October 2021, we initiated a 1,000-patient prospective, observational, multi-center study, which we refer to as the ORACLE study, designed to evaluate the performance of our Guardant Reveal liquid biopsy test to predict cancer recurrence after curative intent treatment, across 11 solid tumor types. In addition, with respect to Guardant Reveal, in December 2022, we entered into a partnership with Susan G. Komen®, the world's leading breast cancer organization, to bring the patient perspective to the development of clinical studies that help identify early-stage breast cancer patients who are at high risk of disease recurrence and may benefit from additional monitoring or therapy. With respect to Shield, in December 2022, we announced that the ECLIPSE study, a registrational study evaluating the performance of our Shield blood test for detecting colorectal cancer in average-risk adults, met co-primary endpoints. The test demonstrated 83% sensitivity in detecting individuals with colorectal cancer. Specificity was 90% in both individuals without advanced neoplasia and in those who had a negative colonoscopy result. These results exceed the performance criteria set forth by the CMS for reimbursement. This test also demonstrated 13% sensitivity in detecting advanced adenomas. Based on these study results, in March 2023, we submitted a PMA to the FDA for our Shield blood test. In July 2024, we received FDA approval of our Shield blood test for colorectal cancer screening in adults age 45 and older who are at average risk for the disease, and in August 2024, our Shield blood test became commercially available in the U.S. as the first blood test approved by the FDA for primary colorectal cancer screening, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines. Shield is also the first blood test for colorectal cancer screening that meets coverage requirements by Medicare. To clinically validate the performance of our next-generation Shield blood test in lung cancer screening in high-risk individuals ages 50-80, in January 2022, we initiated a nearly 10,000-patient prospective, registrational study, which we refer to as the SHIELD LUNG study. In addition, in January 2025, our Shield multi-cancer detection, or MCD, test was selected for the Vanguard study funded by the National Cancer Institute, part of the National Institutes of Health. The Vanguard study is a four-year pilot study which will enroll up to 24,000 people to inform the design of a randomized controlled trial evaluating the use of MCD tests for cancer screening. 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, and partnerships with local research organizations and laboratory companies.

  In May 2018, we formed and capitalized Guardant Health AMEA, Inc., with SoftBank, relating to the sale, marketing and distribution of our tests generally outside the Americas and Europe, and to accelerate commercialization of our products in Asia, the Middle East and Africa. In June 2022, we purchased all of the shares held by SoftBank and its affiliates, and upon completion of the transaction, we obtained full control over operations of Guardant Health AMEA, Inc. In July 2023, Japan's Ministry of Health, Labour and Welfare granted national reimbursement approval for our Guardant360 CDx test for patients with advanced or metastatic solid tumor cancers in Japan.

  In December 2020, we signed our first public private partnership agreement with Vall D'Hebron Institute of Oncology, or VHIO, one of Europe's leading cancer research institutions, and in May 2022, the first blood-based cancer testing services in Europe based on our digital sequencing platform became available at the VHIO testing facility in Spain. In October 2021, we signed a partnership agreement with The Royal Marsden NHS Foundation Trust, or Royal Marsden, a premier cancer center within the United Kingdom, or the UK, for patient care, research and teaching of all types of cancer, and in April 2023, the blood-based cancer testing services based on our digital sequencing platform became available at Royal Marsden testing facility in the UK. In September 2024, we signed a partnership agreement with the Agostino Gemelli University Polyclinic Foundation IRCCS, one of Italy's largest and most renowned hospitals known for its advanced oncology services, including diagnostics, treatment, and research, to establish an in-house liquid biopsy testing service within its hospital system.

  In June 2022, we signed a strategic partnership agreement with Adicon Holdings Limited, or Adicon, a leading independent clinical laboratory company based in China, and in December 2023, the blood-based cancer testing services based on our digital sequencing platform became available at Adicon's testing facility, which offers our industry-leading comprehensive genomic profiling tests to biopharmaceutical companies to advance clinical research and the development of new cancer therapies in China.

  The success of our international expansion strategy depends on a number of factors, including the internal and external constraints placed on our international laboratory partners and biopharmaceutical companies in the context of broader global, regional and U.S. economic and geopolitical conditions. For example, deterioration in the bilateral relationship between the United States and China may impact international trade, government spending, regional stability and macroeconomic conditions. The impact of these potential developments, including any resulting sanctions, export controls or other restrictive actions that may be imposed against governmental or other entities in, for example, China, may contribute to disruption of our international partnerships and instability and volatility in the global markets, which in turn could adversely impact our operations and weaken our financial results.

- ***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, increase in headcount, 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 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.

- ***Other operating expense***. Our financial results might fluctuate significantly based upon the impact of our other operating expense, and in particular, our legal settlement costs, which could potentially decrease or increase significantly.

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.

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 tests to clinical and biopharmaceutical customers, including those tests delivered by labs operated by our strategic partners. In the United States, through December 31, 2024, 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 also submit claims to Medicare for reimbursement for our Guardant360 CDx, Guardant360 LDT, Guardant360 TissueNext, Guardant Reveal and Guardant360 Response clinical testing performed for qualifying patients. Precision oncology revenue from clinical tests for patients covered and administered by Medicare represented approximately 39%, 43% and 45% of our precision oncology revenue from clinical customers for the years ended December 31, 2024, 2023 and 2022, respectively.

Development services and other. Development services revenue primarily represents services that we provide to biopharmaceutical companies, large medical institutions and international laboratory partners. We collaborate with biopharmaceutical companies in the development and clinical studies of new drugs. As part of these collaborations, we provide services related to regulatory filings to support companion diagnostic device submissions for our test panels. Under these arrangements, we generate revenue from progression of our collaboration efforts, as well as from provision of on-going support. In addition to companion diagnostic development and regulatory approval services, we also provide other development services, including clinical study setup, monitoring and maintenance, testing development and support, GuardantConnect and GuardantINFORM. Other revenue includes amounts derived from licensing our technologies, kit fulfillment and delivery of our Shield screening tests.

Costs and operating expenses

Cost of precision oncology testing. Cost of precision oncology testing generally consists of cost of materials, including inventory write-downs; cost of labor, including employee benefits, bonus, and stock-based compensation; equipment and infrastructure expenses associated with processing test samples, such as sample accessioning, library preparation, sequencing, and quality control analyses; freight; curation of test results for physicians; phlebotomy; 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. While we do not believe the technologies underlying the third-party 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 we expect 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 biopharmaceutical customers, and costs associated with our partnership agreements and delivery of Shield screening tests, which comprise of 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 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 studies.

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 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 overhead expenses. In addition, our general and administrative expenses also include severance costs related to workforce reduction. We expect that our general and administrative expenses will continue to increase as we incur additional costs to support the growth of our business. 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, restricted cash and marketable debt securities.

Interest expense

Interest expense consists primarily of charges relating to amortization of debt issuance costs.

Other income (expense), net

Other income (expense), net consists of foreign currency exchange gains and losses, unrealized and realized gains and losses of marketable equity securities, and impairment of non-marketable equity securities and other related assets. 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 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 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 tables set forth the significant components of our results of operations for the periods presented.

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Revenue:		
Precision oncology testing	$ 687,936	$ 514,249
Development services and other	51,080	49,699
Total revenue	739,016	563,948
Costs and operating expenses:		
Cost of precision oncology testing[(1)]	260,581	205,528
Cost of development services and other[(1)]	29,218	21,524
Research and development expense[(1)]	347,753	367,194
Sales and marketing expense[(1)]	364,935	295,227
General and administrative expense[(1)]	180,123	155,800
Other operating expense	—	83,400
Total costs and operating expenses	1,182,610	1,128,673
Loss from operations	(443,594)	(564,725)
Interest income	53,691	35,365
Interest expense	(2,581)	(2,578)
Other income (expense), net	(42,605)	53,174
Loss before provision for income taxes	(435,089)	(478,764)
Provision for income taxes	1,284	685
Net loss	$ (436,373)	$ (479,449)

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Cost of precision oncology testing	$ 5,315	$ 4,614
Cost of development services and other	4,050	1,851
Research and development expense	50,566	34,682
Sales and marketing expense	36,479	24,764
General and administrative expense	44,001	24,848
Total stock-based compensation expense	$ 140,411	$ 90,759

In November 2020 and May 2021, we granted restricted stock units with certain performance metrics, or PSUs, consisting of a performance period of 4 years combined with an additional service period requirement of six months should the vesting criteria be met, with a grant date fair value of $113.40 per share and $148.19 per share, respectively. Before 2024, no compensation expense for these PSUs had been recorded since the achievement of the performance metrics did not meet the criteria for accrual. In 2024, the performance metrics of these PSUs were considered to be achieved; as such we recorded $24.8 million in stock-based compensation expense related to these PSUs, based on 219,161 shares granted with fair values of $113.40 per share and $148.19 per share, of which $2.4 million was recorded to cost of development services and other, and $11.8 million, $6.5 million and $4.1 million was recorded as components of research and development expense, sales and marketing expense, and general and administrative expense, respectively.

Comparison of the Years Ended December 31, 2024 and 2023

Revenue

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Precision oncology testing	$ 687,936	$ 514,249	$ 173,687	34 %
Development services and other	51,080	49,699	1,381	3 %
Total revenue	$ 739,016	$ 563,948	$ 175,068	31 %

Total revenue was $739.0 million for the year ended December 31, 2024, compared to $563.9 million for the year ended December 31, 2023, an increase of $175.1 million, or 31%.

Precision oncology testing revenue increased to $687.9 million for the year ended December 31, 2024, from $514.2 million for the year ended December 31, 2023, an increase of $173.7 million, or 34%.

Precision oncology revenue from tests for clinical customers was $542.8 million for the year ended December 31, 2024, up 34% from $403.9 million for the year ended December 31, 2023. This increase in clinical testing revenue was driven primarily by an increase in sample volume and an increase in reimbursement for our tests. Total tests for clinical customers increased to approximately 206,700 for the year ended December 31, 2024, from approximately 172,900 for the year ended December 31, 2023. The increase in reimbursement for our tests for the year ended December 31, 2024 was primarily attributable to an increase in Medicare reimbursement for our Guardant360 LDT test to $5,000, effective January 1, 2024; and increases in Medicare Advantage and commercial payer reimbursement.

Precision oncology revenue from tests for biopharmaceutical customers was $145.1 million for the year ended December 31, 2024, up 31% from $110.4 million for the year ended December 31, 2023. This increase in revenue was primarily due to an increase in sample volume. Total tests for biopharmaceutical customers increased to approximately 40,500 for the year ended December 31, 2024, from approximately 29,900 for the year ended December 31, 2023.

Development services and other revenue increased to $51.1 million for the year ended December 31, 2024, from $49.7 million for the year ended December 31, 2023, an increase of $1.4 million, or 3%. This increase in development services and other revenue was primarily due to an increase of $9.1 million associated with our companion diagnostics collaboration projects and other service agreements with biopharmaceutical customers, partially offset by a decrease of $7.2 million associated with our partnership agreements, and a reduction of $3.2 million in royalty revenue. The increase in other revenue was also attributable to $4.1 million derived from the delivery of approximately 6,400 of our Shield screening tests for the three months ended December 31, 2024, following the FDA approval.

Cost of Revenue

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Cost of precision oncology testing	$ 260,581	$ 205,528	$ 55,053	27 %
Cost of development services and other	29,218	21,524	7,694	36 %
Total cost of revenue	$ 289,799	$ 227,052	$ 62,747	28 %

Total cost of revenue was $289.8 million for the year ended December 31, 2024, compared to $227.1 million for the year ended December 31, 2023, an increase of $62.7 million, or 28%.

Cost of precision oncology testing was $260.6 million for the year ended December 31, 2024, compared to $205.5 million for the year ended December 31, 2023, an increase of $55.1 million, or 27%. This increase in cost of precision oncology testing was primarily attributable to an increase in sample volumes and an increase in average cost per sample primarily due to changes in product mix, resulting in a $44.7 million increase in material costs, a $4.7 million increase in production labor and overhead costs, and a $4.6 million increase in other costs, including costs related to collection kits, freight and professional services.

