UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2022

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 **001-38943**

Personalis, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**27-5411038**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6600 Dumbarton Circle **Fremont, California**	**94555**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 752-1300**

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 $0.0001	**PSNL**	**The Nasdaq Global 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 15(d) of the 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, 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 ☐

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 stock held by non-affiliates of the Registrant, as of June 30, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $156,000,000 based on the closing price reported for such date on the Nasdaq Global Market.

46,736,830 shares of common stock were issued and outstanding as of February 14, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2023 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The Registrant's definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Auditor Firm ID: 34 Auditor Name: Deloitte & Touche LLP Auditor Location: Austin, Texas, U.S.

PERSONALIS, INC.

Form 10-K
For the Year Ended December 31, 2022

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” or “would” or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the evolution of cancer therapies and market adoption of our services and products;
- estimates of our total addressable market, future revenue and the timing thereof, expenses, use of cash and other resources, cost savings, capital requirements, and our needs for additional financing;
- future reimbursement and reimbursement rulings;
- our ability to enter into and compete in new markets;
- the impact our collaboration agreements and key opinion leaders may have on the broader use of our platform in the future;
- the potential impacts of inflation, macroeconomic conditions, and geopolitical conflicts on our business and operations;
- the potential impact of a public health crisis on our business, our customers’ and suppliers’ businesses and the general economy;
- the benefits of our products and services, including their ability to increase the probability of clinical trial success;
- our ability to compete effectively with existing competitors and new market entrants;
- the expected completion of our move of our Clinical Laboratory Improvement Amendments of 1988-certified and College of American Pathologists-accredited laboratory to our Fremont facility and the timing thereof;
- our plan to discontinue our commercialization efforts and operations in China;
- our ability to manage and grow our business by expanding our sales to existing customers or introducing our services and products to new customers;
- our ability to establish and maintain intellectual property protection for our services and products or avoid claims of infringement;
- potential effects of extensive government regulation;
- our ability to hire and retain key personnel;
- our ability to obtain financing when needed;
- our belief that approval of personalized cancer therapies by the U.S. Food and Drug Administration may drive benefits to our business;
- our future business with the U.S. Department of Veterans Affairs’ Million Veteran Program and Natera, Inc.; and
- our ability to maintain proper and effective internal controls.

Actual events or results may differ from those expressed in forward-looking statements. As such, you should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, operating results, prospects, strategy, and financial needs. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions, and other factors described in the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a highly competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report on Form 10-K. While we believe that such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information, actual results, revised expectations, or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

Unless the context otherwise requires, references in this Annual Report on Form 10-K to the “company,” “Personalis,” “we,” “us” and “our” refer to Personalis, Inc.

PART I

Item 1. Business.

Overview

We strive to develop some of the most comprehensive and actionable cancer genomic tests in the world to help patients live better and longer lives. We believe we have one of the most discerning technologies to both characterize and monitor cancer – with the aim of driving a new paradigm for cancer management and guiding care from biopsy through the life of the patient. Our assays combine tumor-and-normal profiling with proprietary algorithms to deliver advanced insights even as cancer evolves over time. Our products are designed to detect recurrence at the earliest timepoints, enable selection of targeted therapies based on ultra-comprehensive genomic profiling, and enhance biomarker strategy for drug development.

Today, our platforms are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples in their clinical trials and drug development programs. Our advanced genomic sequencing and analytics also support the development of personalized cancer vaccines and other next-generation cancer immunotherapies. For example, we are providing genomic testing to Moderna in its ongoing clinical trials evaluating a personalized cancer vaccine. In addition, we partner with diagnostics companies by providing our advanced tumor profiling and analysis capabilities as an input to their products. More recently, we launched new diagnostic offerings for the clinical setting and are preparing for future expansion in the clinical diagnostics market. Finally, we have also pursued non-cancer related business opportunities, specifically within the population sequencing market, by providing whole genome sequencing ("WGS") services under contract with the U.S. Department of Veterans Affairs Million Veteran Program ("VA MVP").

As part of one of our new strategies for 2023 and beyond, we are working with a growing number of leading cancer centers and world-class academic research institutions to build and publish the clinical evidence-base to support our products and our key indications. Specifically, because of the high sensitivity of our technology, we aim to focus on three indications in the next 2-3 years: immunotherapy (IO) monitoring, breast cancer, and lung cancer. We have announced collaborations with BC Cancer, Duke University, UCSF, Criterium, and Academic Breast Cancer Consortium that will focus on building the evidence-base for our technology and these indications. If the key opinion leaders ("KOLs") we are collaborating with have a positive experience using our platform, we are optimistic this will support broader use of our platform by other KOLS, as well as clinicians in the future.

Our work in oncology is underpinned by our experience and capacity for next-generation sequencing at scale. We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that our capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases. To date, we have sequenced more than 300,000 human samples, of which more than 160,000 were whole human genomes.

In October 2022, we relocated our corporate headquarters from Menlo Park, California to a new facility in Fremont, California. We signed a 13.5-year lease that extends to 2036 for the 100,000 square foot facility, which is approximately triple the amount of space than our Menlo Park location. The new facility allows for expansion of our laboratory for testing to support pharmaceutical customers and clinical diagnostic testing. In addition, the new space is intended to support the expansion of research and development efforts to bring leading edge products and services to the marketplace. Our Menlo Park office currently continues to house our Clinical Laboratory Improvement Amendments of 1988 (“CLIA”)-certified and College of American Pathologists (“CAP”)-accredited laboratory and we expect to move our laboratory operations from Menlo Park to the new facility in 2023.

We were incorporated under the laws of the state of Delaware in February 2011 under the name Personalis, Inc. Our customers include pharmaceutical companies, biopharmaceutical companies, diagnostics companies, healthcare providers, universities, non-profits, and government entities.

Market Opportunities

We have estimated the potential future annual U.S. market opportunity for our current and planned products to be approximately $38 billion as follows:

- **Therapy Selection and Monitoring:** According to the American Cancer Society’s *Cancer Facts & Figures 2020*, more than 16.9 million cancer survivors were alive on January 1, 2019 in the United States. Based on data from *Cancer Treatment and Survivorship Statistics, 2019* and *Cancer Statistics, 2019,* we estimated that approximately 2.2 million of these cancer survivors were diagnosed within the last two years. Over time, the likelihood that the original cancer will reoccur can decline below the baseline likelihood of a new, genetically independent cancer emerging. Therefore, we limited our market size estimates to patients within the period of two years from their initial cancer diagnosis.

  Of these 2.2 million patients, about 200,000 enroll in pharmaceutical clinical trials according to data from the *U.S. National Library of Medicine, ClincalTrials.gov, January 2019*, with the assumption that the remaining cancer patients undergo standard clinical care. As part of that standard care, we assumed that these patients go through therapy selection and eventual monitoring. For therapy selection, we estimated that each of the approximately 2.0 million cancer patients undergoing standard clinical care will have a tissue biopsy sequenced and tested at a cost of approximately $3,000, which is the approved Centers for Medicare & Medicaid Services ("CMS") reimbursement rate, which results in an estimated potential market opportunity of $6 billion per year.

Cancer mutations identified in this initial tissue-biopsy based test can then be used for subsequent monitoring using cell-free DNA ("cfDNA"). For monitoring, we estimated that each patient has a liquid biopsy sequenced and tested four times per year at an estimated cost of $2,840 per test, based on publicly-available data on comparable tests. Our NeXT Dx offering addresses the market for tissue biopsy testing while our NeXT Personal Dx offering is expected to address the liquid-biopsy based monitoring opportunity. Our estimates have led us to project approximately a $22.7 billion potential market opportunity per year for monitoring.

- **Clinical Trial Patients:** For each of the 200,000 pharmaceutical clinical trial patients, we estimated that an initial tissue sample will be sequenced at least once at a cost of $3,000, which is the approved CMS reimbursement rate, with liquid biopsy sample testing then occurring at least eight different time-points per year for monitoring, at an estimated cost of $4,000 per sequencing test, based on the frequency of monitoring in a recent immuno-oncology drug trial and our historical standard pricing for tissue samples and anticipated pricing for liquid biopsy samples. Based on this, we estimated the potential market opportunity to be approximately $7 billion per year for tissue- and liquid-based sequencing of these clinical trial patients.

- **Population Sequencing:** According to publicly-available industry information and presentations, we estimated the potential market for population sequencing services is over $2 billion per year. Our WGS products address this potential market opportunity.

Our Products and Services

Our most advanced cancer genomic tests are powered by our NeXT Platform. Our research-focused products, including exome sequencing, transcriptome sequencing, and targeted cancer panels, are powered by our ACE Platform, the predecessor to NeXT. In addition, we offer WGS for various research applications and population sequencing projects.

NeXT Platform

NeXT is the first platform to enable the comprehensive analysis of both a tumor and its microenvironment from a single sample. Our NeXT Platform is a high-accuracy, next-generation sequencing and analysis platform. We have created an ecosystem of products and capabilities built on the NeXT Platform that synergize to drive value for our customers: ImmunoID NeXT (comprehensive tumor profiling from tissue), NeXT Liquid Biopsy (comprehensive tumor profiling from plasma), NeXT Dx (highly-personalized comprehensive genomic cancer profiling test to optimize therapy selection and match patients to clinical trials), and NeXT Personal (highly-sensitive, tumor-informed liquid biopsy offering for personalized tumor tracking and monitoring). Additionally, the platform offers neoantigen prediction capabilities with Systematic HLA Epitope Ranking Pan Algorithm ("SHERPA"), our pan-predictive machine learning model. Accurate neoantigen prediction with SHERPA is expected to enable the determination of candidate neoantigens for rapid development of personalized cancer therapies, as well as facilitation of the generation of neoantigen burden-based composite biomarkers such as our NEOantigen Presentation Score ("NEOPS") that can potentially better predict response to immunotherapies.

Our NeXT Platform is designed to provide comprehensive analysis of both a tumor and its immune microenvironment from a single limited tissue or plasma sample. Our platform covers the DNA sequence of all of the approximately 20,000 human genes. We also report on the entire transcriptome of a tumor, which encompasses ribonucleic acid (“RNA”) expression across the approximately 20,000 human genes, allowing us to more accurately determine which of the many genomic mutations might actually be driving tumor progression. Furthermore, our platform analyzes elements of the immune cells that have infiltrated a tumor both from the adaptive immune system and the innate immune system.

Given the practical challenges in obtaining high-quality tumor samples via biopsy, we have developed our platform to work with a limited tumor tissue sample. Biopharmaceutical companies, for example, face significant challenges in attempting to divide samples to ship to multiple service providers to perform different tests. If a biopharmaceutical company is successful in acquiring results from multiple service providers, it is challenging to compare the results across multiple data platforms from multiple service providers. Our sequencing approach, validated with orthogonal technologies, allows us to run multiple analyses on a single sample. Our platform is composed of multiple proprietary technologies, many of which we have developed from the ground up. The breadth of the assays that we have integrated into our platform, our proprietary sample preparation process, and the comprehensiveness of our platform allow us to maximize the utility of often limited tumor tissue samples that our customers have from their clinical trials.

Our NeXT Platform can analyze cfDNA obtained from blood plasma, also known as a liquid biopsy. As with a tissue biopsy, we analyze all of the approximately 20,000 human genes in each plasma sample, in contrast to currently marketed liquid biopsy panels, which only analyze roughly 50 to 500 genes. This cfDNA may be obtained by a blood draw concurrently with a tissue sample. Together, the two samples can be used to provide a more comprehensive initial characterization of the tumor. Additionally, our NeXT Personal offering can monitor changes in tumor genetics that arise in response to therapy through serial measurements using cfDNA samples collected across multiple time-points.

An overview of key liquid biopsy capabilities follows.

Liquid biopsy approaches look at cfDNA in plasma samples derived from the blood. cfDNA is DNA that is released into circulation by cells, including tumor cells, most commonly as a result of cell death. This cfDNA can be obtained by a blood draw and can be used to monitor changes in tumor genetics. Circulating tumor DNA ("ctDNA") is a type of cfDNA that derives from tumor cells.

We believe tumor biopsy and liquid biopsy approaches to tumor molecular profiling will provide complementary information for each patient. Tumor biopsies provide tumor immune microenvironment and tumor gene expression information that current liquid biopsy panels do not provide. Liquid biopsies can be useful for providing additional DNA mutation information, especially for monitoring therapy response across different time-points when tumor biopsies are not feasible.

NeXT Personal is an advanced, tumor-informed liquid biopsy assay developed to deliver industry-leading minimal residual disease ("MRD") sensitivity in the range of 1-3 parts per million, representing a 10- to 100-fold improvement over other, previously available methods. NeXT Personal is sample sparing, requiring only a single tube of blood, along with a tumor tissue sample. The use of ctDNA as a predictive biomarker for MRD following treatment for solid tumors is rapidly being integrated into clinical trial design, translational research studies, and is on the verge of use in routine clinical care. While other detection methods for ctDNA have rapidly advanced, the limited sensitivity of these detection methods reduce their utility for diagnosing MRD across a variety of clinical applications. Standard-of-care (“SOC”) radiological-based technologies, including CT, PET and MRI scans, also remain limited in their ability to detect residual disease during or after surgical or systemic therapy due to the minimum tumor volume required. Therefore, reliable, sensitive detection and quantification of MRD remains a key challenge, particularly in early-stage cancers, where timely detection of small micrometastatic lesions may enable treatment that prevents progression to advanced metastatic, incurable disease. We believe that NeXT Personal addresses these challenges. In the biopharma setting, MRD is rapidly emerging as a key biomarker in therapy development, whereby more sensitive detection and quantification of MRD may provide substantial benefits versus less sensitive methods through the reduction of false negative detection of cancer.

NeXT makes comprehensive tumor molecular profiling practical for cancer patients at scale

To deliver a comprehensive immune-genomic assessment of a tumor, we invested substantial resources to engineer NeXT to provide data and analysis that would otherwise be unavailable or require many individual technologies, which collectively present significant costs and logistical impracticalities. With NeXT, we built a proprietary platform that is comprehensive, cost-effective, and scalable and enables a short turnaround time, making it practical to profile cancer patients at scale. This has required innovation on a number of fronts.

Revenue from our NeXT Platform products has grown rapidly in recent years. Excluding population sequencing revenue, revenue from our NeXT Platform products accounted for only a minimal proportion of revenue prior to 2020 but for over two-thirds of revenue in the year ended December 31, 2021 and nearly four-fifths of revenue in the year ended December 31, 2022. Revenue in connection with our ACE Platform products (described below) account for the remainder of revenue.

ACE Platform

The ACE Platform is the predecessor to our NeXT Platform. To address the limitations of typical NGS-based assay, we developed our patented Accuracy and Content Enhanced (“ACE”) technology for next-generation sequencing. ACE improves nucleic acid preparation processes and combines it with patented assay and sequencing methods to achieve superior, high-fidelity, clinical-grade sequencing quality that ensures high sensitivity for mutations that can inform clinical and therapeutic applications such as neoantigen prediction, biomarker identification, and novel drug target selection. Our ACE Platform powers multiple products and services to our customers including: exome sequencing, transcriptome sequencing, and targeted cancer panels.

Our ACE technology provides coverage of difficult-to-sequence gene regions across all of the approximately 20,000 human genes, filling in key gaps left by other NGS approaches. ACE technology provides superior and uniform coverage of difficult genomic regions, such as high GC content areas, and fills gaps and inconsistencies in sequencing to achieve an optimal output. ACE is able to deliver more comprehensive coverage not by simply generating more data, but by generating higher quality data. We and others have shown in two publications that our ACE technology achieves superior gene sequencing coverage and finishing.

Whole Genome Sequencing

In recent years, the declining cost of NGS has resulted in the increased use of broad genomic characterization approaches, including WGS, for various research applications. This cost reduction has coincided with researchers’ need for more comprehensive molecular information in the disease areas of cardiology, endocrinology, rare disease, autoimmunity, and ever-increasingly, cancer. WGS is an attractive option for many researchers due to its ability to provide insights into non-coding variation as well as its unrivaled resolution of genome-wide structural variation, the impact of which is becoming more pronounced in many disease states, especially cancer. Personalis is one of the largest processors of human whole genome sequences in the world today.

The most significant customer of our WGS is the VA MVP. Since 2012, we have been contracted to provide DNA sequencing and data analysis services to the VA MVP. The VA MVP began collecting samples in 2011 and is a landmark research effort aimed at better understanding how genetic variations affect health. The VA MVP is one of the largest population sequencing efforts in the U.S. In September 2017, we entered into a one-year contract with three one-year renewal option periods with the VA for the VA MVP, and received orders under this contract in September 2017, 2018, 2019, 2020 and 2021. In September 2022, we entered into a new contract with the VA MVP for a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. We concurrently received an initial task order with a value of up to $10.0 million, subject to the receipt of samples from the VA MVP. The cumulative value of orders received from the VA MVP since inception is $195.7 million, of which we have recognized all but $9.1 million as revenue as of December 31, 2022.

All of our population sequencing revenue to date has been derived from the VA MVP. The VA MVP has accounted for a significant amount of our revenue in recent years: 13% in 2022, 53% in 2021, and 71% in 2020. To date, we have delivered WGS data sets to the VA MVP for over 155,000 veterans. This relationship with the VA MVP has enabled us to scale our operational infrastructure and achieve greater efficiencies in our lab. It has also supported our development of industry-leading, large-scale cancer genomic testing. The substantial experience that we have developed in WGS also optimally positions us for what we anticipate to be the longer-term strategic direction of the cancer genomics industry, which may include WGS of tumors.

Personalis: The Genomics Engine for Next-Generation Cancer Therapies

Pharmaceutical customers use our comprehensive platform across a diverse set of therapeutic approaches to cancer. We generate and analyze data from patients who participated in clinical trials, which we believe will enable these customers to develop more effective therapies. The information we generate is important to our customers developing three major classes of next-generation therapeutics: immunotherapies, targeted therapies, and personalized cancer therapies.