Cost of development services and other was $29.2 million for the year ended December 31, 2024, compared to $21.5 million for the year ended December 31, 2023, an increase of $7.7 million, or 36%. This increase in cost of development services and other was primarily due to an increase of $4.3 million associated with our companion diagnostics collaboration projects and other service agreements with biopharmaceutical customers, and an increase of $3.3 million associated with providing Shield screening tests during the year ended December 31, 2024.

Operating Expenses

Research and development expense

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Research and development expense	$ 347,753	$ 367,194	$ (19,441)	(5)%

Research and development expenses were $347.8 million for the year ended December 31, 2024, compared to $367.2 million for the year ended December 31, 2023, a decrease of $19.4 million, or 5%. This decrease was primarily due to a decrease of $31.8 million in outside services costs primarily driven by a reduction in the ECLIPSE clinical study costs as the study nears completion, a decrease of $9.7 million in material costs, and a decrease of $3.7 million in information technology infrastructure costs; partially offset by an increase of $15.9 million in stock-based compensation, primarily related to the PSUs of $11.8 million discussed in the *Results of operations* section above; and an increase of $10.0 million in other personnel costs.

Sales and marketing expense

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Sales and marketing expense	$ 364,935	$ 295,227	$ 69,708	24 %

Sales and marketing expenses were $364.9 million for the year ended December 31, 2024, compared to $295.2 million for the year ended December 31, 2023, an increase of $69.7 million, or 24%. This increase was related to commercial team expansion and marketing activities to support existing products and the Shield product launch, primarily resulting in an increase of $34.1 million in other personnel costs; an increase of $14.9 million in marketing activity related costs; an increase of $11.7 million in stock-based compensation, including $6.5 million related to the PSUs discussed in the *Result of operations* section above; and an increase of $10.5 million in information technology infrastructure costs.

General and administrative expense

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
General and administrative expense	$ 180,123	$ 155,800	$ 24,323	16 %

General and administrative expenses were $180.1 million for the year ended December 31, 2024, compared to $155.8 million for the year ended December 31, 2023, an increase of $24.3 million, or 16%. This increase was primarily due to an increase of $19.2 million in stock-based compensation, including $4.1 million related to the PSUs discussed in the *Results of operation* section above; and an increase of $12.4 million in other personnel costs; partially offset by a decrease of $7.5 million in severance costs related to a workforce reduction in the first quarter of 2023, and a decrease of $3.1 million in legal expenses.

Other operating expense

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Other operating expense	$ —	$ 83,400	$ (83,400)	(100)%

Other operating expense for the year ended December 31, 2023 was related to a legal accrual in connection with a jury verdict related to TwinStrand Biosciences, Inc. and the University of Washington entered into in November 2023. See *"Commitments and Contingencies - Legal Proceedings"* in Note 9 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Interest income

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Interest income	$ 53,691	$ 35,365	$ 18,326	52 %

Interest income was $53.7 million for the year ended December 31, 2024, compared to $35.4 million for the year ended December 31, 2023, an increase of $18.3 million, or 52%, primarily attributable to higher rates of return on our investments.

Interest expense

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Interest expense	$ (2,581)	$ (2,578)	$ (3)	— %

Interest expense was primarily attributable to the amortization of debt issuance costs related to our convertible senior notes issued in November 2020, for the years ended December 31, 2024, and 2023.

Other income (expense), net

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Other income (expense), net	$ (42,605)	$ 53,174	$ (95,779)	(180)%

Other income (expense), net was a $42.6 million expense for the year ended December 31, 2024, primarily attributable to $44.4 million of net unrealized and realized losses recorded for our marketable equity security investment in Lunit, Inc. during the period. Other income (expense), net was a $53.2 million income for the year ended December 31, 2023, primarily due to $79.7 million of unrealized gains recorded for our marketable equity security investment in Lunit, Inc., partially offset by $29.1 million of impairment recorded for our non-marketable equity security investments and other related assets during the period.

Provision for income taxes

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Provision for income taxes	$ 1,284	$ 685	$ 599	87 %

The change in the provision for income taxes between the years ended December 31, 2024 and 2023 was insignificant.

Liquidity and capital resources

We have incurred losses and negative cash flows from operations since our inception, and as of December 31, 2024, we had an accumulated deficit of $2.6 billion. We expect to incur additional operating losses in the near future and our operating expenses will increase as we continue to invest in clinical studies and develop new products, 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, 2024, we had cash, cash equivalents, restricted cash and marketable debt securities of $944.2 million. 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. Additionally, we have investments held in marketable debt securities consisting primarily of United States treasury securities that can be immediately liquid.

Based on our current business plan, we believe our current cash, cash equivalents, restricted cash and marketable debt 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 liabilities, which could impact our working capital balances.

If our available cash, cash equivalents, restricted cash and marketable debt securities and anticipated cash flows from operations are insufficient to satisfy our liquidity requirements 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.

At-The-Market Offering Program

In August 2024, we entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or the Agent, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having aggregate gross proceeds of up to $400.0 million through the Agent, subject to the terms and conditions of the Sales Agreement. During the year ended December 31, 2024, no shares of our common stock were sold under the Sales Agreement.

Convertible Notes Exchange

In February 2025, we entered into privately negotiated exchange agreements with certain holders of our convertible senior notes due 2027. See Note 17, *Subsequent Events*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information related to this transaction. The transaction will be accounted for under FASB ASC Topic 470, *Debt*, and relevant accounting guidance, based on which and due to the nature of the transaction, a gain is currently expected to be recorded for the three months ended March 31, 2025.

Cash flows

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (239,858)	$ (324,975)
Net cash (used in) provided by investing activities	(261,308)	840,250
Net cash (used in) provided by financing activities	(996)	477,375

Operating activities

Cash used in operating activities during the year ended December 31, 2024 was $239.9 million, which resulted from a net loss of $436.4 million and changes in our operating assets and liabilities of $60.9 million, partially offset by non-cash charges of $257.4 million. Non-cash charges primarily consisted of $140.4 million of stock-based compensation, $44.4 million of net unrealized and realized losses on marketable equity security investment in Lunit, inc., $42.4 million of depreciation and amortization, and $31.1 million of operating lease costs, partially offset by $6.8 million of amortization of discount on marketable debt securities. The changes in our operating assets and liabilities was primarily the result of a $36.1 million payment of operating lease liabilities net of receipt of tenant improvement allowance, a $21.4 million increase in accounts receivable, net, a $9.1 million increase in inventory, net, a $7.7 million increase in prepaid expenses and other current assets, net, and a $2.8 million decrease in accounts payable and accrued liabilities; partially offset by a $18.7 million increase in deferred revenue.

Cash used in operating activities during the year ended December 31, 2023 was $325.0 million, which resulted from a net loss of $479.4 million, partially offset by non-cash charges of $100.6 million and changes in our operating assets and liabilities of $53.8 million. Non-cash charges primarily consisted of $90.8 million of stock-based compensation, $42.9 million of depreciation and amortization, $29.7 million of operating lease costs, and $29.1 million of impairment on non-marketable equity security investments and other related assets; partially offset by $79.7 million of unrealized gains on marketable equity security investment in Lunit, inc., and $13.6 million of amortization of discount on marketable debt securities. The changes in our operating assets and liabilities was primarily the result of a legal accrual of $83.4 million in connection with a jury verdict entered in favor of TwinStrand Biosciences, Inc. and the University of Washington in November 2023, a $8.4 million decrease in accounts receivable, net, and a $5.2 million increase in accounts payable and accrued liabilities; partially offset by a $31.5 million payment of operating lease liabilities net of receipt of tenant improvement allowance, a $10.4 million increase in inventory, net due to forecasted higher testing volumes, and a $4.3 million increase in prepaid expenses and other current assets, net.

Investing activities

Cash used in investing activities during the year ended December 31, 2024 was $261.3 million, which resulted primarily from purchases of marketable debt securities of $307.3 million, purchases of property and equipment of $35.1 million, and purchases of non-marketable equity security investments of $7.5 million; partially offset by sales of marketable equity security investment in Lunit, Inc. of $53.6 million and maturities of marketable debt securities of $35.0 million.

Cash provided by investing activities during the year ended December 31, 2023 was $840.3 million, which resulted primarily from maturities of marketable debt securities of $1.5 billion; partially offset by purchases of marketable debt securities of $629.9 million, purchases of property and equipment of $20.5 million, and purchases of non-marketable equity security investments and other related assets of $5.6 million.

Financing activities

Cash used in financing activities during the year ended December 31, 2024 was $1.0 million, which was primarily attributable to employee taxes paid related to settlement of restricted stock units of $15.7 million, partially offset by proceeds from issuances of common stock under our employee stock purchase plan of $11.7 million and proceeds from exercise of stock options of $3.1 million.

Cash provided by financing activities during the year ended December 31, 2023 was $477.4 million, which was primarily attributable to proceeds from equity offerings of $493.1 million, and proceeds from issuances of common stock under our employee stock purchase plan of $10.2 million; partially offset by payment of equity offering costs of $21.1 million, and employee taxes paid related to settlement of restricted stock units of $11.2 million.

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, or 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, as well as from development services and other. Precision oncology testing revenue includes amounts derived from the delivery of our precision oncology tests, including those tests delivered by labs operated by our strategic partners. Development services include companion diagnostic development and regulatory approval, clinical study setup, monitoring and maintenance, testing development and support, GuardantConnect and GuardantINFORM. Other revenue includes amounts derived from licensing our technologies, kit fulfillment, and delivery of our Shield screening tests. We currently receive payments from third-party commercial and governmental payers, certain hospitals and oncology centers and individual patients, as well as biopharmaceutical companies, research institutes, international laboratory partners and distributors.

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. FASB ASC Topic 606, *Revenue from Contracts with Customers*, 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 test to a 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 commercial and governmental payers and patients, as well as known 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 significant 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 cumulative 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 number of distinct 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 biopharmaceutical companies in the development of new drugs. As part of these collaborations, we provide services related to regulatory filings to support companion diagnostic device submissions for our testing panels. Under these collaborations, we generate revenue from achievement of milestones, as well as provision of on-going support. For the companion diagnostic development and regulatory approval 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 these 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 to the transaction price such that it is probable a significant cumulative 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.

We recognize companion diagnostic development and regulatory approval services 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 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 and other.

We also recognize revenue from other development services, in addition to companion diagnostic development and regulatory approval services noted above, such as clinical study setup, monitoring and maintenance, testing development and support, GuardantConnect, and GuardantINFORM. These revenues are generally recognized over time based on an input method to measure progress in the period when the associated services have been performed.

In addition, we license our digital sequencing technologies to our domestic customers and international laboratory partners. For the licensed technology, we are compensated through royalty-based payments, non-refundable upfront payments, guaranteed minimum payments, and/or sample milestone payments. Depending on the nature of the technology licensing arrangements, and considering factors including but not limited to enforceable right to payment and payment terms, and if an asset with alternative use is created, these technology licensing revenues are recognized in the period when royalty-bearing sales occur, when the technology transfer is complete, or over the technology transfer period. Other revenue also includes kit fulfillment, which is recognized when such products are delivered. In addition, other revenue includes amounts derived from delivery of our Shield screening tests.

Contracts with multiple performance obligations

Contracts with biopharmaceutical customers and international laboratory partners may include multiple distinct performance obligations, such as provision of precision oncology testing, the above-mentioned development services, and digital sequencing technology licensing, among others. We evaluate the terms and conditions included within our contracts with biopharmaceutical customers and international laboratory partners 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 evaluate 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 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, 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; or by using the residual approach if standalone selling price is not observable, by reference to the total transaction price less the sum of the observable standalone selling prices of other performance obligations promised in the contract.

Stock-based compensation

We measure the grant date fair value of our service-based and performance-based restricted stock units issued to employees and non-employees based on the closing market price of the common stock on the date of grant. For restricted stock units with only service-based vesting conditions, compensation expense is recognized on a straight-line basis over the requisite service period. Compensation expense for restricted stock units with performance metrics, or PSUs, is calculated based upon expected achievement of the metrics specified in the grant, and is recognized using an accelerated attribution model over the requisite service period for each separately vesting portion of the award. No stock-based compensation expense is recorded for PSUs, unless it is determined to be probable that the related performance metrics will be met. In addition, a cumulative adjustment will be recorded in the period when the probability of achieving the related performance metrics is adjusted. Any PSUs that remain unvested at the end of the performance period will be forfeited. Forfeitures are accounted for as they occur.

We measure stock-based compensation expense for stock options granted to our employees, directors, and non-employees on the date of grant based on the fair value of the awards and recognize the corresponding compensation expense of those awards 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.

We estimate the fair value of our stock options 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 our common stock, which is traded on the Nasdaq Global Select Market.

Expected Term

The expected term represents the period that the stock 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 we have concluded that our 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 our common stock on the Nasdaq Global Select Market on October 4, 2018 in connection with our initial public offering, 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.

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

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

Black-Scholes Assumptions

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

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	5.50 – 6.09	5.50 – 6.10	5.50 – 6.10
Expected volatility	67.4% – 69.4%	69.3% – 70.5%	63.3% – 67.6%
Risk-free interest rate	3.8% – 4.5%	3.4% – 4.5%	1.9% – 4.4%
Expected dividend yield	—%	—%	—%

We will continue to use judgment in evaluating the assumptions related to our stock-based compensation on a prospective basis, including probabilities of meeting performance metrics for our PSUs. 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.

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, cash equivalents, restricted cash, marketable debt securities and our indebtedness. As of December 31, 2024, we had cash, cash equivalents, restricted cash and marketable debt securities of $944.2 million held primarily in cash deposits, money market funds and U.S. government debt securities. 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, 2024, a hypothetical 100 basis point increase or decrease in interest rates would have resulted in immaterial decline or increase of the fair value of our investments. 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, 2024, 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, 2024, 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.

Index to Consolidated Financial Statements

As of December 31, 2024 and 2023, and

For the Years Ended December 31, 2024, 2023 and 2022

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. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

We have also 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, 2024, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 20, 2025, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates 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 financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Precision Oncology Testing Revenue – Estimated Transaction Price for Clinical Customers — Refer to Note 2 to the consolidated financial statements

Critical Audit Matter Description

The Company recognizes revenue from the sale of precision oncology tests for clinical customers 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. Except for 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 estimated transaction price under the portfolio approach represents consideration the Company expects to receive 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.

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. 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.

We identified management's estimation of the transaction price for precision oncology tests for clinical customers as a critical audit matter due to the significant judgments required by management to estimate payer reimbursements. This required a high degree of auditor judgment and an increased extent of effort, including the involvement of more experienced engagement team members, when performing audit procedures to evaluate the estimated transaction prices for precision oncology tests.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to estimated transaction prices for precision oncology tests for clinical customers, included the following, among others:

- We understood and tested the design, implementation, and operating effectiveness of controls over management's determination of the assumptions used and the related review and approval of the estimated transaction prices.
- We developed an independent expectation of the estimated transaction prices for precision oncology tests for clinical customers in developing an independent expectation of revenue and comparing the recorded amount to our expectation.
- We tested the assumptions used in our independent expectation of the estimated transaction prices for precision oncology tests for clinical customer by:
    - Testing the historical cash receipts from payers used in the estimate of transaction prices, by making selections and agreeing the selected information to source documents.
    - Testing the completeness and accuracy of the precision oncology tests for clinical customers reported to physicians used in our independent expectation, by making selections and agreeing the selected information to source documents.
- We tested management's ability to estimate transaction prices accurately by comparing recorded revenue to cash receipts received through December 2024.
- We evaluated trends in estimated transaction prices and revenue compared to previous periods to identify evidence that is inconsistent with management's assumptions regarding estimated transaction prices.

/s/ Deloitte & Touche LLP

San Jose, California

February 20, 2025

We have served as the Company's auditor since 2023.

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 consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows of Guardant Health, Inc. (the Company) for the year ended December 31, 2022, 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 results of its operations and its cash flows for the year ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

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.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2015 to 2023.

San Mateo, California
February 23, 2023

except for Note 15, as to which the date is

February 20, 2025

Guardant Health, Inc.

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

	As of December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 525,540	$ 1,133,537
Short-term marketable debt securities	314,438	35,097
Accounts receivable, net	110,253	88,783
Inventory, net	71,083	61,948
Prepaid expenses and other current assets, net	33,800	27,741
Total current assets	1,055,114	1,347,106
Restricted cash	104,215	150
Property and equipment, net	136,813	145,096
Right-of-use assets, net	142,265	157,616
Intangible assets, net	6,760	8,979
Goodwill	3,290	3,290
Other assets, net	37,152	124,184
Total Assets	$ 1,485,609	$ 1,786,421
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 38,551	$ 51,741
Accrued compensation	83,219	72,736
Accrued expenses	68,345	63,475
Deferred revenue	35,468	17,965
Total current liabilities	225,583	205,917
Convertible senior notes, net	1,142,547	1,139,966
Long-term operating lease liabilities	164,292	185,848
Other long-term liabilities	92,834	96,006
Total Liabilities	1,625,256	1,627,737
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2024 and 2023	—	—
Common stock, par value of $0.00001 per share; 350,000,000 shares authorized as of December 31, 2024 and 2023; 123,994,006 and 121,629,861 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1	1
Additional paid-in capital	2,443,788	2,304,220
Accumulated other comprehensive loss	(5,201)	(3,675)
Accumulated deficit	(2,578,235)	(2,141,862)
Total Stockholders' Equity (Deficit)	(139,647)	158,684
Total Liabilities and Stockholders' Equity (Deficit)	$ 1,485,609	$ 1,786,421

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,		
	2024	**2023**	**2022**
Revenue:			
Precision oncology testing	$ 687,936	$ 514,249	$ 392,049
Development services and other	51,080	49,699	57,489
Total revenue	739,016	563,948	449,538
Costs and operating expenses:			
Cost of precision oncology testing	260,581	205,528	148,199
Cost of development services and other	29,218	21,524	8,126
Research and development expense	347,753	367,194	373,807
Sales and marketing expense	364,935	295,227	299,828
General and administrative expense	180,123	155,800	163,956
Other operating expense	—	83,400	—
Total costs and operating expenses	1,182,610	1,128,673	993,916
Loss from operations	(443,594)	(564,725)	(544,378)
Interest income	53,691	35,365	6,069
Interest expense	(2,581)	(2,578)	(2,577)
Other income (expense), net	(42,605)	53,174	(12,778)
Fair value adjustments of noncontrolling interest liability	—	—	(99,785)
Loss before provision for income taxes	(435,089)	(478,764)	(653,449)
Provision for income taxes	1,284	685	1,139
Net loss	$ (436,373)	$ (479,449)	$ (654,588)
Net loss per share, basic and diluted	$ (3.56)	$ (4.28)	$ (6.41)
Weighted-average shares used in computing net loss per share, basic and diluted	122,745	111,988	102,178

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,		
	2024	2023	2022
Net loss	$ (436,373)	$ (479,449)	$ (654,588)
Other comprehensive income (loss), net of tax impact:			
Unrealized gain (loss) on available-for-sale securities	244	16,758	(13,158)
Foreign currency translation adjustments	(1,770)	(911)	(1,600)
Other comprehensive (loss) income	(1,526)	15,847	(14,758)
Comprehensive loss	$ (437,899)	$ (463,602)	$ (669,346)

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

Guardant Health, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance as of January 1, 2022	101,767,446	$ 1	$ 1,657,593	$ (4,764)	$ (1,007,825)	$ 645,005
Issuance of common stock upon exercise of stock options	228,311	—	2,625	—	—	2,625
Vesting of restricted stock units	315,673	—	—	—	—	—
Vesting of common stock exercised early	—	—	8	—	—	8
Issuance of common stock under employee stock purchase plan	307,953	—	9,316	—	—	9,316
Employee taxes paid related to settlement of restricted stock units	—	—	(7,878)	—	—	(7,878)
Stock-based compensation	—	—	94,685	—	—	94,685
Tender offer issued in connection with the Joint Venture Acquisition and acquisition related costs	—	—	(14,235)	—	—	(14,235)
Other comprehensive loss	—	—	—	(14,758)	—	(14,758)
Net loss	—	—	—	—	(654,588)	(654,588)
Balance as of December 31, 2022	102,619,383	1	1,742,114	(19,522)	(1,662,413)	60,180
Issuance of common stock upon follow-on offering, net of offering costs of $21,131	14,375,000	—	381,369	—	—	381,369
Issuance of common stock upon registered direct offering	3,387,446	—	90,616	—	—	90,616
Issuance of common stock upon exercise of stock options	51,124	—	405	—	—	405
Vesting of restricted stock units	732,038	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	464,870	—	10,154	—	—	10,154
Employee taxes paid related to settlement of restricted stock units	—	—	(11,197)	—	—	(11,197)
Stock-based compensation	—	—	90,759	—	—	90,759
Other comprehensive income	—	—	—	15,847	—	15,847
Net loss	—	—	—	—	(479,449)	(479,449)
Balance as of December 31, 2023	121,629,861	1	2,304,220	(3,675)	(2,141,862)	158,684
Issuance of common stock upon exercise of stock options	609,495	—	3,119	—	—	3,119
Vesting of restricted stock units	1,176,892	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	577,758	—	11,719	—	—	11,719
Employee taxes paid related to settlement of restricted stock units	—	—	(15,681)	—	—	(15,681)
Stock-based compensation	—	—	140,411	—	—	140,411
Other comprehensive loss	—	—	—	(1,526)	—	(1,526)
Net loss	—	—	—	—	(436,373)	(436,373)
Balance as of December 31, 2024	123,994,006	$ 1	$ 2,443,788	$ (5,201)	$ (2,578,235)	$ (139,647)

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,		
	2024	2023	2022
OPERATING ACTIVITIES:			
Net loss	$ (436,373)	$ (479,449)	$ (654,588)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	42,387	42,881	35,962
Operating lease costs	31,133	29,699	28,585
Contingent consideration	1,010	110	4,305
Stock-based compensation	140,411	90,759	94,685
Amortization of debt issuance costs	2,581	2,575	2,569
Amortization of (discount) premium on marketable debt securities	(6,774)	(13,552)	4,595
Unrealized and realized losses (gains) on marketable equity securities	44,401	(79,710)	7,793
Impairment of non-marketable equity securities and other related assets	—	29,054	5,261
Fair value adjustments of noncontrolling interest liability	—	—	99,785
Other	2,228	(1,182)	21
Changes in operating assets and liabilities:			
Accounts receivable, net	(21,389)	8,378	375
Inventory, net	(9,135)	(10,350)	(20,926)
Prepaid expenses and other current assets, net	(7,691)	(4,332)	20,444
Other assets, net	(2,375)	1,298	11,698
Accounts payable and accrued liabilities	(2,820)	5,191	60,328
Other legal liabilities	—	83,400	—
Operating lease liabilities	(36,115)	(31,478)	(20,228)
Deferred revenue	18,663	1,733	9,873
Net cash used in operating activities	(239,858)	(324,975)	(309,463)
INVESTING ACTIVITIES:			
Purchases of marketable debt securities	(307,323)	(629,902)	(303,757)
Maturities of marketable debt securities	35,000	1,494,700	555,000
Sales of marketable equity securities and other related assets	53,600	1,531	—
Purchases of non-marketable equity securities and other related assets	(7,500)	(5,593)	(23,966)
Purchases of property and equipment	(35,085)	(20,486)	(77,461)
Net cash (used in) provided by investing activities	(261,308)	840,250	149,816
FINANCING ACTIVITIES:			
Proceeds from issuance of common stock under employee stock purchase plan	11,719	10,154	9,316
Proceeds from issuance of common stock upon exercise of stock options	3,119	405	2,625
Employee taxes paid related to settlement of restricted stock units	(15,681)	(11,197)	(7,878)
Proceeds from equity offerings	—	493,116	—
Payment of equity offering costs	—	(21,131)	—
Joint Venture Acquisition	—	—	(177,785)
Tender offer issued in connection with the Joint Venture Acquisition and acquisition related costs	—	—	(14,235)
Other	(153)	6,028	(1,136)
Net cash (used in) provided by financing activities	(996)	477,375	(189,093)