- **Immunotherapies:** Over the past decade, a number of drugs have emerged based on the discovery that the immune system plays a key role in addressing cancer. Checkpoint inhibitors, a specific type of immunotherapy, have generated substantial commercial success over the past decade; however, the development of new therapies in this category has been challenged by difficulties in understanding the precise interaction between cancer and the immune system. Since our platform provides a broad set of insights on tumor and immune biology, we believe it enables pharmaceutical companies to better understand how therapeutics are working in patients.

- **Targeted Therapies:** A growing category of successful cancer treatments consists of therapies that target specific genes or molecular mechanisms of cancer. Many of these targeted therapies are proposed to be tested in combination with immunotherapies. These therapies have grown to represent a considerable share of the overall oncology therapeutics market today. Comprehensively understanding each patient's genomic and immune profile is critical to understanding how a patient may respond to such therapies. We believe that our coverage of all of the approximately 20,000 genes provides us a strong competitive advantage against existing cancer panels that cover roughly only 50 to 500 genes. We believe our company is positioned to become a leading provider of the complex information that we believe will continue to inform the development of targeted cancer therapies.

- **Personalized Cancer Therapies:** Some pharmaceutical companies are pursuing personalized cancer therapies, which are designed and manufactured individually for each patient based on genomic alterations in a given patient's tumor. While there are many potential approaches to developing these therapies, including neoantigen-based vaccines and T-cell therapies, all of them could benefit from the data and analytics that our platform can generate about a patient's tumor. Our customers have leveraged our FDA Device Master Files as a component of their investigational new drug application ("IND") submissions with the FDA. If drugs that were developed using our platform in clinical trials to form the basis for approval are approved, we may be able to derive additional revenue in connection with the subsequent design of these drugs for cancer patients.

Genes that are involved in the mechanism of action of any of these drugs may develop mutations reducing or eliminating the effectiveness of those drugs. These are called therapy resistance mutations. In many cases, they only become evident after extended treatment of the patient with the drug. When these are detected, it can be an important signal that the patient may benefit from a change to another drug. Thus, it is important not only to test for mutations when a patient is first diagnosed, but periodically to check for the emergence of these potential resistance mutations. Unlike other tumor-informed liquid biopsy tests for MRD, our NeXT Personal liquid biopsy test was designed to also look for the emergence of these potential resistance mutations, which may ultimately help guide decisions about effective therapies for patients.

We anticipate that as the clinical utility of our platform is validated, we will have opportunities in connection with diagnostics and the commercialization of cancer therapeutics, which are significantly larger markets than our clinical-trial focused markets. Over time, we expect our pharmaceutical customers and research collaborators to build evidence of the clinical utility of our platform as a diagnostic for advanced cancer therapies.

Our Strategy

Our mission is to transform the active management of cancer through personalized testing. Our strategy to achieve this mission is to:

- Become a leader in MRD detection for active cancer management with our industry-leading MRD test, NeXT Personal.
- Expand strategic partnerships, in which our products power commercial offerings from other companies.
- Become the solution-of-choice for biopharmaceutical companies developing oncology therapies.

Our Proprietary Software and Robust Operational Infrastructure

We have invested significant resources to develop an operational infrastructure that allows us to easily customize our services for each of our customers and scale rapidly to meet their potential research and commercial demands. Our NeXT Platform is complemented by our enterprise-grade software and bespoke information management systems that we tailor to meet our customers' unique needs and integrate with their workflows. Moreover, our infrastructure provides customers with visibility and control over

processes, ensures consistency across all components used for the duration of each clinical trial, is traceable for compliance purposes, and allows us to scale while maintaining rapid turnaround times.

We designed our proprietary informatics system, the Symphony Enterprise Informatics System ("Symphony"), as a flexible and scalable enterprise-grade system used to manage the unique complexities and challenges of our genomics laboratory. Symphony integrates laboratory information management systems ("LIMS") and bioinformatics systems to connect laboratory operations with downstream data analysis. Symphony orchestrates all operational activities from our laboratory starting with sample receipt to the reporting of results of the genomic profiling and data delivery. We also use machine learning and artificial intelligence approaches to generate substantial performance advantages for our algorithms, such as neoantigen binding prediction.

We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that our capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases. To date, we have sequenced more than 300,000 human samples, of which more than 160,000 were whole human genomes.

We rely on a limited number of suppliers for sequencers and other equipment and raw materials that we use in our laboratory operations. For example, we rely on Illumina, Inc. ("Illumina") as the sole supplier of sequencers and various associated reagents, and as the sole provider of maintenance and repair services for these sequencers. We have certain agreements and purchase arrangements in place with Illumina to satisfy the projected needs of our laboratory operations.

We believe our platform is well positioned to scale rapidly and substantially as the field of personalized cancer therapies matures. We believe our platform could be essential to the design of personalized cancer therapies developed using our platform. Furthermore, we expect that patients would be tested at multiple time-points during the course of treatment: first to design a therapy according to an initial genomic profile generated from a tissue and/or liquid biopsy, and then as follow-up testing via liquid biopsy to detect any changes that would require therapy modifications after initial therapeutic interventions. If a therapy that was developed using our NeXT Platform achieves regulatory approval, we believe that our commercial opportunity may increase substantially.

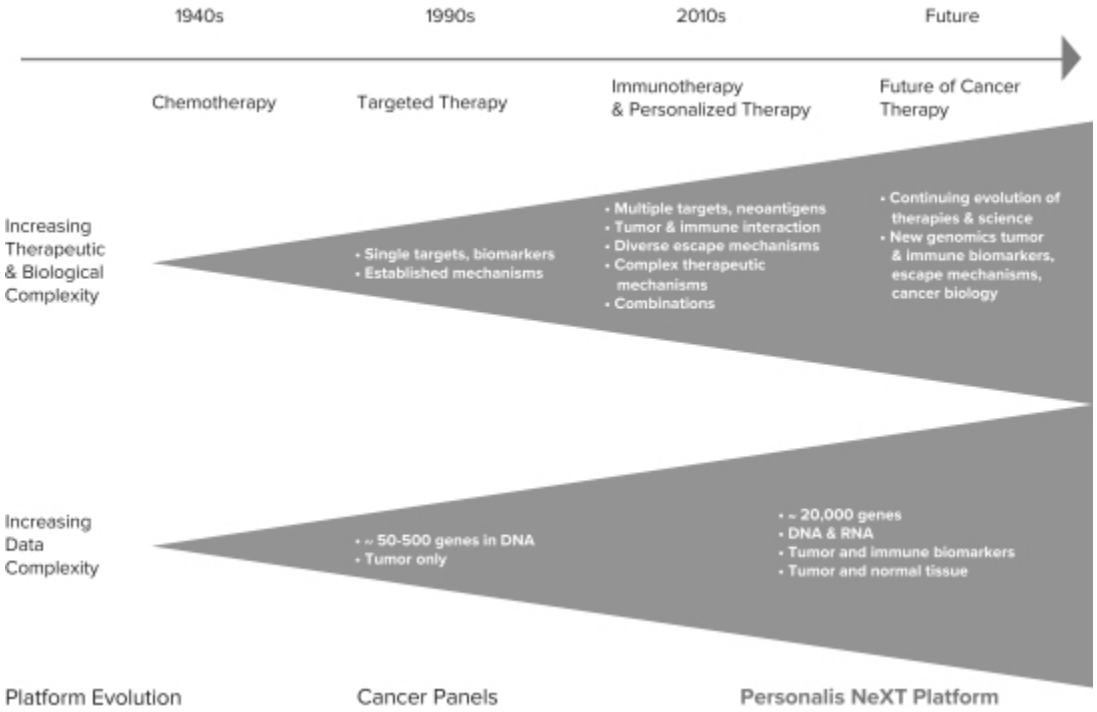
We leverage our proprietary software, laboratory automation and protocols, and other operational and technological know-how to power our NeXT Platform.

Our Industry

Over the past decade, the biopharmaceutical community has achieved major advances in the treatment of cancer, including approval of therapies capable of targeting specific genetic drivers of cancer and novel immunotherapies that empower the immune system to attack cancer cells. Despite these advances, the substantial majority of currently available cancer therapies have significant limitations, including efficacy only in certain subsets of patients, limited long-term survival rates, and significant toxicities. Moreover, the current research and development paradigm in oncology is beset by significant inefficiencies and substantial costs, with the average cost per patient in clinical trials reaching approximately $60,000 (Battelle Technology Partnership Practice, *Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies*, March 2015). While tumor molecular profiling technologies have enhanced research and development efforts, most current tumor biopsy and liquid biopsy tests analyze a relatively narrow set of roughly only 50 to 500 genes, missing key genes and immune mechanisms underlying cancer therapy. With the lack of a comprehensive profiling solution, biopharmaceutical companies often attempt to use a disparate array of tests to compensate, resulting in a fragmented view of the tumor biology, insufficient tumor sample, logistical complexities, and increased costs. The resulting data heterogeneity makes it difficult to mine for new biological insights across cohorts of patients in clinical trials. These piecemeal approaches to tumor molecular profiling often result in solutions that are difficult to use at scale, especially in a clinical or therapeutic setting where simplicity, cost, turnaround time, and validation are important.

Our platforms help biopharmaceutical companies seeking to develop more efficacious therapies by comprehensively interrogating a patient's tumor and immune cells in detail, both to discover tumor vulnerabilities and elucidate potential therapeutic alternatives. To meet the demands of our customers, we built our NeXT Platform to be cost-effective and scalable with rapid turnaround times for tissue sample data and analytics. The NeXT Platform represents the next step of our ACE Platform, allowing customers to move up the value chain by gaining more information from a single sample. We believe that our platforms have the potential to enable a research, development, and treatment paradigm that is dynamic and adaptive to the evolving genomic and immune system landscape of patients' tumors over time. We believe our technology will drive this evolving paradigm, which we believe will ultimately enable our customers to develop safer and more efficacious therapeutics (see Figure 1). As the clinical utility of our platforms increases, we expect to grow our diagnostic capabilities, including the ability to guide therapy based on a patient's changing tumor and immune system, and supporting the commercialization of therapeutics developed by our biopharmaceutical customers.

Figure 1. Personalis NeXT Platform addresses the increasingly complex understanding of cancer.



Despite the large sums invested in research and despite new treatments, cancer remains a major challenge for modern medicine and a source of high unmet medical need. According to the American Cancer Society's *Cancer Facts & Figures 2020*, as of January 1, 2019, there were more than 16.9 million people in the United States who were suffering from cancer or who had previously suffered from cancer. Cancer prevalence is increasing globally as well. The World Health Organization ("WHO") predicted in its September 2018 estimates on the global prevalence of cancer that there would be 18.1 million new cancer cases and nearly 10 million cancer deaths globally in 2018. According to the WHO, the total economic impact of healthcare expenditure and loss of productivity resulting from cancer worldwide was approximately $1.2 trillion in 2010.

Improving Cancer Treatment is Increasingly About Leveraging Molecular Data

Despite the rapid evolution of cancer therapies, the current research and development paradigm in oncology is beset by significant inefficiencies and costs. Cancer therapeutics have one of the lowest clinical trial success rates of all major diseases. According to a study of 7,455 drug development programs during 2006 to 2015, the overall likelihood of FDA approval from Phase I clinical trial for oncology developmental candidates was 5.1% (BIO Industry Analysis, *Clinical Development Success Rates 2006-2015*, June 2016). The majority of currently available cancer therapeutics have serious limitations, including efficacy only in certain subsets of patients, limited long-term survival rates, and significant toxicities. The mechanisms underlying the success or failure of clinical trials are often poorly understood. To develop more efficacious cancer treatments, the biopharmaceutical community is faced with multiple key questions for a given therapeutic approach:

- Why do some patients respond to treatment and others do not?
- What are the underlying mechanisms of treatment resistance?
- Are there additional therapeutic targets or alternative pathways that can improve outcomes?
- What therapeutic combinations can improve outcomes?
- Are there ways to increase patient response through personalized therapeutics?
- Are there ways to reduce toxicity?

There is a growing recognition that there is a tremendous amount of untapped molecular data that can be derived from analyzing tumors from large numbers of cancer patients, whether in cancer clinical trials or post-commercialization, that can help answer some of these seminal questions and accelerate therapeutic development. According to BIO Industry Analysis, *Clinical Development Success Rates 2006-2015*, June 2016, there is a threefold increase in probability of FDA approval from Phase I clinical trial for therapies with biomarkers across all diseases and therapeutic types, which provides an indication of the benefits of leveraging molecular data.

Current Tumor Molecular Profiling Solutions Have Not Kept Pace with New Cancer Therapies

Biopharmaceutical companies are increasingly turning to tumor molecular profiling across large cohorts of patients to generate the data needed to answer these questions. Unfortunately, many current tumor molecular profiling methods have not kept pace with new therapy development and overlook crucial elements of our evolving understanding of cancer biology.

Current Tumor Molecular Profiling Falls Short for New Cancer Immunotherapies

Currently, the most widely-used tumor molecular profiling panels were designed with a focus on targeted therapies, which, along with chemotherapy, have been used for cancer treatment for the past several decades. Targeted therapies treat cancers based on the specific genomic alterations driving their growth. Some targeted therapies have been developed to target specific molecules that are overexpressed or mutated in cancer cells. Because targeted therapies focus on cancer driver genes, the vast majority of tumor molecular profiling performed today, whether tissue or liquid biopsy based, typically sequences the DNA of between 50 to 500 genes, just a small fraction of the approximately 20,000 human genes.

Recently, however, transformational new approaches to cancer therapy that have been developed to harness the patient's own immune system have changed the treatment paradigm and our understanding of cancer biology. These new immunotherapies have dramatically improved the treatment of certain tumors that have previously been difficult to treat. Among these new immunotherapies, checkpoint inhibitors of the CTLA-4 and PD-1/PD-L1 genes are particularly effective. These therapies help "take the brakes off" the immune system and elicit a stronger immune response against the tumor. Patients can also be treated by adoptive cell therapy, in which the patient's immune system is supplemented with cytotoxic cells that have been programmed to attack cells expressing specific antigens on their tumors. There are also new opportunities for personalized cancer therapies where a new therapeutic vaccine or cell therapy is developed for each patient. Despite early success, the majority of patients today still do not respond to immunotherapy, underscoring the importance of gathering data that can help biopharmaceutical companies understand factors governing response and resistance to therapy.

With these new immunotherapies and our rapidly evolving understanding of cancer biology, we believe the data needed to inform therapeutic development goes far beyond the typical 50 to 500 genes on the current most widely used tumor molecular profiling panels. The paradigm has shifted from the need to understand mechanisms behind a single gene target to a dynamic, systems biology view involving complex interactions between thousands of genes in the tumor and the immune system in the pathogenesis of cancer and cancer drug response.

Information about all of the approximately 20,000 human genes allows deeper insight into the biology of cancer, identifying novel or patient-specific therapeutic targets, including neoantigens, and predictive biomarkers of response to therapy. Understanding the immune cell signatures in the tumor microenvironment and immune repertoire changes is critical for understanding drug response. In addition to DNA, comprehensive RNA expression information from the tumor is needed to analyze complex pathways that may be activated in the tumor. It is important to identify the increasingly complex mechanisms of tumor response and resistance to cancer therapy, such as neoantigen burden, tumor antigens, deficient antigen presentation, oncogenic pathways, immune evasion pathways, HLA mutations, T-cell clonality, immune infiltration, and others. Table 1 describes some of the biological gaps in current panels. Most of these elements go beyond the capabilities of today's tumor molecular profiling panels.

Table 1. Most current tumor tissue and liquid biopsy profiling panels miss critical tumor and immune biology.

Key Gaps in Tumor Molecular Profiling Panels	Description
Too few genes sequenced, missed mutations	Most tumor molecular profiling panels (both tissue and liquid biopsy panels) focus on DNA sequencing of roughly 50 to 500 cancer driver genes, a fraction of the approximately 20,000 human genes that can harbor tumor mutations.
Lack of RNA coverage	RNA expression signatures are important biomarkers of therapy response.
No immune repertoire	The immune repertoire of the tumor helps in understanding responses to cancer therapies.
No germline genome	The normal ("germline") genome can contain pertinent information for understanding therapy response and providing a clear view of which mutations are only in the cancer.
Missed neoantigens	Neoantigens are tumor-specific antigens that can trigger an immune response against a tumor.
Missed tumor escape mechanisms, biomarkers	Tumor escape mechanisms may be critical to new immunotherapies and personalized therapies. This includes HLA mutations, MSI, TCR clonality, antigen processing machinery pathways, immune signatures, and other immuno-modulators.
Limited view of the innate immune system	Immune cell expression signatures are important biomarkers of therapy response.

Fragmented Tumor Molecular Profiling Approaches Result in a Fragmented View of Biology and Limited Insights

With the lack of a comprehensive profiling solution, biopharmaceutical companies often turn to fragmented, piecemeal approaches to tumor molecular profiling as a stopgap measure. Those fragmented tumor molecular profiling approaches lead to major problems for therapeutic development. Limitations in available tumor samples, including liquid biopsies, force scientists to pick and choose which profiling platforms to include and which to omit, resulting in a fragmented picture of the biology. Fragmented profiling solutions also result in inconsistent profiling from patient to patient, and clinical trial to clinical trial. This results in data heterogeneity that makes it difficult to mine for new biological insights across cohorts of patients in trials. Finally, these piecemeal approaches to tumor molecular profiling result in solutions that often are difficult to use at scale in a clinical or therapeutic setting where logistical simplicity, cost, turnaround time, and validation are important.

Current Tumor Molecular Profiling Panels Can Become Antiquated with Evolving Science

With the explosion of immunotherapy and advances in our understanding of cancer, new insights into the underlying mechanisms of response and resistance have emerged. New putative genetic or immune biomarkers of response are regularly identified for different therapies in the context of different cancers. For instance, new biomarkers have been identified including tumor mutational burden, neoantigens, HLA type, B2M mutations, TGFß, JAK1/JAK2 mutations, expression signatures, cytotoxicity signatures, and T-cell clonality, among others. A recent Nature Medicine review identified 18 different categories of biomarkers correlating with immunotherapy response spanning tumor, immune cells, and the tumor microenvironment. The limited coverage of the current most widely-used cancer panels may miss these new biomarkers. We believe this problem will continue as research uncovers new insights into cancer.