	Year Ended December 31,		
	2024	2023	2022
Net effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(1,770)	(911)	(1,600)
Net (decrease) increase in cash, cash equivalents and restricted cash	(503,932)	991,739	(350,340)
Cash, cash equivalents and restricted cash – Beginning of period	1,133,687	141,948	492,288
Cash, cash equivalents and restricted cash – End of period	$ 629,755	$ 1,133,687	$ 141,948
Supplemental Disclosures of Cash Flow Information:			
Cash paid for income taxes	$ 1,007	$ 1,969	$ 1,331
Supplemental Disclosures of Noncash Investing and Financing Activities:			
Operating lease liabilities arising from obtaining right-of-use assets	$ 7,899	$ 5,015	$ 4,073
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 3,809	$ 5,279	$ 8,291
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 525,540	$ 1,133,537	$ 141,647
Restricted cash – included in restricted cash	104,215	150	—
Restricted cash – included in other assets, net	—	—	301
Total cash, cash equivalents and restricted cash	$ 629,755	$ 1,133,687	$ 141,948

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., or the Company, is a leading precision oncology company focused on guarding wellness and giving every person more time free from cancer. The Company is transforming patient care by providing critical insights into what drives disease through its advanced blood and tissue tests, and real-world data. The Company's tests help improve outcomes across all stages of care, including screening to find cancer early, monitoring for recurrence in early-stage cancer, and helping doctors select the best treatment for patients with advanced cancer. For patients with advanced stage cancer, the Company has commercially launched Guardant360 LDT and Guardant360 CDx, the first comprehensive liquid biopsy test approved by the U.S. Food and Drug Administration, or the FDA, to provide tumor mutation profiling with solid tumors and to be used as a companion diagnostic in connection with non-small cell lung cancer, or NSCLC, and breast cancer. The Company has also launched the Guardant360 TissueNext tissue test for advanced-stage cancer, Guardant Reveal blood test to detect residual and recurring disease in early-stage colorectal, breast and lung cancer patients, and Guardant360 Response blood test to predict patient response to immunotherapy or targeted therapy eight weeks earlier than current standard-of-care imaging.

The Company also collaborates with biopharmaceutical companies in clinical studies by providing the above-mentioned tests, as well as the GuardantOMNI blood test for advanced-stage cancer, and the GuardantINFINITY blood test, a next-generation Smart Liquid Biopsy that provides new, multi-dimensional insights into the complexities of tumor molecular profiles and immune response to advance cancer research and therapy development. Using data collected from its tests, the Company has also developed its GuardantINFORM platform to help biopharmaceutical companies accelerate precision oncology drug development through the use of this in-silico research platform to unlock further insights into tumor evolution and treatment resistance across various biomarker-driven cancers.

For early cancer detection, in May 2022, the Company launched the Shield LDT test to address the needs of individuals eligible for colorectal cancer screening. From a simple blood draw, Shield uses a novel multimodal approach to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors. In December 2022, the Company announced that the ECLIPSE study, a registrational study evaluating the performance of its Shield blood test for detecting colorectal cancer in average-risk adults, met co-primary endpoints. In addition, in March 2023, the Company submitted a premarket approval application, or PMA, for its Shield blood test to the FDA. In July 2024, the Company received FDA approval of its Shield blood test for colorectal cancer screening in adults age 45 and older who are at average risk for the disease, and in August 2024, the Company's Shield blood test became commercially available in the U.S. as the first blood test approved by the FDA for primary colorectal cancer screening, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines. Shield is also the first blood test for colorectal cancer screening that meets coverage requirements by Medicare.

The Company was incorporated in Delaware in December 2011 and is headquartered in Palo Alto, California.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The Company’s consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and in conjunction with the rules and regulations of the Securities and Exchange Commission, or the SEC. The accompanying consolidated financial statements include the accounts of Guardant Health, Inc., its consolidated Joint Venture (see Note 3, *Joint Venture*), and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company adjusted the accompanying consolidated balance sheet as of December 31, 2023 to separately present accounts payable and accrued expenses, inclusive of accrued compensation. In addition, certain other reclassifications of prior period amounts were made to conform with the current period presentation. The Company determined the adjustment is immaterial based on consideration of quantitative and qualitative factors.

The Company believes that its existing cash, cash equivalents, and marketable debt securities as of December 31, 2024 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, goodwill and identifiable intangible assets, stock-based compensation, incremental borrowing rate for operating leases, contingencies, certain inputs into the provision for income taxes, including related reserves, valuation of non-marketable securities, 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.

Segment Information

The Company operates as one operating and reportable segment. The Company's chief operating decision makers are its Co-Chief Executive Officers, who review financial information presented on a consolidated basis for the purposes of making operating decisions, assessing financial performance and allocating resources.

Cash, 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.

As of December 31, 2024, the Company had restricted cash balance of $104.2 million, of which $103.6 million was related to cash held as collateral under surety bond requirements related to the intellectual property dispute with TwinStrand Biosciences, Inc. and the University of Washington, as described in Note 9 *Commitments and Contingencies* - Legal Proceedings to the Company's consolidated financial statements. As of December 31, 2023, the Company's restricted cash balance was immaterial.

Marketable Debt Securities

Marketable debt securities consist primarily of high-grade U.S. government and agency securities and corporate bonds. Marketable debt securities with original maturities at the time of purchase between three and twelve months from balance sheet dates are classified as short-term marketable debt securities and those with maturities over twelve months from balance sheet dates are classified as long-term marketable debt securities. The Company classifies all marketable debt 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 (deficit). 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 debt securities for impairment. When the fair value of a marketable debt 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 (deficit).

Non-Marketable Securities

The Company acquires certain equity investments in private companies to promote business and strategic objectives. The Company's investments in non-marketable equity securities do not give the Company the ability to control or exercise significant influence over the investees. One of the investees is concluded to be a variable interest entity, or

VIE, but the Company is deemed not to be the primary beneficiary as the Company does not have the power to direct the activities that most significantly impact the VIE's economic performance. The Company's non-marketable equity and other related investments totaled $16.1 million and $8.6 million as of December 31, 2024, and 2023, respectively, and are included in other assets, net on the accompanying consolidated balance sheets.

Non-marketable securities are recorded at cost, subject to periodic impairment reviews and adjustments for observable price changes from orderly transactions. The Company's evaluation of impairment of such non-marketable securities is based on adverse changes in market conditions and the regulatory or economic environment; qualitative and quantitative analysis of the operating performance and financial condition of the investee; changes in operating structure or management of the investee; and additional funding requirements of the investee. As a result of the evaluation, the Company recorded an impairment of $22.1 million for the year ended December 31, 2023 for one of its non-marketable equity security investments, included in other income (expense), net on the accompanying consolidated statements of operations. In addition, in connection with the investment in non-marketable securities purchased by the Company, the Company acquired rights to purchase the investee at a pre-determined price subject to additional adjustments based on the performance of the investee, on or before December 31, 2022. In September 2022, the Company decided not to exercise such rights to purchase the investee and recorded an impairment of $5.3 million for the year ended December 31, 2022, included in other income (expense), net on the accompanying consolidated statements of operations.

Pursuant to another investment in non-marketable securities purchased by the Company, the Company acquired rights to purchase the investee at a pre-determined price subject to additional adjustments based on the performance of the Company, on or before October 1, 2023, and acquired rights to obtain the exclusive license of the investee's certain technologies. In June 2023, the Company decided not to exercise such rights and recorded an impairment of $7.0 million for the year ended December 31, 2023, included in other income (expense), net on the accompanying consolidated statements of operations.

No other impairment or downward adjustments to the carrying value of the Company's non-marketable securities have been otherwise recorded.

Concentration of Risk

The Company is subject to credit risk from its portfolio of cash equivalents, restricted cash and investments in marketable debt 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 and other, primarily with biopharmaceutical companies and international laboratory partners, all of which have 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 net of allowance for credit losses, if any.

A significant customer is any biopharmaceutical customer, clinical testing payer, or international laboratory partner 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, Net	
	Year Ended December 31,			As of December 31,	
	2024	2023	2022	2024	2023
Customer A	*	*	*	14 %	12 %
Customer B	29 %	31 %	30 %	12 %	12 %
Customer C	*	*	*	11 %	10 %

* less than 10%

Accounts Receivable, Net

Accounts receivable represent valid claims against commercial and governmental payers, biopharmaceutical companies, research institutes, international laboratory partners and distributors, including unbilled receivables, and royalty payments due from third parties for licensing the Company's technologies. Unbilled receivables include balances due from biopharmaceutical customers related to development services and other revenues that are recognized upon the achievement of performance-based milestones but prior to the achievement of contractual billing rights. As of December 31, 2024 and 2023, the Company had unbilled receivables of $3.4 million and $4.9 million, respectively.

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. The Company recorded immaterial credit losses related to its accounts receivable for the years ended December 31, 2024, 2023 and 2022.

Inventory, Net

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 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	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

Goodwill and Intangible Assets, net

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill is not amortized but is tested for impairment at least annually during the fourth fiscal quarter, or if circumstances indicate its 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 is tested for impairment at the enterprise level. As of December 31, 2024, 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. Amortization is recorded on a straight-line basis over the intangible asset's useful life, which is approximately 6—12 years.

Impairment for Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, finite-lived intangible assets, and right-of-use assets, 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. The Company had immaterial amount of impairment for long-lived assets for the years ended December 31, 2024, 2023 and 2022.

Leases

The Company determines if an arrangement contains a lease at inception. Operating lease right-of-use, or 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

Convertible senior notes are accounted for as a liability and measured at their amortized cost. Transaction costs related to the issuance of the notes are netted with the liability and are amortized to interest expense over the term of the notes, using an effective interest rate method.

Revenue Recognition

The Company derives revenue from the provision of precision oncology testing services, as well as from development services and other. Precision oncology testing revenue includes amounts derived from the delivery of the Company's precision oncology tests, including those tests delivered by labs operated by our strategic partners. Development services include companion diagnostic development and regulatory approval, clinical study setup, monitoring and maintenance, testing development and support, GuardantConnect and GuardantINFORM. Other revenue includes amounts derived from licensing the Company's technologies, kit fulfillment, and delivery of the Company's Shield screening tests. 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, research institutes, international laboratory partners and distributors.

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. FASB ASC Topic 606, *Revenue from Contracts with Customers*, 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 test to a 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 cumulative 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. The Company identifies its promise to transfer a series of distinct 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 biopharmaceutical 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 testing panels. Under these collaborations, the Company generates revenue from achievement of milestones, as well as provision of on-going support. For the companion diagnostic development and regulatory approval 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 these 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 to the contract price such that it is probable a significant cumulative 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 companion diagnostic development and regulatory approval services revenue 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. 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 recognizes revenue from other development services, in addition to companion diagnostic development and regulatory approval services noted above, such as clinical study setup, monitoring and maintenance, testing development and support, GuardantConnect and GuardantINFORM. These revenues are generally recognized over time based on an input method to measure progress in the period when the associated services have been performed.

In addition, the Company licenses its digital sequencing technologies to its domestic customers and international laboratory partners. For the licensed technology, the Company is compensated through royalty-based payments, non-refundable upfront payments, guaranteed minimum payments, and/or sample milestone payments. Depending on the nature of the technology licensing arrangements, and considering factors including but not limited to enforceable right to payment and payment terms, and if an asset with alternative use is created, these revenues are recognized in the period when royalty-bearing sales occur, when the technology transfer is complete or over the technology transfer period. Other revenue also includes kit fulfillment, which is recognized when such products are delivered. In addition, other revenue includes amounts derived from delivery of the Company's Shield screening tests.

For the years ended December 31, 2024, 2023 and 2022, the Company recorded $35.3 million, $14.2 million and $8.8 million, respectively, as revenue related to performance obligations satisfied in prior periods.

Contracts with multiple performance obligations

Contracts with biopharmaceutical customers and international laboratory partners may include multiple distinct performance obligations, such as provision of precision oncology testing, the above-mentioned development services, and digital sequencing technology licensing, among others. The Company evaluates the terms and conditions included within its contracts with biopharmaceutical customers and international laboratory partners 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; or by using the residual approach if standalone selling price is not observable, by reference to the total transaction price less the sum of the observable standalone selling prices of other performance obligations promised in the contract.

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, 2024 and 2023, the Company's deferred revenue balance was $41.6 million and $22.9 million, respectively, of which $6.1 million and $5.0 million was considered long-term and recorded within other long-term liabilities on the accompanying consolidated balance sheets. Revenue recognized in the year ended December 31, 2024 that was included in the deferred revenue balance as of December 31, 2023 was $14.5 million, and revenue recognized in the year ended December 31, 2023 that was included in the deferred revenue balance as of December 31, 2022 was $13.9 million, respectively.

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 1-2 years.

Costs of Precision Oncology Testing

Cost of precision oncology testing generally consists of cost of materials, cost of labor, including bonus, benefit and stock-based compensation, equipment and infrastructure expenses associated with processing test samples (including sample accessioning, library preparation, sequencing, and quality control analyses), freight, curation of test results for physicians, phlebotomy, and license fees due to third parties. Infrastructure expenses include depreciation of laboratory equipment, lease 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.

Cost of Development Services and Other

Cost of development services and other primarily includes costs incurred for the performance of development services requested by the Company’s biopharmaceutical customers, and costs associated with the Company's partnership agreements and delivery of the Company's Shield screening tests. 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 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 facility occupancy and information technology costs, contract services, other outside costs and costs to develop the Company's 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 technology capabilities are recorded as research and development expenses unless they meet the criteria to be capitalized as internal-use software costs.

Advertising

The Company expenses advertising costs as incurred. For the years ended December 31, 2024, 2023 and 2022, the Company's advertising costs were not material to the consolidated financial statements.

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.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options granted under the 2012 Stock Plan (as amended and restated), or the 2012 Plan, the 2018 Incentive Award Plan, or the 2018 Plan, the former Joint Venture's 2020 Equity Incentive Plan (see Note 11, *Stock-Based Compensation*), and the 2023 Employment Inducement Incentive Award Plan, or the 2023 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 Company measures the grant date fair value of its service-based and performance-based restricted stock units issued to employees and non-employees based on the closing market price of the common stock on the date of grant. For restricted stock units with only service-based vesting conditions, compensation 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, or PSUs, is calculated based upon expected achievement of the metrics specified in the grant, and is recognized in the Company's consolidated statement of operations using an accelerated attribution model over the requisite service period for each separately vesting portion of the award. No stock-based compensation expense is recorded for PSUs, unless it is determined to be probable that the related performance metrics will be met. In addition, a cumulative adjustment will be recorded in the period when the probability of achieving the related performance metrics is adjusted. Any PSUs that remain unvested at the end of the performance period will be forfeited. Forfeitures are accounted for as they occur.

For market-based restricted stock units, or MSUs, the Company derived the grant date fair value and requisite service period using the Monte Carlo simulation model and the related compensation expense was recognized over the derived service period using an accelerated attribution model commencing on the grant date. Stock-based compensation expense was recorded regardless of whether the market conditions were achieved or not. The MSUs were fully expensed as of June 30, 2022.

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

The Company calculates basic net loss per share by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period. The diluted net loss per share 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, stock options, restricted stock units, shares issuable pursuant to the employee stock purchase plan, and contingently issuable shares under the convertible senior notes are considered common stock equivalents but have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive.

Accounting Pronouncements Adopted

In November 2023, the Financial Accounting Standards Board, or FASB, issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires an enhanced disclosure of significant segment expenses on an annual and interim basis. This guidance is effective for the annual reporting periods beginning the year ended December 31, 2024, and will be effective for interim reporting periods beginning January 1, 2025, and should be applied retrospectively. The Company adopted this pronouncement retrospectively in

the fiscal year of 2024 and provided required disclosures in Note 15 *Segment and Geographic Information* to the consolidated financial statements.

New Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which amended existing income tax disclosure guidance, primarily requiring more detailed disclosures on the effective tax rate reconciliation and income taxes paid. This guidance will be effective for annual reporting periods beginning the year ended December 31, 2025, with early adoption permitted and can be applied on either a prospective or retroactive basis. The Company expects to provide required disclosures upon the effective date.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement-Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures*, which requires additional disclosures of specified information about certain costs and expenses in the notes to financial statements. This guidance will be effective for annual reporting periods beginning the year ended December 31, 2027, and for interim reporting periods beginning January 1, 2028, with early adoption permitted and can be applied on either a prospective or retroactive basis. The Company is currently assessing the impact of adopting this accounting pronouncement on its consolidated financial statements.

3. Joint Venture

In May 2018, the Company and an affiliate of SoftBank formed and capitalized Guardant Health AMEA, Inc., the Joint Venture, for the sale, marketing and distribution of the Company’s tests generally outside the Americas and Europe, and to accelerate commercialization of its products in Asia, the Middle East and Africa. Under the terms of the joint venture agreement, each party held an approximately 50% ownership interest in the Joint Venture and two seats on the board of the Joint Venture.

In June 2022, the Company purchased all of the shares held by SoftBank and its affiliates in consideration for a cash payment of the aggregate purchase price of $177.8 million, which resulted in $99.8 million of fair value adjustments to the noncontrolling interest liability for the year ended December 31, 2022. In connection with the Joint Venture Acquisition, the Company also issued a tender offer to purchase the Joint Venture's Class B common stock issued and issuable upon exercise of vested Joint Venture's stock options held by the Joint Venture's employees (see Note 11, *Stock-Based Compensation*).

Prior to the completion of the Joint Venture Acquisition, the Joint Venture was deemed to be a VIE, and the Company had been identified as the VIE’s primary beneficiary. As the primary beneficiary, the Company had consolidated the financial position, results of operations and cash flows of the Joint Venture in its financial statements and all intercompany balances had been eliminated in consolidation. Upon completion of the Joint Venture Acquisition and the tender offer, Guardant Health AMEA, Inc. became the Company's wholly owned subsidiary.

4. Consolidated Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consist of the following:

	As of December 31,	
	2024	2023
	(in thousands)	
Machinery and equipment	$ 124,567	$ 118,117
Leasehold improvements	103,569	102,298
Computer hardware	36,497	34,417
Construction in progress	28,136	7,508
Furniture and fixtures	7,874	7,999
Computer software	1,695	2,065
Property and equipment, gross	302,338	272,404
Less: accumulated depreciation	(165,525)	(127,308)
Property and equipment, net	$ 136,813	$ 145,096

Depreciation expense related to property and equipment was $40.1 million, $40.0 million and $33.4 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2024	2023
	(in thousands)	
Operating lease liabilities	$ 29,213	$ 27,950
Other	39,132	35,525
Total accrued expenses	$ 68,345	$ 63,475

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, and accounts payable and accrued liabilities. Cash equivalents and marketable securities are stated at fair value. Prepaid expenses and other current assets, net, and accounts payable and accrued liabilities 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, 2024			
	Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
Financial Assets:				
Money market funds	$ 57,151	$ 57,151	$ —	$ —
Income deposit funds	103,581	—	103,581	—
U.S. government debt securities	429,294	—	429,294	—
Total cash equivalents and restricted cash	590,026	57,151	532,875	—
U.S. government debt securities	314,438	—	314,438	—
Total short-term marketable debt securities	314,438	—	314,438	—
Total	$ 904,464	$ 57,151	$ 847,313	$ —
Financial Liabilities:				
Contingent consideration	$ 6,050	$ —	$ —	$ 6,050
Total	$ 6,050	$ —	$ —	$ 6,050

	December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
Financial Assets:				
Money market funds	$ 1,032,500	$ 1,032,500	$ —	$ —
Total cash equivalents	1,032,500	1,032,500	—	—
U.S. government debt securities	35,097	—	35,097	—
Total short-term marketable debt securities	35,097	—	35,097	—
Long-term marketable equity securities	98,002	98,002	—	—
Total	$ 1,165,599	$ 1,130,502	$ 35,097	$ —
Financial Liabilities:				
Contingent consideration	$ 6,540	$ —	$ —	$ 6,540
Total	$ 6,540	$ —	$ —	$ 6,540

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Income deposit funds and U.S. government debt securities 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.

In July 2022, one of the Company's equity investees, Lunit Inc., or Lunit, completed its initial public offering, or IPO, subsequent to which, the Company started to account for the investment in Lunit at fair value on a recurring basis, and classified the investment as marketable equity securities within Level 1 of the fair value hierarchy as the

investment is valued using the quoted market price. The Company was subject to a 2-year lock-up period from Lunit's IPO date, during which the Company shall not transfer Lunit's shares between accounts, establish or cancel pledges, sell, or withdraw such shares, without approval from the Korea Exchange. In November 2023, Lunit issued bonus shares to its existing shareholders by allocating one new share for each existing share, and the Company was subject to the same lock-up period with the same restrictions for these bonus shares which expired in July 2024. In 2024, the Company sold all of its investment in Lunit. As of December 31, 2023, the balance of the Company's investment in Lunit was $98.0 million, included in other assets, net, on the accompanying consolidated balance sheets. In addition, the Company recorded $79.7 million unrealized gains and $7.8 million unrealized losses for the years ended December 31, 2023 and 2022, on its investment in Lunit, respectively, included in other income (expense), net on the accompanying consolidated statements of operations.

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

Acquisition-related contingent consideration is measured at fair value on a quarterly basis and changes in estimated contingent consideration to be paid are included in general and administrative expense 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, 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, 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, 2024 and 2023, the Company's acquisition-related contingent consideration liability was $6.1 million and $6.5 million, respectively, of which $2.1 million and $5.0 million was considered long-term and recorded within other long-term liabilities on the accompanying consolidated balance sheets.

Prior to the completion of the Joint Venture Acquisition in June 2022, the fair value of the noncontrolling interest liability was considered to be a Level 3 measurement and was determined based on an annual internal rate of return of 20% on the initial amount of $41.0 million invested by SoftBank in May 2018, to the date of Company's exercising the call right in November 2021. The noncontrolling interest liability was fully paid by June 30, 2022 (see Note 3, *Joint Venture*).

The following tables summarize the activities for the Level 3 financial instruments for the years ended December 31, 2024, 2023 and 2022:

	Contingent Consideration		
	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Fair value — beginning of period	$ 6,540	$ 6,430	$ 3,625
Increase in fair value	1,010	110	4,305
Settlement	(1,500)	—	(1,500)
Fair value — end of period	$ 6,050	$ 6,540	$ 6,430

	Noncontrolling Interest Liability		
	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Fair value — beginning of period	$ —	$ —	$ 78,000
Increase in fair value	—	—	99,785
Settlement	—	—	(177,785)
Fair value — end of period	$ —	$ —	$ —

The Company considers the fair value of the Convertible Notes as of December 31, 2024 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 7, *Debt*, for additional information related to the Convertible Notes.