Sequencing Quality and Coverage

Next generation sequencing ("NGS") is the technological basis for many tumor molecular profiling platforms today. NGS rapidly sequences nucleic acids and then uses a computationally intensive process to reconstruct gene sequences from millions of short sequence segments. These segments are processed in parallel, an approach that greatly increases the speed that the sequence data can be generated. However, because the segments come from random locations in the genome, reassembling the original sequence is both a technically and computationally challenging process. A key objective is to ensure that every portion of the genes being sequenced is covered by at least one sequence segment. The average number of sequence segments representing a gene is referred to as the sequence depth. The deeper the coverage, the greater fraction of the gene is likely to be covered and the higher confidence that low-frequency variants can be found.

However, even when sequenced to high depth, typical NGS approaches can leave uneven, poor coverage in genes with mutations linked to cancer and cancer therapy. Many of these regions cannot be fully covered by simply sequencing to higher depth because their sequencing coverage deficits are due to inherent limitations of the NGS platform. Regions of high guanine-cytosine ("GC") content or repetitive sequence regions are two such examples of regions that are difficult to cover with standard NGS assays. This can leave gaps in coverage of therapeutically important genes. This is particularly problematic in cancer, where there can be significant heterogeneity in the tumor samples that can make it even harder to see mutations in regions of poor coverage.

To address the limitations of typical NGS-based assay, we have developed our patented ACE technology for next-generation sequencing. ACE improves nucleic acid preparation processes and combines it with patented assay and sequencing methods to achieve superior, high-fidelity, clinical-grade sequencing quality that ensures high sensitivity for mutations that can inform clinical and therapeutic applications such as neoantigen prediction, biomarker identification, and novel drug target selection.

Our NeXT Platform uses our ACE technology to provide coverage of difficult-to-sequence gene regions across all of the approximately 20,000 human genes, filling in key gaps left by other NGS approaches. ACE technology provides superior and uniform coverage of difficult genomic regions, such as high GC content areas, and fills gaps and inconsistencies in sequencing to achieve an optimal output. ACE is able to deliver more comprehensive coverage not by simply generating more data, but by generating higher quality data. We and others have shown in two publications that our ACE technology achieves superior gene sequencing coverage and finishing.

Commercialization Strategy

We commercialize our products primarily in the United States and Europe through a targeted sales organization. In June 2020, we entered into a partnership with a clinical genomics and life sciences company headquartered in China as a means to expand business operations into China in the near term. Our first wholly-owned subsidiary was formed in Shanghai in October 2020. However, we recently decided to not pursue commercialization of our products in China and to close our operations in China as expeditiously as possible in 2023.

In 2022, we derived 91% of our revenue from customers in the U.S. Our sales representatives have extensive experience in enterprise/consultative selling in the genomics space. We augment this team with Ph.D.-level Field Application Specialists that provide deep understanding and expertise in the areas of oncology and genomics applications, ensuring top-quality pre- and post-sales customer support. Our commercial efforts are focused on demonstrating the value proposition of the NeXT Platform to biopharmaceutical customers with the goal of both increasing utilization of the product at existing accounts and to drive adoption in new targeted accounts. Our entire commercial organization promotes our ability to support biopharmaceutical customers across several application areas including biomarker discovery, new target discovery, therapy development, and treatment monitoring.

We anticipate that patients in clinical trials for cancer therapies will increasingly be tested pre-treatment and periodically afterwards to understand response to treatment in deep molecular detail, as their tumors evolve under therapeutic pressure. Although the majority of our revenue comes from single time-point testing, we believe our revenue from multiple time-point testing will continue to grow. We also derive revenue from analysis of multiple customer samples from the same patient and time point to assess genetic differences between the primary tumor and metastases. Given the value of comprehensive genomic information from multiple time points or samples, we anticipate that our revenue, and the available market, will continue to grow.

We have developed a highly sensitive MRD test (Next Personal) and are focused on launching it to doctors for patient use in 2023 while developing clinical evidence to justify its use. Our focus is on breast and lung cancer and immuno-therapy monitoring as we believe the performance of our MRD test will be particularly valuable in those clinical indications. Additionally, we believe that there is an opportunity to partner with other diagnostic companies to provide our Next Personal testing service for additional clinical indications through their sales and marketing channels and are pursuing those relationships.

As we build the evidence around our Next Personal products, we are simultaneously focused on developing the use of our Next Dx product and winning early reimbursement. The focus on commercial efforts in 2023 on Next Dx by our sales, medical affairs, billing and reimbursement teams could accelerate uptake and revenue growth from our clinical laboratory business.

Our Customers

Our cancer genomic services are sold primarily to pharmaceutical companies, biopharmaceutical companies, diagnostic testing companies, biotechnology companies, healthcare providers, universities, non-profits, and government entities, while services for population sequencing initiatives are sold primarily to the VA MVP, which is a government entity. Our customers include a majority of the top ten oncology-focused pharmaceutical companies, as measured by annual revenue.

In 2022, we had three customers account for 10% or more of our revenue: Natera, Inc. ("Natera") at 41%, VA MVP at 13% and Merck & Co., Inc. at 11%. In 2021, we had two customers account for 10% or more of our revenue: VA MVP at 53% and Natera at 10%. In 2020, VA MVP accounted for 71% of our revenue and no other customer accounted for 10% or more.

Our Competition

Our principal competition comes from commercial and academic organizations using established and new laboratory tests to produce information that is similar to the information that we generate for our customers. These companies offer services that implement various technological approaches including next-generation sequencing and microarray analyses. Some of our present or potential competitors include Adaptive Biotechnologies Corporation, Adela, Inc., ArcherDx, Inc., which was acquired by Invitae Corporation in October 2020, BillionToOne, Inc., BostonGene Corporation, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, Foresight Diagnostics Inc. ("Foresight"), Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Freenome, Inc., Geneseeq Technology Inc., Genosity, Inc., which was acquired by Invitae Corporation in April 2021, GRAIL, which Illumina announced that it had acquired in August 2021, Guardant Health, Inc., Inivata Limited, which was acquired by NeoGenomics, Inc. in June 2021, Invitae Corporation, Natera, NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Predicine, Inc., Roche Molecular Systems, Inc., Strata Oncology, Inc., and Tempus, Inc.

Additionally, several companies develop next-generation sequencing platforms that can be used for genomic profiling for biopharmaceutical research and development applications. These include Illumina, Thermo Fisher Scientific Inc., and other organizations that specialize in the development of next-generation sequencing instrumentation that can be sold directly to biopharmaceutical companies, clinical laboratories, and research centers. Separate from their instrumentation product lines, both Illumina and Thermo Fisher Scientific Inc., for example, currently market next-generation sequencing clinical oncology kits that are sold to customers who have bought and operate their respective sequencing instruments.

We believe that we compete favorably because of the high sensitivity and comprehensiveness of the data generated by our NeXT Platform. Maximizing insights into both the tumor- and immune-related components of the tumor microenvironment is essential in identifying and understanding the reasons why certain cancer patients respond more favorably to oncology therapies than others. It is via access to such a comprehensive dataset for each patient that our customers can begin to discover new, clinically relevant biomarkers for the immunotherapy era, and ultimately improve cancer patient outcomes with the development of more efficacious therapeutics.

Intellectual Property

Protection of our intellectual property is fundamental to the long-term success of our business. Specifically, our success is dependent on our ability to obtain and maintain proprietary protection for our technology and the know-how related to our business, defend and enforce our intellectual property rights, and operate our business without infringing, misappropriating, or otherwise violating valid and enforceable intellectual property rights of others. We seek to protect our investments made into the development of our technology by relying on a combination of patents, trademarks, copyrights, trade secrets, know-how, confidentiality agreements and procedures, non-disclosure agreements with third parties, employee disclosure and invention assignment agreements, and other contractual rights.

Our patent strategy is focused on seeking coverage for our core technology, our NeXT Platform, including applications and implementations for enhancing sequencing coverage of certain genomic regions, identifying neoantigens, analyzing cell-free nucleic acids, and creating personalized cancer recurrence detection assays. In addition, we file for patent protection on our ongoing research and development efforts, particularly related to other novel assay technologies which may be applicable to the diagnosis and treatment of cancer and other diseases.

Notwithstanding these efforts, we cannot be sure that patents will be granted with respect to any patent applications we have filed or may license or file in the future, and we cannot be sure that any patents we have or may be licensed or granted to us in the future, will not be challenged, invalidated, or circumvented, or that such patents will be commercially useful in protecting our technology. Moreover, we rely, in part, on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. However, trade secrets can be difficult to protect. While we take steps to protect and preserve our trade secrets, including by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors, conducting an annual training for our employees to increase awareness of cybersecurity threats, and maintaining physical security of our premises and physical and electronic security of our information technology systems, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For more information regarding the risks related to our intellectual property, please see "Risk Factors—Intellectual Property Risks."

Our patent portfolio is comprised of patents and patent applications owned by the company. These patents and patent applications generally fall into five broad categories:

- our ACE assay and NeXT Platform technology, including claims directed to methods for enriching nucleic acids from a sample based on differences in various genomic features, such as GC-content, molecular size, presence of genetic variations or rearrangements, identification of biomedically interpretable variants, epigenetic modifications, and/or species-origin (e.g., human and non-human);

- hybrid exome-genome technologies, including claims directed to methods for combining exome and/or whole genome sequencing data generated from a sample, along with the identification of other variants to identify or detect disease;

- liquid biopsy methods, including claims directed to methods of analyzing sequenced nucleic acids obtained from a patient sample in comparison with nucleic acids representing the reference genome, obtained from a blood sample, to identify disease, or recommend a drug treatment;

- clinical interpretation and neoantigen identification and prediction methods, including claims directed to methods of ranking genes associated with a phenotype and inheritance pattern or identifying neoantigens expressed in a disease sample that may be used for targeted treatments; and

- personalized genetic testing assays, including claims directed to methods for using sequencing data to create a personalized genetic test to monitor cancer progression, identify neoantigen candidates for personalized cancer vaccine treatment, or detect the recurrence of disease at the earliest possible timepoint.

As of December 31, 2022, we own 18 issued U.S. patents and 7 issued foreign patents. Issued U.S. patents in our portfolio of company-owned patents are expected to expire between 2033 and 2038, excluding any additional term for patent term adjustments or patent term extensions. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2042.

Government Regulations

Coverage and Reimbursement

Our ability, and the ability of our customers, to commercialize diagnostic tests based on our technology will depend in part on the extent to which coverage and reimbursement for these tests will be available from third-party payors. Coverage and reimbursement of new products and services is uncertain, and whether the companies that use our instruments to develop their own products or services will attain coverage and adequate reimbursement is unknown. In the U.S., there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement. Additionally, the coverage and reimbursement status of newly-approved or cleared laboratory tests, including our NeXT Dx offering, is uncertain. If we decide to seek reimbursement for our NeXT Dx offering or other in vitro diagnostic tests we may develop, and if such tests are inadequately covered by insurance or ineligible for such reimbursement, this could limit our ability to market any such future tests. The commercial success of future products in both domestic and international markets may depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors.

Federal and State Laboratory Licensing Requirements

Under the 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, the CMS does not perform this survey and inspection and relies on our CAP survey and inspection. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory that is certified as “high complexity” under CLIA may develop, manufacture, validate, and use proprietary tests referred to as laboratory developed tests (“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 the 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. 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 also maintain licenses to conduct testing in other states where nonresident laboratories are required to obtain state laboratory licenses, including Maryland, Pennsylvania, Rhode Island, and New York. 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.

Regulatory framework for medical devices in the United States

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

("PMA"). Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Although the FDA regulates medical devices, including IVDs, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and FDA regulations with respect to LDTs, which are a subset of IVDs that are intended for clinical use and developed, validated, and offered within a single laboratory for use only in that laboratory. We currently market our diagnostic test based on the NeXT Platform as an LDT. As a result, we believe our diagnostic services are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions. Despite the FDA's historic enforcement discretion policy with respect to LDTs, if the FDA determines that our tests are subject to enforcement as medical devices, we could be subject to administrative and judicial sanctions, and additional regulatory controls and submissions for our tests, all of which could be burdensome. We and/or our collaborators may also voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, which may be as companion diagnostic medical devices.

If the FDA determines that our tests and associated software do not fall within the definition of an LDT, or there are regulatory or legislative changes, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, we may be required to obtain premarket clearance for our tests and associated software under Section 510(k) of the FDC Act or approval of a PMA. We would also be subject to ongoing regulatory requirements such as registration and listing requirements, medical device reporting requirements, and quality control requirements. If our tests are considered medical devices not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, the regulatory requirements to which our tests are subject would depend on the FDA's classification of our tests. The FDA has issued regulations classifying medical devices into one of three regulatory control categories (Class I, Class II, or Class III) depending on the degree of regulation that the FDA finds necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet both pre- and post-market.

Generally, Class I devices do not require premarket authorization, but are subject to a comprehensive set of regulatory authorities referred to as general controls. Class II devices, in addition to general controls, generally require special controls and premarket clearance through the submission of a section 510(k) premarket notification. Class III devices are subject to general controls and special controls, and also require premarket approval prior to commercial distribution, which is a more rigorous process than premarket clearance. Under the FDC Act, a device that is first marketed after May 28, 1976 is by default a Class III device requiring premarket approval unless it is within a type of generic device class that has been classified as Class I or Class II. Even if a device falls under an existing Class II, non-exempt, device classification, the product must also be shown to be "substantially equivalent" to a legally marketed predicate device through submission of a section 510(k) premarket notification. If after reviewing a firm's 510(k) premarket notification, the FDA determines that a device is not substantially equivalent to a legally marketed predicate device, the new device is classified into Class III, requiring premarket approval. It is possible for a manufacturer to obtain a Class I or Class II designation without an appropriate predicate by submitting a de novo request for reclassification.

The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy, and uncertain. It generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all.

If our tests are considered medical devices not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, one classification regulation that could be relevant to one or more of our tests is a classification for genetic health risk ("GHR") assessment tests, codified at 21 C.F.R. § 866.5950. If our tests are considered medical devices that are not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, and one or more of our tests is considered to fall under the 21 C.F.R. § 866.5950 classification regulation for GHR tests, or under another Class II classification that is subject to a premarket notification requirement, we would be required to obtain marketing clearance for such tests. Further, if considered to fall under the 21 C.F.R. § 866.5950 classification for GHR tests, our tests would be required to adhere to specified special controls, such as labeling and testing specifications and information about the test to be posted on the manufacturer's website.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, set forth in the Quality System Regulation at 21 C.F.R. Part 820, which requires manufacturers to follow elaborate design, testing, control, documentation, and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device or a similar device they market 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 it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or "off-label" uses; the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device which may present a risk to health; and the establishment registration and device listing regulation.

In addition, any clearance or approval we obtain for our products may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the product. The FDA has broad post-market enforcement powers, and if unanticipated problems with our products arise, or if we or our suppliers fail to comply with regulatory requirements following FDA clearance or approval, we may become subject to enforcement actions such as:

- restrictions on manufacturing processes;
- restrictions on product marketing;

- warning letters;
- withdrawal or recall of products from the market;
- refusal to approve pending PMAs, 510(k)s, or supplements to approved PMAs or cleared 510(k)s that we submit;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory clearances or approvals;
- limitation on, or refusal to permit, import or export of our products;
- product seizures;
- injunctions; or
- imposition of civil or criminal penalties.

Moreover, the FDA strictly regulates the promotional claims that may be made about medical devices. In particular, a medical device may not be promoted for uses that are not approved by the FDA as reflected in the device's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal, and administrative penalties.

In addition, many of the products we use to perform our tests, including sequencers and various associated reagents supplied to us by Illumina, are labeled as research use only ("RUO") in the U.S. RUO products are exempt from FDA medical device requirements provided their manufacturers comply with specified labeling and restrictions on distribution. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." Manufacturers of RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and RUO products cannot be intended by the manufacturer for clinical diagnostic use. A product promoted for diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities, including requiring the manufacturer to seek marketing authorization for the products. We currently use Illumina and other RUO products for our clinical diagnostic tests. If the FDA were to require clearance, approval or authorization for the sale of Illumina's RUO products and if Illumina does not obtain such clearance, approval or authorization, we would have to find an alternative sequencing platform for some or all of our clinical diagnostic tests.

Federal and State Fraud and Abuse Laws

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

The AKS prohibits, among other things, 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.

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.

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.

The Eliminating Kickbacks in Recovery Act

The Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and is similar to the federal Anti-Kickback Statute in that it creates criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing unless a specific exception applies. Unlike the federal Anti-Kickback Statute, EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payer" statute). Additionally, most of the safe harbors available under the federal Anti-Kickback Statute are not reiterated under EKRA, and certain EKRA safe harbors conflict with the safe harbors available under the federal Anti-Kickback Statute. Therefore, compliance with a federal Anti-Kickback safe harbor does not guarantee protection under EKRA. Because EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be interpreted, applied and enforced by the government. Currently, there is no proposed regulation interpreting or implementing EKRA, nor any public guidance released by a federal agency concerning EKRA.

Other Federal and State Healthcare Laws

In addition to the requirements discussed above, several other healthcare laws could have an effect on our business. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") fraud and abuse provisions created federal civil and criminal statutes that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense, and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, 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 federal Physician Payments Sunshine Act requires certain manufacturers of drugs, biologicals, and 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 ("CHIP"), with certain exceptions, to report annually to CMS information related to (i) payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members.

The "Anti-Markup Rule" and similar state laws prohibit, among other things, a physician or supplier billing the Medicare program from marking up the price of a purchased diagnostic service performed by another laboratory or supplier that does not "share a practice" with the billing physician or supplier. Penalties may apply to the billing physician or supplier if Medicare or another payer is billed at a rate that exceeds the performing laboratory's charges to the billing physician or supplier, and the performing laboratory could be at risk under false claims laws, described below, for causing the submission of a false claim.