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

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
	(in thousands)			
Money market funds	$ 57,151	$ —	$ —	$ 57,151
Income deposit funds	103,581	—	—	103,581
U.S. government debt securities	743,500	232	—	743,732
Total	$ 904,232	$ 232	$ —	$ 904,464

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
	(in thousands)			
Money market funds	$ 1,032,500	$ —	$ —	$ 1,032,500
U.S. government debt securities	35,108	—	(11)	35,097
Total	$ 1,067,608	$ —	$ (11)	$ 1,067,597

None of the Company's marketable debt securities had been in a continuous unrealized loss position for more than one year as of December 31, 2024 and 2023, respectively.

There have been no material realized gains or losses on marketable debt securities for the periods presented. In addition, there has been no recognition of credit losses on marketable debt securities for the periods presented.

6. Intangible Assets, Net and Goodwill

The following table presents details of purchased intangible assets as of December 31, 2024 and 2023:

	December 31, 2024			
	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	$ (5,795)	$ 6,091	5.8
Non-compete agreements and other covenant rights	5,100	(4,431)	669	1.1
Acquired technology	1,600	(1,600)	—	0.0
Total intangible assets subject to amortization	18,586	(11,826)	6,760	
Intangible assets not subject to amortization:				
Goodwill	3,290	—	3,290	
Total purchased intangible assets	$ 21,876	$ (11,826)	$ 10,050	

	December 31, 2023			
	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	$ (4,686)	$ 7,200	6.8
Non-compete agreements and other covenant rights	5,100	(3,588)	1,512	1.9
Acquired technology	1,600	(1,333)	267	0.3
Total intangible assets subject to amortization	18,586	(9,607)	8,979	
Intangible assets not subject to amortization:				
Goodwill	3,290	—	3,290	
Total purchased intangible assets	$ 21,876	$ (9,607)	$ 12,269	

Amortization of finite-lived intangible assets was $2.2 million, $2.7 million and $2.5 million, for the years ended December 31, 2024, 2023 and 2022, respectively.

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

Year Ending December 31,	(in thousands)
2025	$ 1,670
2026	1,212
2027	1,107
2028	1,109
2029	765
2030 and thereafter	897
Total	$ 6,760

7. Debt

Convertible Senior Notes

In November 2020, the Company issued $1.15 billion principal amount of its 0% Convertible Senior Notes due 2027, or 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, or the sale price condition;
- during the five consecutive business days immediately after any ten consecutive trading day period, or 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.

Since the 2027 Notes were not convertible as of December 31, 2024, the net carrying amount of the 2027 Notes was classified as a long-term liability.

In February 2025, the Company entered into privately negotiated exchange agreements with certain holders of its 2027 Notes. See Note 17, *Subsequent Events,* for additional information related to this transaction.

The following table sets forth the net carrying amounts of the 2027 Notes as of December 31, 2024 and 2023:

	As of December 31,	
	2024	2023
	(in thousands)	
Principal	$ 1,150,000	$ 1,150,000
Less: debt issuance costs, net of amortization	(7,453)	(10,034)
Net carrying amount	$ 1,142,547	$ 1,139,966

The total estimated fair value of the 2027 Notes was $964.9 million and $809.3 million as of December 31, 2024 and 2023, respectively. 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.

The following table sets forth interest expense recognized and effective interest rate represented related to the 2027 Notes:

	For the Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Amortization of debt issuance costs	$ 2,581	$ 2,575	$ 2,569
Total interest expense recognized	$ 2,581	$ 2,575	$ 2,569
Effective interest rate	0.2 %	0.2 %	0.2 %

Note Hedges

To minimize the impact of potential economic dilution upon conversion of the 2027 Notes, the Company entered into convertible note hedge transactions, or 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.

8. Leases

The Company has entered into various operating lease agreements for office space, data center, lab and warehouse use, with remaining terms ranging from 0.2 to 8.5 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 years ended December 31, 2024, 2023 and 2022, was $31.1 million, $29.7 million and $28.6 million, respectively, which includes both lease and non-lease components (primarily common area maintenance charges and property taxes).

	As of December 31,	
	2024	2023
Weighted-average remaining lease term (in years)	7.5	8.3
Weighted-average discount rate	3.82 %	3.87 %

The following table summarizes the Company's future principal contractual obligations for operating lease commitments as of December 31, 2024:

Year Ending December 31,	(in thousands)
2025	$ 35,709
2026	30,193
2027	26,156
2028	24,300
2029	22,946
2030 and thereafter	80,834
Total operating lease payments	220,138
Less: imputed interest	(26,633)
Total operating lease liabilities	$ 193,505

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

9. Commitments and Contingencies

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, 2024.

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 on the Company 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.

Intellectual Property Disputes

In August 2021, TwinStrand Biosciences, Inc., or TwinStrand Biosciences, and the University of Washington filed a patent infringement suit in the United States District Court for the District of Delaware alleging that the Company infringes U.S. Patent Nos. 10,287,631; 10,689,699; 10,752,951; and 10,760,127. The Company answered the complaint in October 2021, denying TwinStrand Biosciences' allegations and asserted counterclaims of invalidity, unenforceability due to inequitable conduct and infringement of four of the Company's patents. Discovery in the case has concluded. In October 2023, the District Court dismissed with prejudice TwinStrand's infringement claims related to U.S. Patent Nos. 10,689,699 and 10,752,951.

On November 14, 2023, a jury verdict was entered in favor of TwinStrand Biosciences and the University of Washington and against the Company. The jury found that the Company willfully infringed U.S. Patent Nos. 10,287,631 and 10,760,127, and awarded TwinStrand Biosciences and the University of Washington $83.4 million in damages, representing a 6% royalty on past sales. As a result, the Company recorded a liability of $83.4 million in the fourth quarter of 2023, which was reflected as a charge to other operating expense on its consolidated statements of operations, and as a component of other long-term liabilities on its consolidated balance sheets. Post-trial motions were filed on March 4, 2024, where the Company moved to overturn the jury's verdict, seek a new trial, and/or amend the judgment, and TwinStrand Biosciences moved for enhanced damages based on the jury's finding of willful infringement, pre- and post-judgment interest, and a go-forward running royalty. A hearing date has not yet been set on the post-trial motions. The Company strongly disagrees with the jury verdict and will vigorously contest the verdict and judgment through post-trial motions in the District Court, and if needed, through appeal to the U.S. Court of Appeals for the Federal Circuit.

On June 11, 2024, the Company filed a patent infringement suit against Tempus AI, Inc. or Tempus, in the United States District Court for the District of Delaware alleging that Tempus infringes U.S. Patent Nos. 11,149,306; 9,902,992; 10,501,810; 10,793,916; and 11,643,693. The Company is seeking an injunction to stop Tempus' infringement and compensatory damages. The case *Guardant Health, Inc. v. Tempus AI, Inc.*, Case No. 1:24-cv-00687, has been assigned to Judge Richard Andrews and does not yet have a scheduling order. On October 21, 2024, Tempus moved to dismiss the Company's suit alleging that some of the asserted patents were invalid. The Company disagrees and will be responding accordingly.

False Advertising Disputes

In May 2021, the Company also filed a lawsuit against Natera, Inc., or Natera, in the United States District Court for the Northern District of California, wherein the Company alleged that Natera is misleading healthcare providers about the performance of the Company's new oncology test, Guardant Reveal, by suggesting the test is inaccurate and/or insensitive, and inferior to Natera's Signatera assay. The Company is seeking an injunction to prevent Natera from continuing to make false and misleading statements and to require Natera to take corrective actions. Natera asserted counterclaims of false and misleading statements, false advertising, unlawful trade practices and unfair competition. The Company moved to dismiss Natera's counterclaims, and in January 2022, the court granted in part and denied in part the Company's motion to dismiss.

On November 25, 2024, after a three-week trial before Judge Edward M. Chen, the jury unanimously found in favor of the Company on all of its claims against Natera for false advertising and unfair competition. The jury awarded the Company $292.5 million, including $175.5 million in punitive damages. The jury also unanimously rejected all of Natera's counterclaims against the Company. Both parties have filed post-trial briefing, which will be considered by Judge Chen at a hearing scheduled for March 2025.

On January 13, 2025, Tempus sent the Company a letter alleging that the Company made certain false or misleading statements in its advertising related to Guardant360 and Tempus' xF+ assay. The Company strongly disagrees with Tempus' allegations and responded to each allegation. On January 17, 2025, the Company filed a declaratory judgment action against Tempus in the United States District Court for the District of Delaware, seeking to show that Tempus' allegations are without merit.

10. Common Stock

The Company's common stockholders are entitled to dividends if and when declared by the Company's Board of Directors, or the Board of Directors. As of December 31, 2024 and 2023, 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,	
	2024	2023
Shares underlying outstanding stock options	4,631,750	4,012,903
Shares underlying unvested restricted stock units	7,020,251	4,346,785
Shares underlying unvested market-based restricted stock units	—	2,260,764
Shares underlying unvested performance-based restricted stock units	1,290,684	412,490
Shares available for issuance under the 2018 Incentive Award Plan	8,079,498	7,053,406
Shares available for issuance under the 2018 Employee Stock Purchase Plan	2,208,577	1,679,635
Shares available for issuance under the 2023 Employment Inducement Incentive Award Plan	3,916,766	4,949,988
Total	27,147,526	24,715,971

Equity Offering

In May 2023, the Company completed a follow-on underwritten public offering, in which it issued and sold 14,375,000 shares of its common stock at a price of $28.00 per share, and received net proceeds of $381.4 million after deducting underwriting discounts and commissions and other offering costs of $21.1 million. In December 2023, the Company completed a registered direct offering with an investment management firm, in which it issued and sold 3,387,446 shares of its common stock at a price of $26.77 per share, and received net proceeds of $90.6 million.

At-The-Market Offering Program

In August 2024, the Company entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or the Agent, with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having aggregate gross proceeds of up to $400.0 million through the Agent, subject to the terms and conditions of the Sales Agreement. During the year ended December 31, 2024, no shares of the Company's common stock were sold under the Sales Agreement.

11. 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), or the 2012 Plan, and the Company's 2018 Incentive Award Plan, or the 2018 Plan, respectively, under which the Company may grant cash and equity incentive awards to its employees and non-employees. 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. The number of shares of common stock available for issuance under the 2018 Plan may be increased on January 1 of each calendar year beginning in 2019 and ending in 2028 by an amount equal to the least of (i) 3,689,000 shares, (ii) four percent of the shares of common stock outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, assuming the conversion of any shares of preferred stock, but excluding shares issuable upon the exercise or payment of stock options, warrants or other equity securities with respect to which shares have not actually been issued, and (iii) such smaller number of shares as determined by the Company's Board of Directors.

2023 Employment Inducement Incentive Award Plan

In August 2023, the Company's Board of Directors adopted the 2023 Employment Inducement Incentive Award Plan, or the 2023 Plan, under which the Company may exclusively grant awards to its new employees as an inducement material to the employee's entry into employment with the Company. The 2023 Plan was approved by the Company's Board of Directors without stockholder approval in accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules.

Stock Option Activity

A summary of the Company's stock option activity under the 2012 Plan, the 2018 Plan and the 2023 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, 2022	5,231,624	2,624,974	$ 29.17	6.5	$ 193,014
2018 Plan annual increase[1]	3,689,000	—			
Granted	(1,051,466)	1,051,466	44.86		
Granted in connection with the Joint Venture Acquisition	(15,128)	15,128	4.90		
Exercised	—	(228,311)	6.29		
Canceled	56,391	(60,683)	90.84		
Restricted stock units granted	(2,995,533)	—			
Restricted stock units canceled	490,525	—			
Performance-based restricted stock units granted	(26,935)	—			
Performance-based restricted stock units canceled	59,818	—			
Balance as of December 31, 2022	5,438,296	3,402,574	34.34	6.8	39,749
2018 Plan annual increase[1]	3,689,000	—			
Shares authorized under the 2023 Plan	5,000,000	—			
Granted	(1,000,760)	1,000,760	30.80		
Exercised	—	(51,124)	7.93		
Canceled	338,570	(339,307)	58.45		
Restricted stock units granted	(2,436,947)	—			
Restricted stock units canceled	1,049,447	—			
Performance-based restricted stock units granted	(126,041)	—			
Performance-based restricted stock units canceled	51,829	—			
Balance as of December 31, 2023	12,003,394	4,012,903	31.76	6.6	39,115
2018 Plan annual increase[1]	3,689,000	—			
Granted	(1,440,273)	1,440,273	27.07		
Exercised	—	(609,495)	5.12		
Canceled	211,931	(211,931)	49.71		
Restricted stock units granted	(5,004,910)	—			
Restricted stock units canceled	1,164,260	—			
Market-based restricted stock units canceled	2,260,764	—			
Performance-based restricted stock units granted	(913,829)	—			
Performance-based restricted stock units adjusted for performance achievement	(48,234)	—			
Performance-based restricted stock units canceled	74,161	—			
Balance as of December 31, 2024	11,996,264	4,631,750	$ 32.98	7.1	$ 35,980
Vested and Exercisable as of December 31, 2024		2,429,278	$ 33.88	5.3	$ 30,205

(1) Effective as of January 1, 2022, 2023 and 2024, an additional 3,689,000 shares of common stock became available for issuance under the 2018 Plan, as a result of the operation of the 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 $9.4 million, $1.0 million and $12.2 million for the years ended December 31, 2024, 2023 and 2022, respectively.

The weighted-average grant date fair value of options granted was $17.20, $19.90 and $28.61 per share for the years ended December 31, 2024, 2023 and 2022, respectively.

Future stock-based compensation for unvested options as of December 31, 2024 was $40.7 million, which is expected to be recognized over a weighted-average period of 2.1 years.

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, the 2018 Plan and the 2023 Plan, and related information is as follows:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of January 1, 2022	1,498,553	$ 109.72
Granted	2,902,217	45.04
Granted in connection with the Joint Venture Acquisition	93,316	38.24
Vested and released	(315,673)	96.36
Canceled	(490,525)	90.52
Balance as of December 31, 2022	3,687,888	60.70
Granted	2,436,947	26.62
Vested and released	(728,603)	60.07
Canceled	(1,049,447)	56.85
Balance as of December 31, 2023	4,346,785	42.63
Granted	5,004,910	25.94
Vested and released	(1,167,184)	46.36
Canceled	(1,164,260)	42.61
Balance as of December 31, 2024	7,020,251	$ 30.11

Future stock-based compensation for unvested restricted stock units as of December 31, 2024 was $181.5 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Performance-based Restricted Stock Units

Since November 2020, the Compensation Committee of the Board of Directors started to approve, and the Company started to grant performance-based restricted stock units, or PSUs, to its employees and non-employees. The PSUs granted consist of financial and/or operational metrics to be met over a performance period of approximately 0.6 to 4 years and an additional service period requirement of up to 2 years after the performance metrics are met. In addition, granted units might be adjusted when certain performance metrics are met. The PSUs are expected to be expensed over a period of approximately 0.6 to 4.5 years subject to meeting the respective performance metrics and service requirements.

In November 2020 and May 2021, and as part of these PSU programs, the Company granted PSUs consisting of a performance period of 4 years combined with an additional service period requirement of six months should the vesting criteria be met with a grant date fair value of $113.40 per share and $148.19 per share, respectively. Before 2024, no compensation expense for these PSUs had been recorded since the achievement of the performance metrics did not meet the criteria for accrual. In 2024, the performance metrics of these PSUs were considered to be achieved; as such the Company recorded $24.8 million in stock-based compensation expense related to these PSUs, based on 219,161 shares granted with fair values of $113.40 per share and $148.19 per share.

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

	Performance-based Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of January 1, 2022	374,596	$ 116.58
Granted	26,935	37.50
Canceled	(59,818)	114.94
Balance as of December 31, 2022	341,713	110.64
Granted	126,041	32.84
Vested and released	(3,435)	32.86
Canceled	(51,829)	80.91
Balance as of December 31, 2023	412,490	91.25
Granted	913,829	18.73
Vested and released	(9,708)	94.73
Adjusted for performance achievement	48,234	32.84
Canceled	(74,161)	102.14
Balance as of December 31, 2024	1,290,684	$ 37.07

Stock-based compensation recorded for the PSUs for the years ended December 31, 2024, 2023 and 2022 was $33.3 million, $2.6 million and $1.3 million, respectively. Future stock-based compensation for unvested PSUs that are probable to vest as of December 31, 2024 was $16.1 million, which is expected to be recognized over a weighted-average period of 1.9 years.

Market-based Restricted Stock Units

In May 2020, the Board of Directors approved and granted 1,695,574 market-based restricted stock units, or MSUs, under the 2018 Plan to each of the Company's Co-Chief Executive Officers, 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 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 was recognized based on an accelerated attribution method over the estimated derived service period, which was 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 weighted-average grant date fair value of the MSUs was $67.00 per share and the weighted-average derived service period was estimated to be in the range of 0.83 – 2.07 years.

All three tranches of the MSUs were fully expensed as of June 30, 2022. Stock-based compensation for the MSUs for the year ended December 31, 2022 was $16.1 million, which was recorded in general and administrative expenses on the accompanying consolidated statement of operations.

On January 1, 2021, Tranche 1 of the MSUs became vested because it had met both service requirement and market-based performance metrics. No MSUs were granted, vested or canceled during the years ended December 31, 2023, and 2022. As of December 31, 2023, 2,260,764 shares of the MSUs, with a weighted-average grant date fair value of $65.20 per share, were outstanding under the 2018 Plan. In March 2024, the Board of Directors approved to cancel the unvested MSUs and concurrently approved to grant new awards to the Co-Chief Executive Officers, which was accounted for as a modification, however no stock-based compensation expense was reversed as the Company's Co-Chief Executive Officers had fulfilled the service requirement.

AMEA 2020 Equity Incentive Plan

In August 2020, the board of directors of the Joint Venture approved its 2020 Equity Incentive Plan, or the AMEA 2020 Plan, under which the Joint Venture may grant equity incentive awards to its employees and non-employees.

In June 2022, in connection with the Joint Venture Acquisition, the Company issued a tender offer to purchase the Joint Venture's Class B common stock issued and issuable upon exercise of vested Joint Venture's stock options, at a price of $4.44 per share determined pursuant to an independent valuation. In July 2022, the Company settled the tender offer with the 39 grantees for a total amount of $13.7 million. In addition, in connection with the Joint Venture Acquisition, the unvested Joint Venture's stock options were cancelled and such grantees received replacement awards covering a number of shares of the Company's common stock. The replacement awards, valued at $4.1 million, are subject to the same vesting schedule that applied to the unvested Joint Venture's stock option immediately prior to the close of the Joint Venture Acquisition transaction, to be recognized over a weighted-average period of 2.2 years. The Company accounted for this as a modification which resulted in an immaterial incremental stock-based compensation expense. After the settlement of the tender offer in July 2022, the Company cancelled 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 January 1, 2022	340,928	3,652,219	$ 0.58	8.8	$ —
Exercised	—	(2,051,645)	0.58		
Canceled	82,407	(82,407)	0.58		
Canceled in connection with the Joint Venture Acquisition	(423,335)	(1,518,167)	0.58		
Balance as of December 31, 2022	—	—	$ —	0.0	$ —

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,		
	2024	2023	2022
		(in thousands)	
Cost of precision oncology testing	$ 5,315	$ 4,614	$ 5,498
Cost of development services and other	4,050	1,851	—
Research and development expense	50,566	34,682	26,630
Sales and marketing expense	36,479	24,764	25,442
General and administrative expense	44,001	24,848	37,115
Total stock-based compensation expense	$ 140,411	$ 90,759	$ 94,685

Valuation of Stock Options

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

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	5.50 – 6.09	5.50 – 6.10	5.50 – 6.10
Expected volatility	67.4% – 69.4%	69.3% – 70.5%	63.3% – 67.6%
Risk-free interest rate	3.8% – 4.5%	3.4% – 4.5%	1.9% – 4.4%
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, 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

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.

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 its 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.

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

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, or the ESPP. A total of 922,250 shares of common stock were initially reserved for issuance under the ESPP. On the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028, the number of shares of common stock available for issuance under the ESPP may be increased by the least of (i) 1,106,700 shares, (ii) 1% of the shares outstanding (on an as-converted basis) on the last day of the immediately preceding calendar year, assuming the conversion of any shares of preferred stock, but excluding shares issuable upon the exercise or payment of stock options, warrants or other equity securities with respect to which shares have not actually been issued, and (iii) such smaller number of shares as determined by the Company's Board of Directors. Effective as of January 1, 2020, March 2, 2023 and February 23, 2024, an additional 942,614, 1,026,194 and 1,106,700 shares of common stock became available for issuance under the ESPP.

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 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 577,758, 464,870 and 307,953, for the years ended December 31, 2024, 2023 and 2022, respectively. The total compensation expense related to the ESPP was $4.7 million, $5.1 million and $4.6 million, for the years ended December 31, 2024, 2023 and 2022, respectively.

The grant date 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 following assumptions used in the valuation were substantially consistent with the assumptions used to value stock options with the exception of the expected term which was based on the term of each purchase period:

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	0.50	0.50	0.50
Expected volatility	62.7% – 64.2%	51.5% – 76.6%	81.8% – 92.0%
Risk-free interest rate	4.4% – 5.4%	5.2% – 5.4%	1.5% – 4.5%
Expected dividend yield	—%	—%	—%

As of December 31, 2024, the unrecognized stock-based compensation expense related to the ESPP was $2.5 million, which is expected to be recognized over the remaining term of the offering period of 0.4 years.

12. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands, except per share data)		
Net loss, basic and diluted	$ (436,373)	$ (479,449)	$ (654,588)
Net loss per share, basic and diluted	$ (3.56)	$ (4.28)	$ (6.41)
Weighted-average shares used in computing net loss per share, basic and diluted	122,745	111,988	102,178

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share, 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 for the periods presented as they had an anti-dilutive effect:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Stock options	3,990	3,566	2,799
Restricted stock units	5,199	3,474	2,342
MSUs	484	2,261	2,261
PSUs	1,125	389	354
ESPP obligation	209	176	105
Convertible senior notes	8,225	8,225	8,225
Total	19,232	18,091	16,086

13. Income Taxes

The components of (loss) income before provision for income taxes are as follows:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
United States	$ (437,179)	$ (481,405)	$ (659,757)
Foreign	2,090	2,641	6,308
Total	$ (435,089)	$ (478,764)	$ (653,449)

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

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Current:			
State	$ 126	$ 35	$ 127
Foreign	871	1,191	1,248
Total current tax expense	997	1,226	1,375
Deferred:			
Federal	—	—	18
State	—	—	3
Foreign	287	(541)	(257)
Total deferred tax expense	287	(541)	(236)
Total provision for income taxes	$ 1,284	$ 685	$ 1,139

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 and deferred tax liabilities are as follows:

	As of December 31,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating losses carryforwards	$ 422,990	$ 344,314
Capitalized research and development costs	118,340	122,162
Property, equipment and intangible assets	14,429	12,161
Accruals and reserves	42,043	40,172
Research and development credits	71,330	62,533
Stock-based compensation	12,923	18,278
Lease liabilities	49,538	54,564
Other	2,379	73
Total deferred tax assets	733,972	654,257
Deferred tax liabilities:		
Right-of-use asset	(36,426)	(40,213)
Equity security investments	—	(9,044)
Other	(313)	(206)
Total deferred tax liabilities	(36,739)	(49,463)
Less: valuation allowance	(696,473)	(603,747)
Net deferred tax assets	$ 760	$ 1,047

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,		
	2024	2023	2022
	(in thousands)		
Taxes at the statutory federal rate	$ (91,369)	$ (100,553)	$ (137,276)
Change in valuation allowance	92,726	114,707	175,916
Stock-based compensation	12,012	8,077	7,905
Research and development credits	(11,000)	(14,549)	(15,738)
State taxes, net of federal benefits	(15,918)	(19,117)	(28,522)
Prior period true-up	7,962	8,212	—
Other	6,871	3,908	(1,146)
Total provision for income taxes	$ 1,284	$ 685	$ 1,139

The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the years ended December 31, 2024, 2023 and 2022, primarily due to the change in valuation allowance, state income taxes net of federal benefits, withholding taxes, research and development tax credits, and stock-based compensation expenses.