The "14-Day Rule," also known as the Medicare Date of Service Rule, prohibits a laboratory supplier from billing the Medicare program for tests performed on samples collected during or within 14 days of an inpatient hospital stay, unless an exception applies, and requires the laboratory supplier to bill the hospital in those cases. Penalties may apply to the laboratory supplier if Medicare determines that the Medicare program was inappropriately billed for testing that should have been billed to the hospital where the sample was collected.

State client billing laws specify whether a person that did not perform the service is permitted to submit the claim for payment and if so, whether the non-performing person is permitted to mark up the cost of the services in excess of the price the purchasing provider paid for such services. For example, California has an anti-markup statute which prohibits providers from charging for any laboratory test that it did not perform unless the provider (a) notifies the patient, client or customer of the name, address, and charges of the laboratory performing the test, and (b) charges no more than what the provider was charged by the clinical laboratory which performed the test except for any other service actually rendered to the patient by the provider (for example, specimen collection, processing and handling) (California Business and Professions Code Section 655.5). This provision applies, with certain limited exceptions, to licensed persons such as physicians and clinical laboratories regulated under the Business and Professions Code. In addition, many states also have "direct-bill" laws, which means that the services actually performed by an individual or entity must be billed by such individual or entity, thus preventing ordering physicians from purchasing services from a laboratory and rebilling for the services they order. For example, California has a direct bill rule specific to anatomic pathology services that prohibits any provider from billing for anatomic pathology services if those services were not actually rendered by that person or under his or her direct supervision with some exemptions (California Business and Professions Code Section 655.7).

In addition, we may be subject to state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; employing, exercising control over, licensed professionals in violation of state laws prohibiting corporate practice of medicine and other professions, and prohibitions against the splitting of professional fees with licensed professionals.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the HHS Office of Inspector General (the "OIG"), and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the Anti-Kickback Statute. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare 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. If any of the 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 significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

HIPAA and HITECH

Under the administrative simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), the U.S. Department of Health and Human Services ("HHS") issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information ("PHI"), used or disclosed by covered entities and business associates. Covered entities and business associates are subject to HIPAA and HITECH. Our subcontractors that create, receive, maintain, transmit, or otherwise process PHI on behalf of us are HIPAA "business associates" and must also comply with HIPAA as a business associate.

HIPAA and HITECH include privacy and security rules, breach notification requirements, and electronic transaction standards.

The Privacy Rule covers the use and disclosure of PHI by covered entities and business associates. The Privacy Rule generally prohibits the use or disclosure of PHI, except as permitted under the Rule. The Privacy Rule also sets forth individual patient rights, such as the right to access or amend certain records containing his or her PHI, or to request restrictions on the use or disclosure of his or her PHI.

The Security Rule requires covered entities and business associates to safeguard the confidentiality, integrity, and availability of electronically transmitted or stored PHI by implementing administrative, physical, and technical safeguards. Under HITECH's Breach Notification Rule, a covered entity must notify individuals, the Secretary of the HHS, and in some circumstances, the media of breaches of unsecured PHI.

In addition, we may be subject to state health information privacy and data breach notification laws, which may govern the collection, use, disclosure, and protection of health-related and other personal information. California, for example, has enacted the Confidentiality of Medical Information Act, which sets forth standards in addition to HIPAA and HITECH with which all California health care providers like us must abide. State laws may be more stringent, broader in scope, or offer greater individual rights with respect to PHI than HIPAA, and state laws may differ from each other, which may complicate compliance efforts.

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

U.S. Healthcare Reform

In the United States, there have been a number of legislative and regulatory changes at the federal and state levels that 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 Reconciliation Act (collectively, the "ACA"), became law. This law substantially changed the way health care is financed by both commercial payers and government payers, and significantly impacted our industry. The ACA contained a number of provisions expected to impact the clinical laboratory industry, such as changes governing enrollment in state and federal health care programs, reimbursement changes, and fraud and abuse.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. Since January 2017, former President Trump signed two executive orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress considered legislation that would repeal, or repeal and replace, all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA 2022") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the health reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2031, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA"), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates, and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models ("APMs"), and the Merit-based Incentive Payment System ("MIPS"). In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will continue to impact physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the Medicare Clinical Laboratory Fee Schedule (the "Physician Fee Schedule") are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payer payment rates and volumes for their tests. CMS will use this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare reimbursement rates for the tests. Laboratories that fail to report the required

payment information may be subject to substantial civil monetary penalties. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2023 and March 31, 2023, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2024 to 2026 CLFS rates. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our current tests or those in development. Pursuant to the CARES Act, the statutory phase-in of the payment reductions has been extended through 2024 with a 0% reduction cap for 2021-2022 and a 15% reduction cap for 2023 through 2025. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

We also anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and private payers to reduce 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 payers, including commercial payers and government payers.

VA MVP Agreements

In September 2017, we entered into a contract with the VA for the VA MVP to provide them with a combination of WGS services (the "2017 VA MVP Agreement"). The 2017 VA MVP Agreement was a one-year contract with three one-year renewal option periods, all of which were exercised by the VA MVP. In September 2022, we entered into a new contract with the VA MVP (the "2022 VA MVP Agreement" and together with the 2017 VA MVP Agreement, the "VA MVP Agreements") for a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. Each task order issued against one of the VA MVP Agreements has a separate period of performance and is subject to the terms and conditions of the applicable VA MVP Agreement. Funds are obligated by the VA MVP under each task order based on actual needs. Concurrent with the execution of the 2022 VA MVP Agreement, we received an initial task order with a value of up to $10.0 million, subject to the receipt of samples from the VA MVP. The cumulative value of orders received pursuant to VA MVP Agreements since the beginning of our relationship with the VA is $195.7 million, of which we have recognized all but $9.1 million as revenue as of December 31, 2022.

All materials and samples utilized during the course of the VA MVP Agreements and all data first produced or delivered under the VA MVP Agreements are the sole property of the VA MVP. Under the VA MVP Agreements, we are subject to confidentiality and security obligations, as well as various obligations upon events of default.

The VA MVP may terminate the VA MVP Agreements, or any part thereof, at its sole convenience. Subject to the terms of the VA MVP Agreements, we shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges that we can demonstrate have resulted from the termination.

The VA MVP may terminate the VA MVP Agreements, or any part thereof, for cause in the event of any default by us, or if we fail to comply with any contract terms and conditions, or fail to provide the VA MVP, upon request, with adequate assurances of future performance. In the event of termination for cause, the VA MVP shall not be liable to us for any amount for supplies or services not accepted, and we shall be liable to the VA MVP for any and all rights and remedies provided by law. If it is determined that the VA MVP improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

Illumina Agreements

In connection with the 2017 VA MVP Agreement, we entered into two agreements with Illumina. One agreement was a master services subcontract agreement entered into in November 2017 for Illumina to perform certain genotyping services on our behalf (the 2022 VA MVP Agreement does not require genotyping services) and the other agreement was a pricing agreement entered into in March 2019 that provided pricing terms for NovaSeq™ reagent kits. Each of these agreements expired with the expiration of the term of the 2017 VA MVP Agreement.

In December 2022, we received a quotation from Illumina against which we can issue purchase orders for promotional pricing for NovaSeq™ 6000 S4 Reagent Kits (each, a “Kit”) to be used exclusively in connection with the 2022 VA MVP Agreement. The promotional pricing is contingent on us remaining in good standing with the VA to perform high-throughput sequencing of veterans' samples for the VA MVP project, issuing a related purchase order prior to the quotation expiration date, and only using such purchased Kits for purposes of performing services as part of the VA MVP project. We issued a purchase order against the quotation in December 2022.

Human Capital Management within Our Company

We recognize that our employees are both our most valuable asset and our most important investment. The success of our organization is reliant upon each individual’s significant contribution to our corporate culture and goals. Following is a list of our core company values:

- Integrity
- Trust
- Respect
- Teamwork and collaboration

- Commitment to scientific excellence
- Dedication to discovery and innovation
- Passion

At a foundational level, employees receive training related to workplace safety and emergency preparedness, awareness and expectations of inclusion and diversity, required data protection, and other regulatory matters. We offer competitive total rewards programs, ongoing training and development, and a commitment to the safety and health of our employees. We also practice a commitment to diversity by including broader outreach and sourcing for candidates for new roles as well as education and a visible commitment to diversity and inclusion internally. For example, we established a Diversity Committee in 2020 with its mission to promote a sense of belonging for all our employees.

An engaged workforce with skills specific to our needs is critical for our successful growth in a competitive market and sector. We regularly benchmark our compensation and benefits by geography, industry (life sciences), and by role to ensure we maintain our status as an employer of choice in these areas. Our turnover rates over the last three years have been consistent with such benchmarks. Reports of our position relative to the benchmarks are reported to management and the compensation committee of our board of directors on a periodic basis.

As of December 31, 2022, we had 399 employees, of which 395 were full-time employees. Of these full-time employees, 166 were in research and development, 94 in laboratory operations, 71 in commercial operations and 64 in general and administrative functions. 377 of our full-time employees were located in the United States, 6 were located in Europe and 12 were located in China. As of December 31, 2022, more than 45% of our employees had completed a Ph.D. or other advanced science or medical degree.

None of our employees are represented by a labor union or covered by collective bargaining agreements, and we have not experienced any work stoppages. We consider our relations with our employees to be good. The use of independent contractors is not a material part of our workforce strategy.

In January 2023, our Board of Directors approved a reduction in our workforce by up to approximately 30% to reduce operating costs and improve operating efficiency. The reduction in workforce is expected to be completed by March 2023.

Environment

We believe we are in compliance with the regulations established by the state of California Division of Occupational Safety and Health Requirements and California Environmental Protection Agency applicable to our operations in Menlo Park and Fremont, California. This includes, but is not limited to, having an Injury and Illness Prevention Program, a Hazard Communication Program, an Emergency Action Plan, a Chemical Hygiene Plan and an Exposure Control Plan, which are captured in written standard operating procedures (“SOPs”). We provide training to our employees on these SOPs. We are committed to evaluate our compliance to such regulations on a recurring basis.

Available Information

Our website is located at https://www.personalis.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 also use the investor relations page on our website as a channel of distribution for important company information, including press releases, analyst coverage and financial information regarding us, as well as corporate governance 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 or therein 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.

Summary of Risk Factors

The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors below under the heading "Risk Factors".

Operational, Strategic and Business Risks

- We have a history of losses and we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or sustain profitability.
- If we are unable to increase sales of our current services or successfully develop and commercialize other services or products, or if we are unable to execute our sales and marketing strategy for our services or unable to gain sufficient acceptance in the market, we may fail to generate sufficient revenue to achieve profitability and sustain our business.
- We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our revenue and accounts receivable; in particular, we currently derive a substantial portion of our revenue from one of our largest customers, Natera, and in the past have derived a substantial portion of our revenue from another of our largest customers, the VA MVP.
- We rely on a limited number of suppliers, or in some cases, a sole supplier, for some laboratory instruments and materials, and we may not be able to replace or immediately transition to alternative suppliers should we need to do so.
- We will need to invest in our infrastructure in advance of increased demand for our services; our failure to accurately forecast demand would have a negative impact on our business and our ability to achieve or sustain profitability.
- If our facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.
- If we cannot develop services and products to keep pace with rapid advances in technology, medicine, and science our operating results and competitive position could be harmed.
- Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in our inability to achieve regulatory approval, commercialization, or payor coverage, any of which could adversely affect our business.
- The loss of key members of our executive management team or the inability to hire, retain, or motivate highly skilled personnel could adversely affect our business.
- We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.
- We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute stockholders' ownership, or cause us to incur debt or significant expense.

Regulatory, Legal and Cybersecurity Risks

- Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and we may be subject to regulatory action if we or our service or product offerings do not comply with applicable requirements.
- Our internal information technology systems, or those of our third-party vendors, contractors, or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could adversely affect our business.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the cost of our offerings, limit their use or adoption, and otherwise negatively affect our operating results and business.
- Our employees may engage in misconduct or other improper activities, such as noncompliance with regulatory standards and requirements, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery laws, which could cause significant liability for us and harm our reputation.
- Changes in health care policy could increase our costs, decrease our revenue, and impact sales of and reimbursement for our tests. When we grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.
- The exit of the United Kingdom from the EU could lead to further regulatory divergence and require us to incur additional expenses in order to develop, manufacture, and commercialize our products and services.

Intellectual Property Risks

- Litigation or other proceedings or claims of intellectual property infringement, misappropriation, breach of license terms or other violations may require us to spend significant time and money, including damages, and could prevent us from selling our tests.
- If we cannot license rights to use necessary technologies on reasonable terms, we may not be able to commercialize new services and products.
- If we are not able to obtain, maintain and enforce patent protection for our products, services or technologies, our competitors and other third parties could develop and commercialize products, services and technologies similar or identical to ours, and our ability to successfully commercialize our products, services, and technologies may be adversely affected.
- If we are unable to protect the confidentiality of our trade secrets and know-how, our business would be harmed.
- Our use of “open source” software could subject our proprietary software to general release, adversely affect our ability to sell our products and services, and subject us to possible litigation.
- If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Financial and Market Risks and Risks Related to Owning Our Common Stock

- Our inability to raise additional capital on acceptable terms in the future may limit our ability to continue to operate our business and further expand our operations.
- The market price of our common stock may be volatile or may decline steeply or suddenly regardless of our operating performance, we may not be able to meet investor or analyst expectations, and you may lose all or part of your investment.
- Our quarterly results may fluctuate significantly, which could adversely impact our common stock’s value.
- Insiders may exercise significant control over our company and will be able to influence corporate matters.
- Future sales of shares by existing stockholders, or the perception that such sales could occur, could cause the stock price of our common stock to decline.
- We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.
- If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.
- Our ability to use net operating losses to offset future taxable income may be subject to limitations.
- Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our common stock; our amended and restated certificate of incorporation has an exclusive forum provision, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.
- Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

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 audited consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks or others not specified below materialize, our business, financial condition, and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline.

Operational, Strategic and Business Risks

We have a history of losses and we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or sustain profitability.

We have incurred net losses since our inception. For the years ended December 31, 2022, 2021, and 2020 we had net losses of $113.3 million, $65.2 million, and $41.3 million, respectively. As of December 31, 2022, we had an accumulated deficit of $360.4 million. To date, we have not generated sufficient revenue to achieve profitability, and we may never achieve or sustain profitability. In addition, we expect to continue to incur net losses for the foreseeable future, and we expect our accumulated deficit to continue to increase as we focus on scaling our business and operations. Our efforts to sustain and grow our business may be more costly than we expect, and we may not be able to increase our revenue sufficiently to offset our higher operating expenses. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations, and cash flows, and could cause the market price of our common stock to decline.

If we are unable to increase sales of our current services or successfully develop and commercialize other services or products, or if we are unable to execute our sales and marketing strategy for our services or unable to gain sufficient acceptance in the market, we may fail to generate sufficient revenue to achieve profitability and sustain our business.

We currently derive substantially all of our revenue from sales of our services. We began offering our services through our CLIA-certified, CAP-accredited, and state-licensed laboratory in 2013. We are in varying stages of research and development for other services and products that we may offer. If we are unable to increase sales of our existing services or successfully develop and commercialize other services and products, we will not generate sufficient revenue to become profitable.

In addition, as a growing genomics company, we have engaged in targeted sales and marketing activities for our services. Although we have had revenue from sales of our services since 2013, our services may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or permit us to become profitable. We will need to further establish and grow the market for our services through the expansion of our current relationships and development of new relationships with biopharmaceutical customers. Gaining acceptance in medical communities can be supported by, among other things, publications in leading peer-reviewed journals of results from studies using our services. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our services.

Our ability to successfully market our services that we have developed, and may develop in the future, will depend on numerous factors, including:

- our ability to demonstrate the utility and value of our services to our customers and potential customers;
- the success of our commercial team, including sales and business development personnel;
- the recruitment, hiring, and retention of our commercial team personnel;
- whether our customers and potential customers accept that our services are sufficiently sensitive and specific;
- our ability to convince our customers and potential customers of the utility of the comprehensiveness of our services and of testing patients at multiple time-points;
- our ability to continue to fund sales and marketing activities;
- whether our services are considered superior to those of our competitors;
- any negative publicity regarding our or our competitors' services resulting from defects or errors;
- our success obtaining and maintaining patent and trade secret protection for our services and technologies; and
- our success enforcing and defending intellectual property rights and claims.

Failure to achieve broad market acceptance of our services would materially harm our business, financial condition, and results of operations.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

Our principal competition comes from commercial and academic organizations using established and new laboratory tests to produce information that is similar to the information that we generate for our customers. These commercial and academic organizations may not utilize our services or may not believe them to be superior to those tests that they currently use or others that are developed. Further, it may be difficult to convince our customers and potential customers to use our comprehensive test rather than simpler panels provided by our competitors. For example, the information that we provide may be more challenging or require additional resources for our customers to interpret than the information provided by our competitors' less comprehensive assays. In addition, our suppliers or competitors may announce the development of new products, services or features that results in our customers' or potential customers' decision to reduce, postpone or cancel orders from us while they wait to determine which products, services or features are or will be perceived as technologically superior, more commercially successful or adopted as standards in the industry; such decisions by our customers or potential customers may be influenced by their concerns regarding the potential obsolescence of data generated using our services and features if our services or features are or will not be perceived as technologically superior, commercially successful or adopted as standards in the industry.