As of December 31, 2024 and 2023, the Company had net operating loss carryforwards of $1.6 billion and $1.4 billion for federal purposes, and $1.4 billion and $1.0 billion 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 purposes, and 2025 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, 2024, the Company had federal and state research and development tax credit carryforwards of $47.9 million, net of reserve of $25.8 million, and $29.7 million, net of reserve of $16.0 million, respectively. As of December 31, 2023, the Company had federal and state research and development tax credit carryforwards of $41.9 million, net of reserve of $22.6 million, and $26.1 million, net of reserve of $14.0 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, or 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, or 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 an increase of $92.7 million, an increase of $114.7 million and an increase of $175.9 million for the years ended December 31, 2024, 2023 and 2022, respectively.

The Company considers the earnings of certain non-U.S. subsidiaries to be indefinitely reinvested outside the United States on the basis of estimates that future domestic cash generation will be sufficient to meet future domestic cash needs and our specific plans for reinvestment of those subsidiary earnings. The Company has not recorded a provision for deferred U.S. federal and state income tax expense and foreign withholding taxes on approximately $3.7 million of undistributed earnings of foreign subsidiaries indefinitely reinvested outside the United States. If the foreign earnings are repatriated, the income tax provision would be adjusted in the period the earnings are determined to be no longer indefinitely reinvested outside the United States.

The Company has made an accounting policy election to treat Global Intangible Low-Taxed Income, or 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 $42.1 million and $36.9 million as of December 31, 2024 and 2023, respectively, which, if recognized, would not affect the effective income tax rate due to the valuation allowance that currently offsets the deferred tax assets.

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

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Unrecognized tax benefits - Beginning of period	$ 36,946	$ 29,634	$ 20,100
Increases related to current year's tax positions	6,414	8,465	9,233
(Decreases) increases related to prior years' tax positions	(1,274)	(1,153)	301
Unrecognized tax benefits - End of period	$ 42,086	$ 36,946	$ 29,634

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, 2024, 2023 and 2022, 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.

14. Employee Benefit Plan

The Company sponsors a defined contribution plan, or 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, 2024, 2023 and 2022, the Company contributed $7.9 million, $7.1 million and $6.7 million, respectively, to match employee contributions as permitted by the plan. The Company pays the administrative costs for the plan.

15. Segment and Geographic Information

The Company operates as one operating segment, and the Company's chief operating decision makers, or the CODMs, are its Co-Chief Executive Officers. The CODMs review segment financial information presented on a consolidated basis, including revenue, gross profit, operating expenses, net loss and adjusted EBITDA, and considers budget-to-actual variances for the purposes of making operating decisions, assessing financial performance and allocating resources. The CODMs do not evaluate operating segment performance using asset information.

The following table presents a summary of the Company's segment information:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Revenue	$ 739,016	$ 563,948	$ 449,538
Less:			
Cost of precision oncology testing [1]	254,551	200,202	141,691
Cost of development services and other [1]	24,886	18,863	8,126
Research and development expense [1]	295,866	329,826	341,650
Sales and marketing expense [1]	328,064	270,132	273,961
General and administrative expense [1]	133,352	129,247	121,023
Other segment items [2]	138,670	95,127	217,675
Net loss	$ (436,373)	$ (479,449)	$ (654,588)

(1) Excludes stock-based compensation and related employer payroll tax payments, contingent consideration, and amortization of intangible assets.

(2) Includes stock-based compensation and related employer payroll tax payments, contingent consideration, amortization of intangible assets, interest income and expense, provision for income taxes, and other income and expense.

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

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
United States	$ 697,162	$ 526,524	$ 420,618
International	41,854	37,424	28,920
Total revenue	$ 739,016	$ 563,948	$ 449,538

As of December 31, 2024 and 2023, 99% and 98%, respectively, of the Company’s long-lived assets and right-of-use assets are located in the United States.

16. Related Party Transactions

As discussed in Note 3, *Joint Venture*, in May 2018, 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. Prior to the completion of the Joint Venture Acquisition in June 2022, the Company had consolidated the financial position, results of operations and cash flows of the Joint Venture in its financial statements and all intercompany balances had been eliminated in consolidation.

17. Subsequent Events

In February 2025, the Company entered into privately negotiated exchange agreements with certain holders of its 2027 Notes, pursuant to which the Company issued $600.0 million aggregate principal amount of 1.25% Convertible Senior Notes due 2031, or the New Notes, in exchange for the retirement of $659.3 million aggregate principal amount of the 2027 Notes, or the Transaction. The Company will settle conversions of the New Notes 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 of the New Notes is 16.0716 shares of common stock per $1,000 principal amount of the New Notes, which represents an initial conversion price of approximately $62.22 per share of common stock, which reflects a conversion premium of approximately 35% to the last reported sale price of the Company’s common stock on February 6, 2025. The conversion rate and conversion price is subject to customary adjustments upon the occurrence of certain events. Following the closing of the Transaction, $490.7 million in aggregate principal amount of the 2027 Notes remain outstanding with terms unchanged.

In connection with the Transaction, in February 2025, the Company repurchased $45.0 million of shares of its common stock from certain participants in the Transaction through a financial intermediary at a price of $46.09 per share, which was the last reported sale price of its common stock on February 6, 2025.

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 co-chief executive officers, or Co-CEOs, 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 Co-CEOs and CFO have concluded that as of December 31, 2024, 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 Co-CEOs 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 Co-CEOs 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, 2024. The effectiveness of our internal control over financial reporting as of December 31, 2024, has been audited by an independent registered public accounting firm, as stated in their report included in this section 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 for the quarter ended December 31, 2024, 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 Co-CEOs 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 the internal control over financial reporting of Guardant Health, Inc. and subsidiaries (the "Company") as of December 31, 2024, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2024, of the Company and our report dated February 20, 2025, expressed an unqualified opinion on those financial statements.

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 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/ Deloitte & Touche LLP

San Jose, California
February 20, 2025

Item 9B. Other Information

During the fiscal quarter ended December 31, 2024, none of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K, except as described in the table below:

Name and Title of Insider	Adoption, Modification or Termination	Applicable Date	Duration of Trading Arrangement	Rule 10b5-1 Trading Arrangement? (Y / N) [1]	Aggregate Number of Securities Subject to the Trading Arrangement
AmirAli Talasaz, Co-Chief Executive Officer and Director[2]	Adoption	12/17/2024	5/1/2025 - 4/30/2026	Y	540,000

(1) Denotes whether the trading plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) when adopted.

(2) The plan was adopted by a trust as to which Mr. Talasaz has voting and dispositive power over the shares held by the trust.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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 2025 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2025 Annual Meeting of Stockholders and is incorporated herein by reference. The 2025 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 2025 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 2025 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 2025 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 2025 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 2012 Stock Plan	S-1	333-227206	10.3	9/6/2018	
10.1(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	
10.2#	2018 Incentive Award Plan	S-8	333-227762	99.2(a)	10/10/2018	
10.2(a)#	Form of Stock Option Agreement under the 2018 Incentive Award Plan	10-Q	001-38683	10.2	8/7/2024	
10.2(b)#	Form of Restricted Stock Award Agreement under the 2018 Incentive Award Plan	S-1/A	333-227206	10.9(b)	9/21/2018	
10.2(c)#	Form of Restricted Stock Unit Award Agreement under the 2018 Incentive Award Plan	10-Q	001-38683	10.3	8/7/2024	
10.2(d)#	Forms of Performance-Based Restricted Stock Unit Award Agreement under the 2018 Incentive Award Plan	10-Q	001-38683	10.4	8/7/2024	
10.3#	2018 Employee Stock Purchase Plan	S-8	333-227762	99.3	10/10/2018	
10.3(a)#	First Amendment to 2018 Employee Stock Purchase Plan	10-K	001-38683	10.4(a)	3/29/2019	
10.4#	Amended and Restated Executive Severance Plan	10-Q	001-38683	10.1	8/7/2024	
10.5#	Non-Employee Director Compensation Program, effective as of June 12, 2020	10-Q	001-38683	10.1	8/6/2020	
10.6	Form of Indemnification Agreement between Guardant Health, Inc. and its directors and officers	S-1/A	333-227206	10.8	9/18/2018	
10.7	Lease, dated November 1, 2014, by and between the Registrant and Metropolitan Life Insurance Company	S-1	333-227206	10.2	9/6/2018	
10.8	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	
10.9	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	
10.10§	Supply Agreement, dated September 15, 2014, by and between the Registrant and Illumina, Inc.	S-1	333-227206	10.7	9/6/2018	
10.11§	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	
10.12§	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	
10.13§	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	
10.14§	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	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.15§	Amendment #5 to Supply Agreement, dated January 1, 2021, by and between the Registrant and Illumina, Inc.	10-K	001-38683	10.19	2/25/2021	
10.16#	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	
10.17#	Form of Waiver Letter Agreement	8-K	001-38683	10.2	5/27/2020	
10.18	Form of Capped Call Confirmation	8-K	001-38683	10.1	11/20/2020	
10.19#	2023 Employment Inducement Award Plan, as approved on August 2, 2023	10-Q	001-38683	10.1	11/6/2023	
10.19(a)#	Form of Stock Option Grant Notice and Restricted Stock Unit Grant Notice under the 2023 Employment Inducement Incentive Award Plan	10-Q	001-38683	10.5	8/7/2024	
10.20#	Form of Letter Agreement	8-K	001-38683	10.1	3/22/2024	
10.21	Open Market Sales Agreement℠ by and between the Registrant and Jefferies LLC dated August 23, 2024	8-K	001-38683	1.1	8/23/2024	
10.22	2018 Incentive Award Plan Annual Cash Incentive Program					*
19.1	Insider Trading Compliance Policy					*
21.1	List of Subsidiaries					*
23.1	Consent of Independent Registered Public Accounting Firm					*
23.2	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 Co-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 Co-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					*
31.3	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 Co-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 Co-Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
32.3	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					**
97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	001-38683	97.1	2/22/2024	
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					*

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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 20, 2025

By: /s/ Helmy Eltoukhy
Name: Helmy Eltoukhy
Title: Co-Chief Executive Officer and Chairman of the Board

By: /s/ AmirAli Talasaz
Name: AmirAli Talasaz
Title: Co-Chief Executive Officer and Director

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Helmy Eltoukhy and AmirAli Talasaz, 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	Co-Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	February 20, 2025
/s/ AmirAli Talasaz AmirAli Talasaz	Co-Chief Executive Officer and Director (Principal Executive Officer)	February 20, 2025
/s/ Michael Bell Michael Bell	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	February 20, 2025
/s/ Ian Clark Ian Clark	Lead Independent Director	February 20, 2025
/s/ Vijaya Gadde Vijaya Gadde	Director	February 20, 2025
/s/ Steve Krognes Steve Krognes	Director	February 20, 2025
/s/ Meghan Joyce Meghan Joyce	Director	February 20, 2025
/s/ Musa Tariq Musa Tariq	Director	February 20, 2025
/s/ Myrtle Potter Myrtle Potter	Director	February 20, 2025
/s/ Manuel Hidalgo Medina Manuel Hidalgo Medina	Director	February 20, 2025
/s/ Roberto Mignone Roberto Mignone	Director	February 20, 2025