Some of our present or potential competitors, including Adaptive Biotechnologies Corporation, Adela, Inc., ArcherDx, Inc., which was acquired by Invitae Corporation in October 2020, BillionToOne, Inc., BostonGene Corporation, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, Foresight Diagnostics Inc. ("Foresight"), Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Freenome, Inc., Geneseeq Technology Inc., Genosity, Inc., which was acquired by Invitae Corporation in April 2021, GRAIL, which Illumina announced that it had acquired in August 2021, Guardant Health, Inc., Inivata Limited, which was acquired by NeoGenomics, Inc. in June 2021, Invitae Corporation, Natera, NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Predicine, Inc., Roche Molecular Systems, Inc., Strata Oncology, Inc., and Tempus, Inc., may have more widespread brand recognition or substantially greater financial or technical resources, development or production capacities, or marketing capabilities than we do. They may be able to devote greater resources to the development, promotion and sale of their products and services than we do or sell their products and services at prices designed to win more significant levels of market share. Also, we have had, and may have in the future, customer or supply relationships with our present or potential competitors. For example, we have an agreement with Natera to provide advanced tumor analysis for use in Natera's MRD testing offerings. During the year ended December 31, 2022, revenue under our agreement accounted for 41% of our total revenue. See "—We currently derive a substantial portion of our revenue from DNA sequencing and data analysis services that we provide to Natera. If Natera's demand for our DNA sequencing and data analysis services were to be substantially reduced, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed." In addition, our present or potential competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, more well-established and well-financed companies. For example, in August 2021, Illumina announced it completed its acquisition of GRAIL, a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology, which we view as a potential competitor. Illumina is also one of our significant suppliers. See "—We rely on a limited number of suppliers, or in some cases, a sole supplier, for some of our laboratory instruments and materials, and we may not be able to find replacements or immediately transition to alternative suppliers should we need to do so." Others may develop lower-priced, less complex products and services that pharmaceutical companies could view as functionally equivalent to our current or planned future services, which could force us to lower the price of our services and impact our operating margins and our ability to achieve and maintain profitability. In addition, companies or governments that control access to genetic testing and related services through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. In addition, technological innovations that result in the creation of enhanced products or diagnostic tools that are more sensitive or specific than ours may enable other clinical laboratories, hospitals, physicians, or medical providers to provide specialized products or services similar to ours in a more patient-friendly, efficient, or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, or if we cannot maintain successful customer or supply relationships with Natera, Illumina or other present or potential competitors, we may be unable to ensure or increase market acceptance and sales of our current or planned future services, which could prevent us from increasing or sustaining our revenue or achieving or sustaining profitability.

We expect that biopharmaceutical companies will increasingly focus attention and resources on the targeted and personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics increases. For example, the FDA has approved several such targeted oncology therapies that use companion diagnostics, including the anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. for use with Xalkori® from Pfizer Inc., the BRAF kinase V600 mutation test from Roche Molecular Systems, Inc. for use with Zelboraf® from Daiichi-Sankyo/Genentech/Roche, and the BRAF kinase V600 mutation test from bioMerieux for use with Tafinlar® from GlaxoSmithKline. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests, such as the ones we currently offer as part of our services, would be considered an off-label use and this may limit our access to this market segment. Our customers and potential customers may request, or in some cases have requested, that we consider developing and seeking FDA approval for companion diagnostic tests to accompany those customers' therapeutic product candidates, and it may be necessary for us to do so in order to successfully compete for the business of these customers. If we do not successfully develop FDA-approved companion diagnostics, we may be at a competitive disadvantage and may be unable to increase market acceptance and sales of our other service or product offerings, which would prevent us from increasing or sustaining our revenue or achieving or sustaining profitability. If we were to develop one or more FDA-approved companion diagnostics, we would incur increased research and development expenses, and such activities may also divert our resources or the attention of our management and may create competing internal priorities for us. In addition, we have limited experience developing diagnostics, have

never developed an FDA-approved companion diagnostic, and may be unable to successfully compete against companies with more experience developing and commercializing companion diagnostics.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States of America (the "U.S.") and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products and services aimed at identifying treatment options will be developed and that these products and services may compete with our services. In addition, competitors may develop their own versions of our current or planned future services and products in countries where we did not apply for or receive patents and compete with us in those countries, including encouraging the use of their products or services by biopharmaceutical companies in other countries.

We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our revenue and accounts receivable; in particular, we currently derive a substantial portion of our revenue from one of our largest customers, Natera, and in the past have derived a substantial portion of our revenue from another of our largest customers, the VA MVP.

Like other genomic profiling companies that sell to the pharmaceutical industry, we have substantial customer concentration. We currently derive a significant portion of our revenue from the VA MVP, which accounted for 13%, 53% and 71% of our revenue for the years ended December 31, 2022, 2021 and 2020, respectively. Revenue from Natera accounted for 41% and 10% of our revenue for the years ended December 31, 2022 and 2021, respectively. Our top five customers, including the VA MVP and Natera, accounted for 76%, 84% and 87% of our revenue for the years ended December 31, 2022, 2021 and 2020, respectively. There are inherent risks whenever a large percentage of revenue is concentrated with a limited number of customers. While we have attempted to grow our customer base and diversify our revenue concentration beyond the VA MVP and Natera, we may not be able to successfully do so in the future. Our predictions regarding the future level of demand for our services that will be generated by these customers may be wrong. In addition, revenue from our larger customers have historically fluctuated and may continue to fluctuate based on the commencement and completion of clinical trials or other projects, the timing of which may be affected by market conditions or other factors, some of which may be outside of our control. Further, while we have long-term contractual arrangements with certain of our customers, including Natera, these customers are not required to purchase a minimum number of analyses. Some of our customers have in the past suspended or terminated clinical trials or projects, received less funding than expected, experienced declining or delayed sales, or otherwise decided to reduce or eliminate their use of our services, and these and other customers may also do so in the future. As a result, we could be pressured to reduce the prices we charge for our services, which would have an adverse effect on our margins and financial position, and which would likely negatively affect our revenue and results of operations. In particular, if we do not win future VA MVP renewals with a value comparable to that of our historical contracted orders, it may have a material adverse effect on our revenue, cash position, and results of operations. Similarly, if the VA MVP was eliminated, awarded its contract to one of our competitors, further reduced the size of our contract or failed to renew our contract in the future, then our revenue, cash position, and results of operations would be materially adversely impacted. Likewise, if Natera or any of our other significant customers were to reduce or cease their use of our services, then our revenue, cash position, and results of operations may be materially adversely impacted. Further, if any of our significant customers were to stop payment for our services, it would have a material adverse effect on our accounts receivable, increasing our credit risk. The failure of these customers to pay their balances, or any customer to pay future outstanding balances, would result in an operating expense and reduce our cash flows.

We currently derive a substantial portion of our revenue from DNA sequencing and data analysis services that we provide to Natera. If Natera's demand for our DNA sequencing and data analysis services were to be substantially reduced, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed.

In February 2021, we entered into a partnership in the field of personalized oncology with Natera, pairing our NeXT tumor profiling and diagnostic services and products with Natera's personalized ctDNA platform Signatera™ for treatment monitoring and MRD assessment. Under this non-exclusive agreement, Natera is responsible for validating the design of, and commercialization of, Signatera personalized ctDNA assays using matched tumor and normal exome sequence data from us. The agreement covers MRD testing for both clinical use and research use. Since that time, Natera's sample volumes have increased such that we currently derive a significant portion of our revenue from sales of our DNA sequencing and data analysis services to Natera under our agreement. For example, in 2022, revenue under our agreement accounted for 41% of our total revenue. While our agreement with Natera is a long-term contractual arrangement, Natera is not required to purchase a minimum number of analyses from us under the agreement, and we have only limited visibility to Natera's forecasted sample volumes for future periods. We are aware that Natera has at least one third party supplier of DNA sequencing and analysis services, such that Natera has elected, and may continue to elect in the future, to send a portion (or all) of its samples to its other supplier(s) instead of us, which it is not contractually prohibited from doing, given the non-exclusive nature of our agreement. Natera may also bring a portion (or all) of such services in-house in the future, which may result in them purchasing fewer (or no) such services from us, or none from us at all. Our agreement with Natera requires us to achieve certain quality and turnaround time metrics for Natera samples. Recently, the volumes of samples sent to us by Natera have fluctuated significantly and may continue to do so in the future, which could cause us to experience difficulty in achieving such metrics from time to time, or to meet our other obligations under our agreement. If we consistently fail to achieve such metrics, or any of our other obligations under our agreement with Natera, Natera may elect to send a portion (or all) of its samples to its other supplier(s) and/or bring such services in-house.

Additionally, Natera may allege that such failures to achieve the required metrics are a breach of our agreement and seek to terminate our agreement and/or pursue any remedies available to it under the agreement, at law or in equity. Relatedly, we have incurred

expenses in connection with our scale-up activities under our agreement with Natera, and we may incur additional expenses to increase our laboratory's capacity to process increased sample volumes from Natera, in addition to those from our other customers, in the future. Our activities under our agreement with Natera have had, and may continue to have, an impact on our business, including diversion of our resources and the attention of our management, including with respect to our internal research and development objectives and projects for our other customers, collaborators and/or partners. If we are unable to successfully increase our laboratory's capacity and manage any such competing objectives and/or projects for other customers, we may be unable to meet the quality and timing requirements of our agreement with Natera or our other customers, collaborators and/or partners. We may also be unable to successfully research, develop, launch and/or commercialize our services or service capabilities. Furthermore, we recently announced the launch of NeXT Personal, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify MRD and recurrence in patients previously diagnosed with cancer. If NeXT Personal or any of our other services is seen as competing with Signatera or any of Natera's other services, we will still be required to fulfill our obligations to Natera under our agreement, although Natera may elect to send a portion (or all) of its samples to its other supplier(s) and/or bring such services in-house. If the volume of samples received under our agreement with Natera were to be significantly reduced or eliminated, or if our agreement with Natera were to be terminated, for these or other reasons, or if we are unable to successfully research, develop, launch and/or commercialize our services or service capabilities, including NeXT Personal, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed.

We have derived a substantial portion of our current revenue from DNA sequencing and data analysis services that we provided to our largest customer, the VA MVP. If the VA MVP's demand for and/or funding for our DNA sequencing and data analysis services continues to be substantially reduced, or if our new contract with the VA MVP were to be terminated, our business, financial condition, revenue and other operating results, and cash flows will be materially harmed.

We have derived a substantial portion of our revenue from sales of our DNA sequencing and data analysis services to the VA MVP. In September 2017, we entered into a one-year contract with three one-year optional renewal periods with the VA for the VA MVP, pursuant to which we received contracted orders from the VA MVP in September 2017, 2018, 2019, 2020, and 2021. That contract did not include a renewal option. In September 2022, we entered into a new contract with the VA MVP to continue providing them WGS services. The performance period under the new contract includes a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. We concurrently received an initial task order with a value of up to $10.0 million, subject to the receipt of samples from the VA MVP.

The VA MVP's contracted orders for DNA sequencing and data analysis services have fluctuated significantly in value over time and are subject to the availability of funding, enrollment of veterans in the VA MVP study, and the VA MVP's continued demand, if any, for our services among other factors. For example, the VA MVP contracted order received in September 2020 had a value of $30.9 million, whereas the VA MVP contracted orders received in September 2021 and 2022 had values of $9.7 million and $10.0 million, respectively, which represents a substantial decline. We have no certainty that funding will be made available for our services, or that the VA MVP will award any future contracts, contract renewals or contracted orders to us. The priorities of the VA, the VA MVP, or the U.S. government may change, including in response to COVID-19 or another health epidemic or pandemic. For example, funding for our services may be limited or not available, and our business, financial condition, and operating results and cash flows will be materially harmed. Similarly, if we do not win future VA MVP contracts and renewals (whether due to being outbid by a competitor or the VA MVP's decision not to award a future contract on a timely basis or at all, or to terminate for convenience or failure to renew any contract, for whatever reason) with a value comparable to that of our historical contracted orders, our business, financial condition, revenue and other operating results and cash flows may be materially harmed.

We have only recognized revenue under our VA MVP contract upon the receipt and processing of samples, and the timing and number of VA MVP samples we have received has been and could in the future be negatively affected by factors beyond our control, which has resulted, and may result in the future, in delaying our ability to process and recognize revenue for such samples. For example, the revenue we recognized during the contract year that began in September 2020 significantly exceeded the value of the VA MVP contracted order we received in September 2020 because we continued to receive after such date, and subsequently processed, samples under VA MVP contracted orders that remained unfulfilled as of September 2020 due to the time required for the VA to select optimal samples from its collection for research and then provide us those samples. Therefore, period-to-period comparisons of our operating results relating to VA MVP contracted orders may not be meaningful. The timing and number of VA MVP samples may also be negatively affected by a public health crisis, such as COVID-19. For example, in March 2020, the VA MVP announced that it was suspending sample collection due to the COVID-19 pandemic. In addition, we believe the COVID-19 pandemic may have been a contributing factor to the reduction in values of the September 2021 and 2022 VA MVP contracted orders compared to the September 2020 contracted order, as the VA MVP delayed new enrollment and also may have needed to divert resources to respond to the pandemic. A resurgence of COVID-19 or another health epidemic or pandemic may negatively impact the value of any potential new VA MVP contract or order.

If we cannot maintain our current customer relationships, or fail to acquire new customers, our revenue prospects will be reduced. Many of our customers are biopharmaceutical companies engaged in clinical trials of new drug candidates, which trials are expensive, can take many years to complete, and have inherently uncertain outcomes.

Our customers other than the VA MVP and Natera are primarily biopharmaceutical companies that use our services to support clinical trials. Our future success is substantially dependent on our ability to maintain our customer relationships and to establish new ones. Many factors have the potential to impact our customer relations, including the type of support our customers and potential customers require and our ability to deliver it, our customers' satisfaction with our services, and other factors that may be beyond our

control. Furthermore, our customers may decide to decrease or discontinue their use of our services due to changes in research and product development plans (including as a result of a public health crisis), failures in their clinical trials (which failures are statistically much more likely to occur than not at some point in the clinical development process, notwithstanding any enhanced patient stratification from the use of our proprietary tests and algorithms), financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control.

We engage in conversations with customers regarding potential commercial opportunities on an ongoing basis in the event that one of these customers' drug candidates is approved. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential relationships with biopharmaceutical companies could be a catalyst for adverse speculation about us, our services, and our technology, which can adversely affect our reputation and our business. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue.

Our customers' clinical trials are expensive, can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and early clinical trials. Many of the biopharmaceutical companies that are our customers do not have products approved for commercial sale and are not profitable. These customers must continue to raise capital in order to continue their development programs and to potentially continue as our customers. If our customers' clinical trials fail or they are unable to raise sufficient capital to continue investing in their clinical programs, our revenue from these customers may decrease or cease entirely, and our business may be harmed. Furthermore, even if these customers have a drug approved for commercial sale, they may not choose to use our services as a companion diagnostic with their drug, thereby limiting our potential revenue.

When we grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.

The coverage and reimbursement status of newly-approved or cleared laboratory tests, including our NeXT Dx offering, is uncertain. We are seeking reimbursement for our NeXT Dx offering and other in vitro diagnostic tests we may develop, and if such tests are inadequately covered by insurance or ineligible for such reimbursement, this could limit our ability to derive revenue from any such future tests. The commercial success of future services and products in both domestic and international markets may depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, or equivalent foreign programs, managed care organizations, and other third-party payors. The government and other third-party payors are increasingly attempting to contain health care costs by limiting both insurance coverage and the level of reimbursement for new diagnostic tests. As a result, they may not cover or provide adequate payment for any future in vitro diagnostic tests that we develop. These payors may conclude that our services or products are less safe, less effective, or less cost-effective than existing or later-introduced services or products. These payors may also conclude that the overall cost of using one of our tests exceeds the overall cost of using a competing test, and third-party payors may not approve any future in vitro diagnostic tests we develop for insurance coverage and adequate reimbursement.

We rely on a limited number of suppliers, or in some cases, a sole supplier, for some of our laboratory instruments and materials, and we may not be able to find replacements or immediately transition to alternative suppliers should we need to do so.

We rely on a limited number of suppliers for sequencers and other equipment and materials that we use in our laboratory operations. For example, we rely on Illumina as our sole supplier of sequencers and various associated reagents and other materials used in our routine laboratory operations, and as the sole provider of maintenance and repair services for these sequencers. In August 2021, Illumina completed its acquisition of GRAIL, a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology. Any disruption in Illumina's operations, or our inability to negotiate pricing with Illumina on acceptable terms, or at all, or any competitive pressure resulting from Illumina's acquisition of GRAIL, could negatively impact our supply chain and laboratory operations and our ability to conduct our business and generate revenue. Additionally, COVID-19 previously disrupted Illumina's ability to fulfill our purchase orders for reagents or other materials in a timely manner and a resurgence of COVID-19 or another health epidemic or pandemic may disrupt the ability of Illumina and our other suppliers to fulfill our purchase orders in a timely manner or at all. Our suppliers, including Illumina, could cease supplying these materials and equipment at any time, could increase the price of these materials or equipment (including the promotional pricing offered to us by Illumina for our 2022 VA MVP Agreement) or fail to provide us with sufficient quantities of materials or equipment that meet our specifications. Our laboratory operations have been and in the future could be interrupted if we encounter delays or difficulties in securing sequencers or other equipment or materials, or if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations, and reputation.

We believe that there are only a few manufacturers other than Illumina that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. Likewise, we believe that there are a limited number of manufacturers and suppliers for other reagents and materials necessary for our laboratory operations, such as the sample preparation reagents required for our ACE technology, which enables our NeXT Platform to provide more comprehensive sequencing coverage, as well as those required to create personalized liquid biopsy panels for each patient as part of our NeXT Personal assay. Although we have evaluated and may continue in the future to evaluate equipment and materials from other suppliers, the use of

equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, would likely result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations, or could require that we revalidate our tests. Additionally, an existing supplier of ours may allege that such activities constitute a breach of its agreement with us and may cease supplying us with sufficient quantities of materials or equipment that meet our specifications, in a timely manner or at all. Moreover, an existing supplier or third party may allege that such activities, replacement equipment or materials infringe, misappropriate or otherwise violate its intellectual property, and may bring infringement or other intellectual property-related claims against us. See "—Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price, any of which could have a material adverse effect." We cannot assure you that, if we were forced to replace Illumina or another supplier on which we rely, we would be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and other materials on-line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our services, our business, financial condition, results of operations, and reputation could be adversely affected.

In addition, the Device Master Files that we filed with the FDA, which are focused on the technology, quality management, and validation of our platform, specifically on its use for the development of personalized immunotherapies, are predicated on our use of specified equipment and processes, including Illumina sequencers and related equipment. The detailed information in the Device Master Files is not shared with our customers, but with our permission they can reference our FDA file numbers in their Investigational New Drug filings with the FDA. If we were required to transition to a new supplier of sequencers or certain other equipment or processes in our laboratory, our Device Master Files would need to be replaced or updated, and until such time as that occurred, customers for which we deliver services after the transition would not be able to reference our Device Master Files, which would cause us to lose a competitive advantage.

We will need to invest in our infrastructure in advance of increased demand for our services; our failure to accurately forecast demand would have a negative impact on our business and our ability to achieve and sustain profitability.

In order to execute our business model, we need to invest in scaling our infrastructure, including expanding laboratory capacity. 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, or that we will have adequate space in our laboratory facilities to accommodate such required expansion. We expect that much of this growth will be in advance of increased demand for our services. Our current and projected future expense levels are to a large extent fixed and are largely based on our current investment plans and our estimates of future test volume. As a result, if revenue does not meet our expectations we may not be able to promptly adjust or reduce our spending to levels commensurate with our revenue. If we fail to generate demand commensurate with our infrastructure growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition, and results of operations could be adversely affected.

As we commercialize additional services or products, we may need to incorporate new equipment, implement new technology systems and laboratory processes, or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher costs, declining service and/or 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 services, and could damage our reputation and the prospects for our business.

If our facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.

We currently derive our revenue from our genomic analysis conducted in our laboratories. Currently, our only clinical reference or research and development laboratory facilities are our facilities in Menlo Park, California, and Fremont, California and the facilities that we plan to discontinue in Shanghai, China. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fires, earthquakes, flooding, and power outages, which may render it difficult or impossible for us to sell or perform our services for some period of time. See "—Our planned opening of our new laboratory facilities in Fremont, California has diverted and could continue to divert management's attention and has disrupted and could continue to disrupt our ongoing business." Northern California has recently experienced serious fires and storms and the San Francisco Bay Area is considered to lie in an area with earthquake risk. The inability to sell or to perform our sequencing and analysis services, disruptions in our operations, or the backlog of samples that could develop if our facilities are inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. For example, access to our laboratory facilities was limited during the COVID-19 pandemic, which resulted in a loss in productivity, including delays to research and development programs. Furthermore, our facilities and the equipment we use to perform our services and our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples as the basis for the development of our services, and our services typically involve using biological samples provided by or on behalf of our customers. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples were

damaged or compromised, our ability to pursue our research and development projects or provide our services, as well as our reputation, could be jeopardized. We carry insurance for damage to our property or to our customer's property while in our possession, and we also carry insurance for the disruption of our business, but these types of insurance may not be sufficient to cover all of our potential losses or liabilities and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratory facilities became inoperable, we would likely not be able to license or transfer our technology to other facilities with the qualifications, including state licensure and CLIA certification, that would be necessary to cover the scope of our current and our planned future services. Even if we were to find facilities with such qualifications to perform our services, they may not be available to us on commercially reasonable terms.

Our success depends on our ability to provide reliable and timely, high-quality genomic data and analyses and to rapidly evolve to meet our customers' needs.

Errors, including if our tests fail to accurately detect gene variants, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business. We classify variants in accordance with guidelines that are subject to change and subject to our interpretation. There have also been and could in the future be flaws in the databases, third-party tools or algorithms we use, or in the software that handles automated parts of our classification protocol. If we receive poor quality or degraded samples, our tests may be unable to accurately detect gene variants or we may fail to or incompletely or incorrectly identify the significance of gene variants, which could have a significant adverse impact on our business. In addition, our customers require timely turnaround of high-quality genomic data and analyses, and if we were not able to meet our customers' specific requirements, it could also have a significant adverse effect on our business.

Inaccurate results or misunderstandings of, or inappropriate reliance on, the information we provide to our customers could lead to, or be associated with, lack of efficacy, side effects or adverse events in patients who use our tests, or who rely on our tests to determine therapies to develop, select or monitor, including treatment-related death, and could lead to termination of our services or result in claims against us. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Although we maintain liability insurance, including for errors and omissions and professional liability, we cannot assure you that our insurance would be sufficient to protect us from the financial impact of defending against these types of claims, or any judgments, fines, or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests or cause a suspension of our license to operate. The occurrence of any of these events could have an adverse effect on our business, reputation, and results of operations.

If we cannot develop services and products to keep pace with rapid advances in technology, medicine, and science, or if we experience delays in developing such services and products, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. Several new cancer drugs have been approved, and a number of new drugs are in pre-clinical and clinical development. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new services and products, enhance any existing services, and avoid delays in such developments and enhancements to keep pace with evolving technologies on a timely and cost-effective basis. Our current services and our planned future services and products could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring, or prognosis of patients with cancer. New cancer therapies typically have only a few years of clinical data associated with them, and much of that data may not be disclosed by the pharmaceutical company that conducted the clinical trials. This could limit our ability to develop services and products based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the clinical utility of our services and our planned future services and products to new treatments, sales of our services could decline, which would have a material adverse effect on our business, financial condition, and results of operations.

We are researching and developing improvements to our tests and test features on a continuous basis, but we may not be able to make these improvements on a timely basis, and even if we do, we may not realize the benefits of these efforts in our financial results.

To remain competitive, we must continually research and develop improvements to our tests or test features. However, we cannot assure you that we will be able to develop and commercialize the improvements to our tests or test features on a timely basis. Our competitors may develop and commercialize competing or alternative tests and improvements faster than we are able to do so. In addition, we must expend significant time and funds in order to conduct research and development, further develop and scale our laboratory processes, and further develop and scale our infrastructure. We may never realize a return on investment on this effort and expense, especially if our improvements fail to perform as expected. If we are not able to realize the benefits of our efforts to improve our tests or test features, it could have an adverse effect on our business, financial condition, and results of operations.

Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in or inability to achieve regulatory approval, commercialization, or payor coverage, any of which could adversely affect our business.

We currently work with certain companies developing personalized cancer therapies, and our future success will in part depend on our personalized cancer customers obtaining regulatory approval for and commercializing their product candidates. Because personalized cancer therapies represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing personalized cancer therapies is subject to a number of challenges.

Actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical studies, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market requirements, and additional information regarding benefits or risks of our services may emerge at any time prior to or after regulatory approval.

In the European Economic Area (and Northern Ireland) ("EEA"), in order to place an in vitro diagnostic medical device ("IVD"), or an accessory to an IVD, on the market, or put it into service in the EEA, the device must be designed, developed, manufactured and marketed in compliance with the relevant legal framework. On May 26, 2022, the Regulation on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746) ("IVDR") entered into application, repealing and replacing the Directive on In-Vitro Diagnostic Devices (98/79/EC) (the "IVDD"). The IVDR and its associated guidance documents and harmonized standards governing, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs must comply with the General Safety and Performance Requirements ("GSPRs") set out in Annex I of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE Mark to IVDs, without which they cannot be marketed or sold in the EEA.

In accordance with the IVDR, devices that are not placed on the market but are used within the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, or by other means of communication, directly or through intermediaries, to a natural or legal person established in the EEA (and Northern Ireland) will be subject to the IVDR. As a result, diagnostic and therapeutic services offered to customers in the EEA (and Northern Ireland) (whether directly or via intermediaries) by providers that are based outside the EEA will be covered by the IVDR.

Fulfillment of the obligations imposed by the IVDR are likely to increase the cost and time required in order to obtain regulatory approval for products and services in the EEA. If we offer tests or services to customers within the EEA (and Northern Ireland) (whether directly or via intermediaries) that fall within the scope of the IVDR, we may be unable to fulfill these obligations, or a notified body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the IVDR. Our ability, and the ability of our customers, to commercialize diagnostic tests based on our technology will depend in part on the extent to which coverage and reimbursement for these tests will be available from third-party payors. Coverage and reimbursement of new products and services is uncertain, and whether the companies that use our instruments to develop their own products or services will attain coverage and adequate reimbursement is unknown. In the U.S. and the EU, there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement.

Physicians, hospitals, and third-party payors often are slow to adopt new products, services, technologies, and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt personalized cancer therapies, may decide that such therapies are too complex to adopt without appropriate training or not cost-efficient, and may choose not to administer these therapies. Based on these and other factors, hospitals and payors may decide that the benefits of personalized cancer therapies do not or will not outweigh their costs.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience, and performance of key members of our executive management team and others in key management positions. The collective efforts of each of our executives and others working with them as a team are critical to us as we continue to develop our technologies, services, products, and research and development programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Effective December 31, 2022, John West retired from his role as our Chief Executive Officer and Aaron Tachibana, our Chief Financial Officer, was appointed to serve as our interim Chief Executive Officer and Christopher Hall, our SVP and Head, Diagnostics Business, was appointed to serve as our President. As with any change in leadership, there is a risk to organizational effectiveness and employee retention as well as the potential for disruption to our business. Integrating members into new or different management roles could prove disruptive to our operations, require substantial resources and management attention and ultimately prove unsuccessful. Each member of our executive management team has an employment agreement; however, the existence of an employment agreement

does not guarantee retention of members of our executive management team, and we may not be able to retain those individuals or replace them in the event we lose their services. We do not maintain “key person” life insurance on any of our employees.

In addition, we rely on collaborators, consultants, and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants, and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

The loss or extended illness of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

We rely on highly skilled personnel in a broad array of disciplines and if we are unable to hire, retain, or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depends on our continuing ability to identify, hire, develop, motivate, and retain highly skilled personnel for all areas of our organization. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future, including bioinformatic scientists, bioinformatic engineers, software engineers, statisticians, variant curators, clinical laboratory scientists (“CLS”), and genetic counselors, due to the competition for qualified personnel among life science businesses, technology companies, as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. For example, California has a shortage of qualified CLS, who must be licensed by the California Department of Public Health to perform clinical testing in laboratories located in California such as our CLIA-certified and CAP-accredited laboratory. We face intense competition for, and we have experienced and may in the future experience difficulty attracting and retaining, sufficient numbers of licensed and qualified CLS to support the needs of our business and our laboratory capacity expansion efforts. All of our U.S. employees are at-will, which means that either we or the employee may terminate their employment at any time. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees for reasons that may include movements in our stock price. If we are not able to attract and retain the necessary personnel, including licensed and qualified CLS, to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business and support our research and development efforts and our laboratory operations. We believe that our corporate culture fosters innovation, creativity, and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

Our planned opening of our new laboratory facilities in Fremont, California has diverted and could continue to divert management’s attention and has disrupted and could continue to disrupt our ongoing business.

We have relocated our corporate headquarters to Fremont, California. We also plan to move our laboratory operations to our Fremont facility in 2023. These efforts have involved, and will continue to involve, significant tenant improvements, construction and regulatory compliance activities to be undertaken. Such efforts have distracted and may continue to distract management from current operations, have disrupted and may continue to disrupt planned research, development or regulatory compliance activities, and have resulted in and may continue to result in greater than expected liabilities and expenses, any of which could result in a material adverse effect on our business prospects, financial condition, or results of operations. For example, delays in the completion of updates to our new corporate headquarters delayed our previously planned move-in date. In addition, since January 20, 2023, we have experienced substantial disruption to our use of the Fremont facility due to a failure of a bus duct serving the facility. Since that time, we have been using, and we may need to continue using, backup generators to power our laboratories and emergency lights at the facility, and we have been, and may continue to be, unable to use the office and manufacturing portions of the facility, or use the facility’s heating, ventilation and air conditioning system. We have incurred, and may continue to incur, costs in maintaining temporary power to the facility and in attempting to permanently remedy the problem, including obtaining additional backup generators, equipment, and back up batteries, and purchasing fuel for the generators on a daily basis. While the bus duct and related electrical main equipment are the landlord’s responsibility under our lease for the facility, and we expect the landlord to reimburse our costs incurred in connection with remedying the electrical failure, there is no guarantee we will be successful in obtaining such reimbursement within a reasonable timeframe or at all. Although we are still able to conduct most or all of our laboratory operations from our facility in Menlo Park, California, if we are unable to restore permanent power to our Fremont facility within a reasonable time, it could further delay the completion of our move to the Fremont facility, may result in a loss in productivity, including delays to research and development programs, and could render it difficult or impossible for us to sell or perform certain of our services for some period of time. Additionally, if the backup generators were to fail, it could result in damage to biological samples stored within the Fremont facility, which may include certain customer samples. See “—If our facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.”

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative, and operational infrastructure, including facilities (such as our new facility in Fremont, California), laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand

as our test volume grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and management controls, as well as our reporting systems and procedures. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We may also pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. As an organization, we have limited experience with respect to acquisitions as well as the formation of strategic alliances and joint ventures. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, and their consideration may be distracting to our management or prevent us from pursuing other opportunities. In addition, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future such transactions by us also could result in significant write-offs, the incurrence of debt and contingent liabilities, exposure to additional liability, exposure to additional revenue concentration, additional regulatory obligations and exposure to additional potential liability, any of which could harm our operating results and future prospects. If we make any acquisitions in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Integration of an acquired company or business also may require management resources that otherwise would be available for ongoing development of our existing business.

To finance any acquisitions or investments, we may choose to raise additional funds. The various ways we could raise additional funds carry potential risks. See "—Financial and Market Risks and Risks Related to Owning Our Common Stock—Our inability to raise additional capital on acceptable terms in the future may limit our ability to continue to operate our business and further expand our operations." If the price of our common stock is low or volatile, we may not be able to acquire other companies using stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Ethical, legal, and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal, and social concerns regarding privacy and the appropriate uses of the resulting information. Governmental authorities have, through the Genetic Information Nondisclosure Act, and could further, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Ethical and social concerns may also influence governmental authorities to deny or delay the issuance of patents for technology relevant to our business. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genetic tests even if permissible. These and other ethical, legal, and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition, or results of operations.

Any collaboration arrangements that we have entered into or may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our services and products.

Any current or future collaborations, including any strategic alliances or any collaborations to develop companion diagnostic tests, that we have entered (for example, our collaborations with BC Cancer, Duke University, UCSF, and Criterium (d/b/a Academic Breast Cancer Consortium)) or may enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which include that:

- we may incur increased research and development expenses, and such activities may also divert management attention and resources and/or create competing internal priorities for us, which could prevent us from successfully conducting other parts of our business or collaborating with others;
- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our services or products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive services or products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities for our collaborator;
- collaborators could independently develop, or develop with third parties, services or products that compete directly or indirectly with our services or products;
- collaborators with marketing, manufacturing, and distribution rights to one or more services or products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- a large percentage of our revenue may be concentrated with the collaborators if the collaborations are successful and we may experience further losses if they are or later become unsuccessful;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future services or products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future services or products;
- collaborators may own or co-own intellectual property covering our services or products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- collaborators' activities or use of our services or deliverables may create additional regulatory obligations and could lead to side effects or adverse events in patients, exposing us to potential liability or regulatory review; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Our operations and employees face risks related to health crises that could adversely affect our operations, our financial condition, and the business or operations of our customers or other third parties with whom we conduct business.

Our business could be adversely impacted by the effects of a health crisis that could cause significant disruption in the operations of our customers and third-party suppliers upon whom we rely. Our laboratory facilities, executive team, and most of our employees are located in the San Francisco Bay Area. In the event of a health crisis that becomes widespread in or around the San Francisco Bay Area, we may proactively, or be ordered by government officials to, take precautionary measures such as suspending our lab operations, implementing alternative work arrangements for our employees, and limiting our employees' travel activities.

Our operations were previously impacted by the COVID-19 pandemic. For example, the previous shelter-in-place order and health orders negatively impacted productivity, disrupted our business, and slowed research and development activities due to us limiting access to our laboratory space that would otherwise be used by our research and development group, and, to the extent such orders return in similar or more stringent form, they may cause similar effects on our operations. COVID-19 disrupted, and may disrupt in the future, the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we use certain consumables in our operations, and we have faced, and may face in the future, difficulties in acquiring such consumables if our suppliers prioritize orders related to COVID-19 or another health epidemic or pandemic or if other supply chain issues arise as a result of such a public health crisis. Several of our customers were delayed in sending us samples due to the inability to collect or ship samples during the COVID-19 pandemic, and these and additional customers may be disrupted from collecting samples or sending purchase orders or samples to us in the future in the event of a resurgence of COVID-19 or the emergence of another health epidemic or pandemic.

Moreover, the ultimate impact of a health epidemic or pandemic on our business, operations, or the global economy as a whole is highly uncertain, but a continued and prolonged public health crisis could have a material negative impact on our business, financial condition, and operating results.

Expansion into international markets would subject us to increased regulatory oversight and regulatory, economic, social, health and political uncertainties, which could cause a material adverse effect on our business, financial position, and results of operations.

We may in the future expand our business and operations into international jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals and marketing and selling products and services. As we expand internationally, our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, increased government regulation, social instability, local or regional health crises, and political, economic or diplomatic developments in the future. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations in such jurisdictions to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, anti-bribery and anti-corruption laws may conflict with some local customs and practices in foreign jurisdictions. Our international operations may subject us to heightened scrutiny under the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the United Kingdom (the "U.K.") Bribery Act and similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws. As a result of our policy to comply with the FCPA, the U.K. Bribery Act and similar anti-bribery laws, we may be at a competitive

disadvantage to competitors that are not subject to, or do not comply with, such laws. Further, notwithstanding our compliance programs, there can be no assurances that our policies will prevent our employees or agents from violating these laws or protect us from any such violations. Additionally, we cannot predict the nature, scope or impact of any future regulatory requirements that may apply to our international operations or how foreign governments will interpret existing or new laws. Alleged, perceived, or actual violations of any such existing or future laws by us or due to the acts of others, may result in criminal or civil sanctions, including contract cancellations or debarment, and damage to our reputation, any of which could have a material adverse effect on our business.

Regulatory, Legal and Cybersecurity Risks

Our tests may be subject to regulatory action if regulatory agencies determine that our tests do not appropriately comply with statutory and regulatory requirements enforced by the FDA, or equivalent foreign regulatory authorities and/or CLIA requirements for quality laboratory testing or equivalent foreign requirements.

The laws and regulations governing the marketing of clinical laboratory tests are extremely complex and in many instances there are no significant regulatory or judicial interpretations of these laws and regulations. The Federal Food, Drug and Cosmetic Act (the "FDC Act") 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. Some of our tests may be considered by the FDA to be in vitro diagnostic products that are subject to regulation as medical devices. Among other things, pursuant to the FDC Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the U.S. 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.

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs, which are a subset of in vitro diagnostic devices that are intended for clinical use and designed, manufactured, and used entirely within a single laboratory. We currently market our tests as LDTs and, therefore, we believe that they are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions. Despite the FDA's historic enforcement discretion policy with respect to LDTs, in November 2017, the FDA finalized a classification order setting out the regulatory requirements that apply to certain genetic health risk tests and revised a separate classification order exempting certain carrier screening tests from FDA premarket clearance and approval requirements when certain regulatory requirements are met. None of our tests comply with these classification orders because we market our tests as LDTs that are subject to the FDA's policy of enforcement discretion. However, the FDA may find that our tests do not fall within the definition of an LDT, and may determine that our tests are subject to the FDA's enforcement of its medical device regulations, including the recent classification orders, and the applicable FDC Act provisions. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition. If the FDA determines that our tests are subject to enforcement as medical devices, we could be subject to enforcement action, including administrative and judicial sanctions, and additional regulatory controls and submissions for our tests, all of which could be burdensome. We and/or our collaborators may also voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices. For example, under our collaboration with MapKure, we expect to develop new, advanced biomarkers selected by MapKure for regulatory submission and approval as a companion diagnostic, in which case we would also be subject to potentially burdensome additional regulatory controls and submissions for one or more of our tests. See "—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."

Moreover, LDTs may in the future become subject to more onerous regulation by the FDA. A significant change in any of the laws, regulations, or policies may require us to change our business model in order to maintain regulatory compliance. At various times since 2006, the FDA has issued documents outlining its intent to require varying levels of FDA oversight of many types of LDTs. In October 2014, the FDA issued two non-binding draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA indicated that it did not intend to implement its proposed framework until the draft guidance documents are finalized. The FDA was expected to finalize its proposal for the oversight of LDTs before the end of 2016, but in November 2016, the FDA announced that it would halt finalizing of the guidance documents and continue to work with stakeholders, the incoming administration, and Congress on the approach to LDT regulation. This announcement was followed by the issuance of an information discussion paper on January 13, 2017, in which the FDA outlined a substantially revised "possible approach" to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it is not enforceable and does not represent the FDA's "formal position." It is unclear at this time if or when the FDA will finalize its plans to end enforcement discretion for LDTs, and even then, whether the new regulatory requirements are expected to be phased-in over time. However, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.

Legislative proposals addressing oversight of genetic testing and LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time to time in the future. For example, the proposed "Verifying Accurate, Leading-edge IVCT Development" Act (the "VALID Act") would clarify and enhance FDA's authority to regulate LDTs, including pre-

market review of non-exempted tests. We cannot predict whether the VALID Act will become legislation and cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through finalization of guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA that may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. This legislative and regulatory uncertainty exposes us to the possibility of enforcement action or additional regulatory controls and submissions for our tests, both of which could be burdensome. In addition, we cannot be certain that the FDA will not enact rules or guidance documents that could impact our ability to purchase certain materials necessary for the performance of our tests, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting, or prohibiting the purchase of reagents necessary to perform testing.

In the EEA, IVDs are governed by the IVDR and must comply with the requirements of the IVDR in order to be placed on the market or put into service in the EEA. The IVDR does not specifically address the regulation of products falling within the description "laboratory-developed tests". Moreover, while the Regulation includes only limited exemptions for devices that are manufactured and used only within health institutions established in the EEA, diagnostic and therapeutic services undertaken outside of the EEA (for example at our facilities in the U.S.) would not fall within the scope of such exemptions. We do not currently offer tests or services to customers established in the EEA which would fall within the scope of the IVDR. If, in the future, we offer tests or services to customers within the EEA (whether directly or via intermediaries) that fall within the scope of the IVDR, it is unlikely that we will benefit from IVDR exemptions foreseen for health institutions established in the EEA. This means that we will have to comply with the IVDR in full.

If the FDA determines that our services are subject to enforcement as medical devices, or if foreign regulatory authorities regulate our products as IVDs, we could incur substantial costs and time delays associated with satisfying statutory and regulatory requirements such as pre-market clearance, approval or certification, and we could incur additional expense in offering our tests and tests that we may develop in the future.

If the FDA determines that our tests and associated software do not fall within the definition of an LDT, or there are regulatory or legislative changes, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, we may be required to obtain premarket clearance for our tests and associated software under Section 510(k) of the FDC Act or approval of a premarket approval application (“PMA”). We would also be subject to ongoing regulatory requirements such as registration and listing requirements, medical device reporting requirements, and quality control requirements. If our tests are considered medical devices not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, the regulatory requirements to which our tests are subject would depend on the FDA’s classification of our tests. The FDA has issued regulations classifying generic types of medical devices into one of three regulatory control categories (Class I, Class II, or Class III) depending on the degree of regulation that the FDA finds necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet both pre- and post-market.

Generally, Class I devices do not require premarket authorization, but are subject to a comprehensive set of regulatory authorities referred to as general controls. Class II devices, in addition to general controls, generally require special controls and premarket clearance through the submission of a section 510(k) premarket notification. Class III devices are subject to general controls and special controls, and also require premarket approval prior to commercial distribution, which is a more rigorous process than premarket clearance. Under the FDC Act, a device that is first marketed after May 28, 1976 is by default a Class III device requiring premarket approval unless it is within a type of generic device class that has been classified as Class I or Class II. Even if a device falls under an existing Class II, non-exempt, device classification, the device must also be shown to be “substantially equivalent” to a legally marketed predicate device through submission of a section 510(k) premarket notification. If after reviewing a firm’s 510(k) premarket notification, the FDA determines that a device is not substantially equivalent to a legally marketed predicate device, the new device is classified into Class III, requiring premarket approval. It is possible for a manufacturer to obtain a Class I or Class II designation without an appropriate predicate by submitting a de novo request for reclassification.

The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy, and uncertain. It generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all.

If our tests are considered medical devices not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, one classification regulation that could be relevant to one or more of our tests is a classification for genetic health risk (“GHR”) assessment tests, codified at 21 C.F.R. § 866.5950. If our tests are considered medical devices that are not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, and one or more of our tests is considered to fall under the 21 C.F.R. § 866.5950 classification regulation for GHR tests, or under another Class II classification that is subject to a premarket notification requirement, we would be required to obtain marketing clearance for such tests. Further, if considered to fall under the 21 C.F.R. § 866.5950 classification for GHR tests, our tests would be required to adhere to specified special controls, such as labeling and testing specifications and information about the test to be posted on the manufacturer’s website. If any of our current or pipeline tests

are not considered by the FDA to be GHR tests or do not qualify for the limited exemption for a sponsor's subsequent GHR tests once the assessment system has been reviewed and cleared by FDA, or if any of our tests fall under a different non-exempt classification or are unclassified, we could be required to obtain 510(k) clearance or approval of a PMA for such test in the future.

If premarket review of our tests is required, the premarket review process may involve, among other things, successfully completing additional clinical trials. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our service and product development costs, delay commercialization of any future services or products, and interrupt sales of our current services and products. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the concerns around genetic testing, the nature of the protocol, the proximity of patients to clinical sites, and the eligibility criteria for the clinical trial.

If we are required to conduct clinical trials, we and any third-party contractors we engage would be required to comply with good clinical practices ("GCPs"), which are regulations and guidelines enforced by the FDA, for devices in clinical development. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests or to achieve or sustain profitability. Similar actions and obligations may be imposed by the competent authorities of an EU Member State, or a foreign regulatory authority.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, set forth in the Quality System Regulation at 21 C.F.R. Part 820, which requires manufacturers to follow elaborate design, testing, control, documentation, and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device or a similar device they market 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 it were to recur; labeling regulations, including the FDA's general prohibition against promoting devices for unapproved or "off-label" uses; the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device which may present a risk to health; and the establishment registration and device listing regulation.

Moreover, there can be no assurance that any cleared or approved labeling claims will be consistent with our current claims or adequate to support continued adoption of our services and products. If premarket review is required for some or all of our services and products, the FDA may require that we stop selling such services and products pending clearance or approval, which would negatively impact our business. Even if our services and products are allowed to remain on the market prior to clearance or approval, demand for our services and products may decline if there is uncertainty about our services or products, if we are required to label our services or products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our services or products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our services and products, or from other services or products now in development.

In addition, any clearance or approval we obtain for our services or products may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the product. The FDA has broad post-market enforcement powers, and if unanticipated problems with our services or products arise, or if we or our suppliers fail to comply with regulatory requirements following FDA clearance or approval, we may become subject to enforcement actions such as:

- restrictions on manufacturing processes;
- restrictions on service or product marketing;
- warning letters;
- withdrawal or recall of services or products from the market;
- refusal to approve pending PMAs, 510(k)s, or supplements to approved PMAs or cleared 510(k)s that we submit;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory clearances or approvals;
- limitation on, or refusal to permit, import or export of our products;

- product seizures;
- injunctions; or
- imposition of civil or criminal penalties.

Moreover, the FDA strictly regulates the promotional claims that may be made about medical devices. In particular, a medical device may not be promoted for uses that are not approved by the FDA as reflected in the device's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the device's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal, and administrative penalties.

In addition, many of the products we use to perform our tests, including sequencers and various associated reagents supplied to us by Illumina, are labeled as research use only ("RUO") in the U.S. RUO products are exempt from FDA medical device requirements provided their manufacturers comply with specified labeling and restrictions on distribution. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." Manufacturers of RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and RUO products cannot be intended by the manufacturer for clinical diagnostic use. A product promoted for diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities, including requiring the manufacturer to seek marketing authorization for the products. We currently use Illumina and other RUO products for our clinical diagnostic tests. If the FDA were to require clearance, approval or authorization for the sale of Illumina's RUO products and if Illumina does not obtain such clearance, approval or authorization, we would have to find an alternative sequencing platform for some or all of our clinical diagnostic tests. We currently have not validated an alternative sequencing platform on which our tests could be run in a commercially viable manner. If we were not successful in selecting, acquiring on commercially reasonable terms and implementing an alternative platform on a timely basis, our business, financial condition and results of operations would be adversely affected. Similarly, a finding that any of our other suppliers failed to comply with applicable requirements could result in interruptions in our ability to supply our services to the market and adversely affect our operations.

In addition, if we offer tests or services to customers within the EEA (and Northern Ireland) (whether directly or via intermediaries) that fall within the scope of the IVDR, we would be required to comply with strict requirements in order to affix the CE mark to our products, including requirements for clinical evidence, pre-market assessment of safety and performance, quality management system, traceability of products, promotion and advertising, and conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EEA and detailed reporting obligations.

Failure to comply with federal, state, and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, or equivalent foreign 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 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. We have a current CLIA certificate to conduct our tests at our laboratory in Menlo Park, California. To renew this certificate, we are subject to survey and inspection every two years. Because we are a CAP-accredited laboratory, the 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. To operate our laboratory in the new Fremont facility, we will need to transfer our existing certification.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory in Menlo Park, including the training and skills required of personnel and quality control. Several other states in which we operate also require that we hold licenses to test specimens from patients in those states, under certain circumstances. For example, our clinical reference laboratory is required to be licensed on a test-specific basis by New York as an out-of-state laboratory, and our LDTs must be approved by the New York State Department of Health (the "NYDOH") on a test-by-test basis before they are offered in New York. We are subject to periodic inspection by the NYDOH and are required to demonstrate ongoing compliance with NYDOH regulations and standards. To the extent NYDOH 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. Additionally, states such as Maryland, Pennsylvania, and Rhode Island also require us to maintain out-of-state licenses. Other states may have similar requirements or may adopt similar requirements in the future. Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future. We will need to transfer our existing state licenses to continue our current laboratory operation in the new Fremont facility. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or 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 human blood necessary for us to perform our tests that may limit our ability to make our tests available outside of the U.S. Complying with licensure requirements in new jurisdictions may be expensive and/or time-consuming, may subject us to significant and unanticipated delays, or may be in conflict with other applicable requirements.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, and criminal

sanctions as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition, and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

Failure to comply with the IVDR may result in a range of enforcement actions by the regulatory authorities of EU Member States as well as repercussions for any CE Certificates of Conformity issued by notified bodies, including fines, suspension variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Although we market our tests as LDTs that are currently subject to the FDA's exercise of enforcement discretion, if we fail to operate within the conditions of that exercise of enforcement discretion, if any of our services or products otherwise fail to comply with FDA regulatory requirements as enforced, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, we would be subject to the applicable requirements of the FDC Act and the FDA's implementing regulations. The FDA is empowered to impose sanctions for violations of the FDC Act and the FDA's implementing regulations, including warning letters, civil and criminal penalties, injunctions, product seizure or recall, import bans, restrictions on the conduct of our operations and total or partial suspension of production. Any of the aforementioned sanctions could cause reputational damage, undermine our ability to maintain and increase our revenue, and harm our business, financial condition, and results of operations. In particular, if we or the FDA discover that any of our services or products have defects that call into question the accuracy of their results, we may be required to undertake a retest of all results and analyses provided during the period relevant to the defect, or recall the affected services and products. The direct costs incurred in connection with such a recall in terms of management time, administrative, and legal expenses and lost revenue, together with the indirect costs to our reputation could harm our business, financial condition, and results of operations, and our ability to execute our business strategy. While we believe that we are currently in material compliance with applicable laws and regulations as currently enforced, the FDA or other regulatory agencies may not agree, and a determination that we have violated these laws or a public announcement that we are being investigated for possible violations of these laws could adversely affect our business, financial condition, results of operations, and prospects.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we collect, process, receive, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share and store (collectively, "process") proprietary, confidential, and sensitive information, including protected health information ("PHI"), personal information, credit card and other financial information, intellectual property, trade secrets, medical information, biometric information and genomic information (collectively, "sensitive information") owned or controlled by ourselves or our customers, payors, and other parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, including the war in Ukraine, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell, and distribute our platform, products, and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, natural disasters, terrorism, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Most of our employees are working remotely at least part of the time and such remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, on-site systems and cloud-based data centers, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of sensitive information, including research and development information, patient data, commercial information, and business and financial information. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place. If any of our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if any of our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services.

Despite the measures we have taken to prevent 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 conducting tests, preparing and providing reports to our customers, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, and managing the administrative aspects of our business. For example, in 2018, we experienced downtime in our information technology systems in connection with the adoption of certain new information technology, and our results of operations in the first and second quarters of 2018 were adversely affected as a result. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our platform, products, and services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain certain measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, if the information technology systems of the third parties upon which we rely become subject to security incidents, we may have insufficient recourse against such third parties, and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Unauthorized access, loss, or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. For example, like many companies, we use Log4j with respect to certain software or systems to log security and performance information. In early 2022, we discovered a Log4j vulnerability in our environment although to date we have found no indication that our or our partners' data was exposed. Upon learning of this vulnerability, we applied a patch and made updates to our systems and infrastructure intended to reduce risks associated with the vulnerability.

Applicable data privacy and security obligations, including applicable federal and/or state breach notification laws and foreign equivalents, may require us to notify relevant stakeholders and other individuals of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our platform, products, and services, deter new customers from using our platform, products, and services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our data privacy and security practices. Additionally, we cannot be sure that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process sensitive information, including data we collect from our customers about trial participants in connection with clinical trials. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy, and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Penalties for failure to comply with HIPAA and HITECH include significant civil monetary penalties and criminal penalties in certain circumstances with fines up to $250,000 per violation and/or imprisonment. 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. 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 and applicable to us, 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. Similarly, the California Consumer Privacy Act of 2018 (“CCPA”) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase our compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the California Privacy Rights Act of 2020 expands the CCPA’s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado, Connecticut and Utah have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely and our customers. Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information.

Outside the U.S., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the General Data Protection Regulation 2016/679 (“EU GDPR”), the United Kingdom’s GDPR (“UK GDPR”), Brazil’s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais) (Law No. 13,709/2018), and China’s Personal Information Protection Law (“PIPL”) impose strict requirements for processing personal information. Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, the Personal Information Protection and Electronic Documents Act (“PIPEDA”) and various related provincial laws, as well as Canada’s Anti-Spam Legislation (“CASL”), applies to our operations. We also receive personal information from customers in Asia and may be subject to new and emerging data privacy and security regimes in Asia, including Japan’s Act on the Protection of Personal Information.

In the ordinary course of business, we may transfer personal information from Europe and other jurisdictions to the U.S. or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the EEA and the U.K. have significantly restricted the transfer of personal information to the U.S. and other countries whose data privacy and security laws they believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and U.K. to the U.S. in compliance with law, such as the EEA and UK’s standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the U.S. If there is no lawful manner for us to transfer personal information from the EEA, the U.K. or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Additionally, companies that transfer personal information out of the EEA and U.K. to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR’s cross-border data transfer limitations. EEA countries may also introduce national legislation further limiting the processing of personal genetic, biometric, or health data, which could limit our ability to collect, use and share data originating from the EEA, or could cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition.

In addition to data privacy and security laws, because we process some credit card payments through a third-party payment processing partner, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. For example, we may also be subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from $5,000 to $100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We also rely on vendors to process payment card data, who may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our platform, products and/or services, information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change our business model. Our business model materially depends on our ability to process personal information, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. For example, because we process PHI, personal information and sensitive information, we may be at heightened risk of regulatory scrutiny, and any changes in the regulatory framework could require us to fundamentally change our business model, including causing us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We typically rely on our customers to obtain valid and appropriate consents from data subjects whose genetic samples and data we process on such customers' behalf particularly with respect to our RUO and clinical trial services, and we also typically rely on each provider ordering our LDTs or diagnostic services to obtain valid and appropriate consent from each of his or her patients whose genetic samples and data we process on such patient's behalf. Given that we do not typically obtain direct consent from such data subjects or patients, and we do not audit our customers or the ordering providers to ensure that they have obtained the necessary consents required by law, the failure of our customers or the order providers to obtain consents that are valid under applicable law could result in our own non-compliance with data privacy and security laws. For example, our NeXT Personal RUO test leverages WGS, and the scope of existing consents from our customers' clinical trial subjects may be insufficient to cover use of NeXT Personal on their samples, which may either limit uptake of NeXT Personal or expose our customers and ourselves to risk of exceeding the scope of prior consent for specimen testing. If we fail, or are perceived to have failed, to address or comply with U.S. and foreign privacy, data protection, and data security laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data privacy and security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our platform, products, and services; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with government regulations, including federal and state healthcare fraud and abuse laws and regulations, to misuse information, including patient information, and to report financial information or data accurately or disclose unauthorized activities to us. 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 have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such 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 have a significant impact on our business and results of operations, including the imposition of significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from government healthcare programs, contractual

damages, refunding of payments received by us, reputational harm, 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. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

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

- the federal Anti-Kickback Statute, which 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 a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim under the False Claims Act;
- the Anti-Markup Rule, which, among other things, prohibit a physician or supplier billing the Medicare program from marking up the price of a purchased diagnostic service performed by another laboratory or supplier that does not “share a practice” with the billing physician or supplier. Penalties may apply to the billing physician or supplier if Medicare or another payer is billed at a rate that exceeds the performing laboratory’s charges to the billing physician or supplier, and the performing laboratory could be at risk under false claims laws, described below, for causing the submission of a false claim;
- the 14-Day Rule, also known as the Medicare Date of Service Rule, which prohibits a laboratory supplier from billing the Medicare program for tests performed on samples collected during or within 14 days of an inpatient hospital stay, unless an exception applies, and requires the laboratory supplier to bill the hospital in those cases. Penalties may apply to the laboratory supplier if Medicare determines that the Medicare program was inappropriately billed for testing that should have been billed to the hospital where the sample was collected;
- state client billing laws, which specify whether a person that did not perform the service is permitted to submit the claim for payment and if so, whether the non-performing person is permitted to mark up the cost of the services in excess of the price the purchasing provider paid for such services. For example, California has an anti-markup statute which prohibits providers from charging for any laboratory test that it did not perform unless the provider (a) notifies the patient, client or customer of the name, address, and charges of the laboratory performing the test, and (b) charges no more than what the provider was charged by the clinical laboratory which performed the test except for any other service actually rendered to the patient by the provider (for example, specimen collection, processing and handling) (California Business and Professions Code Section 655.5). This provision applies, with certain limited exceptions, to licensed persons such as physicians and clinical laboratories regulated under the Business and Professions Code. In addition, many states also have “direct-bill” laws, which means that the services actually performed by an individual or entity must be billed by such individual or entity, thus preventing ordering physicians from purchasing services from a laboratory and rebilling for the services they order. For example, California has a direct bill rule specific to anatomic pathology services that prohibits any provider from billing for anatomic pathology services if those services were not actually rendered by that person or under his or her direct supervision with some exemptions (California Business and Professions Code Section 655.7);
- the federal civil and criminal false claims laws, including the False Claims Act, which impose 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. These laws can apply to entities that provide information on coverage, coding, and reimbursement of their products and services and assistance with obtaining reimbursement to persons who bill payors. Private individuals can bring False Claims Act “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;
- 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, biologicals, and 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, with certain exceptions, to report annually to the Centers

for Medicare & Medicaid Services ("CMS") information related to (i) payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members;

- the HIPAA fraud and abuse provisions, which created federal civil and criminal statutes that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense, and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, 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;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, known as business associates, as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”), which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and is similar to the federal Anti-Kickback Statute in that it creates criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing unless a specific exception applies. Unlike the federal Anti-Kickback Statute, EKRA’s reach extends beyond federal health care programs to include private insurance (i.e., it is an “all payer” statute). Additionally, most of the safe harbors available under the federal Anti-Kickback Statute are not reiterated under EKRA, and certain EKRA safe harbors conflict with the safe harbors available under the federal Anti-Kickback Statute. Therefore, compliance with a federal Anti-Kickback safe harbor does not guarantee protection under EKRA. Because EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be interpreted, applied and enforced by the government. Currently, there is no proposed regulation interpreting or implementing EKRA, nor any public guidance released by a federal agency concerning EKRA;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any payer, including private insurers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing physicians for testing that they order as discussed above; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; employing, exercising control over, licensed professionals in violation of state laws prohibiting corporate practice of medicine and other professions, and prohibitions against the splitting of professional fees with licensed professionals; and
- similar foreign laws and regulations that apply to us 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 government regulatory agencies such as the Department of Justice, the HHS Office of Inspector General (the “OIG”), and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the Anti-Kickback Statute. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from patients. 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 applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories.

The growth of our business, including services we provide under our agreement with Natera, and our expansion outside of the U.S. may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and reputational harm and divert our management’s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, integrity oversight and reporting obligations, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We could be adversely affected by violations of the FCPA and other worldwide 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. Other U.S. companies in the medical device and pharmaceutical fields 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 U.K.'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 you 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, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

Changes in health care policy could increase our costs, decrease our revenue, and impact sales of and reimbursement for our tests.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "ACA"), became law. This law substantially changed the way health care is financed by both commercial payers and government payers, and significantly impacts our industry. The ACA contains a number of provisions that are expected to impact the business and operations of our customers, some of which in ways we cannot currently predict, including those governing enrollment in state and federal health care programs, reimbursement changes, and fraud and abuse, which will impact existing state and federal health care programs and will result in the development of new programs.

Among other things, the ACA:

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research; and
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the former Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, former President Trump signed several Executive Orders and other directives to delay the implementation of certain requirements of the ACA. Concurrently, Congress considered legislation that would repeal, or repeal and replace, all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's "individual mandate" to carry health insurance and eliminating the implementation of certain ACA-mandated fees. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA 2022") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. Efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA create considerable uncertainties for all businesses involved in healthcare, including our own. It is unclear how such future efforts to repeal and replace the ACA will impact the ACA and our business. Additional legislation may be enacted that further amends, or repeals, the ACA, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our and our customers' business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain until 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicate payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA") repealed the formula by which Medicare made annual payment adjustments to physicians and

replaced the former formula with fixed annual updates, and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the APMs, and the Merit-based Incentive Payment System. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will continue to impact physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payer payment rates and volumes for their tests. CMS will use this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare reimbursement rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2023 and March 31, 2023, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2024 to 2026 Clinical Laboratory Fee Schedule rates. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our current tests or those in development.

Pursuant to the CARES Act, the statutory phase-in of the payment reductions has been extended through 2024 with a 0% reduction cap for 2021-2022 and a 15% reduction cap for 2023 through 2025. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows. We also anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and private payers to reduce 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 payers, including commercial payers and government payers.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of an accidental environmental release or injury to employees or third parties from the use, storage, handling, or disposal of these materials. In the event of an environmental release or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of maintaining compliance with these laws and regulations may become significant and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

Changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, former President Trump signed into law comprehensive tax legislation (the "Tax Cuts and Jobs Act") that significantly revised the Internal Revenue Code of 1986, as amended (the "Code"). Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, on March 27, 2020, the CARES Act was enacted, which includes changes to the tax provisions that benefit business entities and makes certain technical corrections to the Tax Cuts and Jobs Act. On December 27, 2020, the Consolidated Appropriations Act, a coronavirus relief package that extended and expanded various tax provisions, was signed into law. The IRA 2022 includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act, or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, IRA 2022, or any newly enacted federal tax legislation.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories, as well as various non-U.S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each jurisdiction. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the Tax Cuts and Jobs Act and the CARES Act, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. The foregoing items could increase our future tax expense, change our future intentions regarding reinvestment of foreign earnings, and could have a material

adverse effect on our business, financial condition and results of operations. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

The exit of the U.K. from the EU could lead to further regulatory divergence and require us to incur additional expenses in order to develop, manufacture, and commercialize our products and services.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as “Brexit.” Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (the “Transition Period”), during which EU rules continued to apply. The U.K. and the EU have signed the EU-U.K. Trade and Cooperation Agreement ("TCA"), which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the U.K. and EU's relationship will operate in the future. However, there are still many uncertainties. On May 26, 2022, the IVDR entered into application in the EU. However, the IVDR is not applicable in the U.K. In the U.K., IVDs are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which retains a regulatory framework similar to the framework set out by the IVDD. As a result, there will be some regulatory divergence in the U.K. from the EU in light of the fact that the CE marking process is set out in EU law, which no longer applies in the U.K. The U.K. has devised a new route to market culminating in a U.K. Conformity Assessed ("UKCA") mark to replace the CE Mark for placing IVDs on the market in Great Britain (“G.B.”). Northern Ireland will, however, continue to be covered by the regulations governing CE Marks (a CE Mark or a CE Mark and UKNI Mark will be required to place products on the Northern Ireland market). It is anticipated that CE Marks will, at least in the short term, continue to be recognized in G.B. for medical devices until June 30, 2024, however, all medical devices and IVDs must be registered with the MHRA, in order to be placed on the G.B. market. The EU legal framework, including the IVDR, remains applicable in Northern Ireland (any products placed on the market in the NI must be compliant with EU law). From July 1, 2024, in principle, a UKCA mark will be required in order to place a device on the G.B. market. The nature of any new regulation in the U.K. is uncertain, and as such, we may experience delays in obtaining future access to the U.K. and other European markets. The U.K.’s departure from the EU has also impacted customs regulations and impacted timing and ease of shipments into the EU from the U.K.

Should the U.K. or G.B. further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees in the U.K., particularly those from the EU.

Our business could be negatively impacted by environmental, social and corporate governance (ESG) matters or our reporting of such matters.

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. Moreover, the SEC has recently proposed, and may continue to propose, certain mandated ESG reporting requirements, such as the SEC's proposed rules designed to enhance and standardize climate-related disclosures, which, if finally approved, would significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation and/or that harm our stock price. We currently do not report our environmental emissions and absent a legal requirement to do so we currently do not plan to report our environmental emissions, and lack of reporting could result in certain investors declining to invest in our common stock.

Intellectual Property Risks

Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price, any of which could have a material adverse effect.

Our commercial success will depend, in part, on our avoiding infringement of patents and the infringement, misappropriation, or other violation of proprietary rights of third parties, including, for example, the intellectual property of competitors. There is extensive intellectual property litigation involving the biotechnology and pharmaceutical industries and genetic sequencing technology, including with regard to liquid biopsy assays such as those designed to detect or quantify MRD or recurrence in patients previously diagnosed with cancer. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign patents and pending patent applications exist in the genetic testing market and are owned by third parties. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. For example, we are aware of several third-party issued U.S. patents and pending patent applications with claims relating to genetic sequencing technology and methodology that may be asserted against us and may be construed to encompass our products and services. In order to avoid liability related to an allegation of infringement of these third-party patents, we may find it necessary or prudent to initiate invalidity proceedings against such patents or to obtain licenses from such third-party intellectual property holders. If we are not able to invalidate such patents or obtain or maintain a license on commercially reasonable terms and such third parties assert infringement claims against us, we may be prevented from exploiting our technology and our business, financial condition, results of operations, and prospects may be materially and adversely

affected. We may also be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Patent applications in the U.S. and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the U.S. can remain confidential until patents issue. Therefore, patent applications covering our products, services, or technologies could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products, services, technologies, and their use. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent, and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and services. Further, we may incorrectly determine that our technologies, products, or services are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or services.

Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our technologies, products, and services. Regardless of the merit of third parties' claims against us for infringement, misappropriation, or violations of their intellectual property rights, such third parties may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, even if such claims are resolved in our favor, could cause us to incur substantial expenses and be a substantial diversion of our employee resources even if we are ultimately successful. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources.

As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, other competitors or potential competitors might claim that our tests infringe, misappropriate, or violate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. If such a suit were brought, regardless of merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. Even if we are successful in defending against such a suit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products, services or technologies we may develop and any other technologies covered by the asserted third-party patents and any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement; obtain one or more licenses from third parties in order to continue developing and marketing our products, services and technology, which may not be available on commercially reasonable terms (if at all) or may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; pay substantial royalties and other fees; and redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure; or be prohibited from commercializing certain tests, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Where we collaborate with third parties in the development of technology, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers, and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new services or products in the future.

In the future, we may identify additional third-party intellectual property we may need to license in order to engage in our business, including to develop or commercialize new products or services. However, such licenses may not be available on acceptable terms, or at all. Even if such licenses are available, we may be required to pay the licensor substantial royalties based on sales of our products and services. Such royalties are a component of the cost of our products or services and may affect the margins on our products and services. In addition, such licenses may be nonexclusive, which could give our competitors access to the same intellectual property licensed to us. If we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if our licensors fail to abide by the terms of the licenses, if our licensors fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments or uncertainty in the patent statute, patent case law, or U.S. Patent and Trademark Office ("USPTO"), rules and regulations may impact the validity, scope or enforceability of our patent rights, thereby impairing our ability to protect our services and products.

Our patent rights, their associated costs, and the enforcement or defense of such patent rights may be affected by developments or uncertainty in the patent statute, patent case law, or USPTO rules and regulations.

The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. As such, we do not know the degree of future protection that we will have on our technologies, products, and services. While we will endeavor to try to protect our technologies, products, and services with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and sometimes unpredictable.

In addition, the patent position of companies engaged in the development and commercialization of diagnostic tests is particularly uncertain. Various courts, including the 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 a law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the U.S. 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 countries do not protect intellectual property rights to the same extent as the laws of the U.S., and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, and services are obtained, once the patent life has expired, we may be open to competition from competitive products or services. Our issued patents will expire on dates ranging from 2033 to 2038, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2042. In addition, although upon issuance in the U.S., a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products and services, our competitive position, business, financial condition, results of operations, and prospects will be adversely affected.

If we are not able to obtain and enforce patent protection for any services or products we develop and for our technologies, or if the scope of patent protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize products, services and technology similar or identical to ours, and our ability to successfully commercialize our products, services, and technologies may be adversely affected.

We have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, the patent process is expensive, time consuming, and complex, and we may not be able to apply for patents on certain aspects of our services, products, and other technologies in a timely fashion, at a reasonable cost, in all jurisdictions or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.
Moreover, the patent position of biotechnology companies can be highly uncertain because it involves 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 U.S. 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 nucleic acid sequences.

Others may independently develop similar or alternative technologies or design around technologies for which we may not be able to obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated, rendered unenforceable or narrowed in scope after they are issued, and there is no guarantee any of our issued patents include or will include claims that are sufficiently broad to cover our products, services, and other technologies or to provide meaningful protection from our competitors. Consequently, we do not know whether any of our platform advances, products, services,

and other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies, services, or products in a non-infringing manner.

Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our technologies, products, and services, or prevent others from designing around our claims. Any finding that our patents or applications are invalid, unpatentable, or unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the granted claims thus attacked, or may lose the granted claims altogether. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, services, or products and compete directly with us, without payment to us, or result in our inability to commercialize our products, services, and technologies without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products, services, or technologies. In addition, there can be no assurance that:

- others will not or may not be able to make, use, offer to sell, or sell tests that are the same as or similar to our products or services but that are not covered by the claims of the patents that we own or license;
- we or our future licensors or collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our future licensors or collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable, and infringed;
- any issued patents that we own or may license will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop or in-license additional proprietary technologies that are patentable;
- pending patent applications that we own or may license will lead to issued patents;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products or services for sale in our major commercial markets.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability. Some of our patents or patent applications may be challenged at a future point in time in opposition, derivation, reexamination, *inter partes* review, post-grant review, or interference proceedings. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products, services, or technologies that we may develop, which could lead to increased competition to our business and harm our business. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our technologies, products, or services. Furthermore, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

It is also possible that we fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, *inter partes* review proceedings, or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the U.S. allow for various post-grant opposition proceedings, such as *inter partes* review proceedings, providing additional methods for others to challenge our patents. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

We are involved in legal proceedings to enforce our intellectual property rights and may in the future become involved in other lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and unsuccessful.

Our intellectual property rights involve complex factual, scientific and legal questions. We operate in an industry characterized by significant intellectual property litigation. Even though we may believe that we have a valid patent on a particular technology, others may infringe our patents or the patents of our licensing partners. For example, in August 2022, we filed an amended complaint in the U.S. District Court for the District of Colorado against Foresight for patent infringement and in October 2022 Foresight filed its answer and counterclaims (see the section titled "Contingencies" in Note 9 to our consolidated financial statements). Further, Foresight has filed four *inter partes* review petitions with the USPTO in an effort to invalidate the patents that we are asserting against Foresight in our patent infringement action. The USPTO has yet to issue a decision regarding whether it will institute the *inter partes* reviews. In addition, our patents or the patents of our licensors may become involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. Further in such proceedings, the defendant could counterclaim that our asserted patent covering our services or product is invalid or unenforceable, and the court may agree that our asserted patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our services or product or the services or products of our competitors. The outcome following legal 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. An adverse result in any litigation or other proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Such a loss of patent protection could have a material adverse impact on our business. 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.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position would be harmed.

We seek protection for certain aspects of our technologies, products, and services through the filing of patents, registration of copyrights, and use of non-disclosure agreements. In addition, we also rely on trade secrets and proprietary know-how protection for our

confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how, or other confidential information. Among other things, we seek to protect our trade secrets, know-how, and confidential information by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors, and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Moreover, there can be no assurance that any confidentiality agreements that we have with our employees, consultants, or other third parties will provide meaningful protection for our trade secrets, know-how, and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Despite these efforts, 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. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Accordingly, there also can be no assurance that our trade secrets or know-how will not otherwise become known or be independently developed by competitors.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position would be materially and adversely harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, 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. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our products and provision of our services, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, license agreements, collaboration agreements, supply agreements, consulting agreements, or other similar agreements with our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how, and other confidential information increases the risk that such trade secrets and know-how become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or know-how, or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets or know-how, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets and know-how, our competitors may discover our trade secrets or know-how, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets or know-how would impair our competitive position and have a material adverse impact on our business.

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

Filing, prosecuting, maintaining, defending, and enforcing patents on our products, services, and technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and services and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the U.S. These services and products may compete with our services and products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S., and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the U.S. These challenges can be caused by the absence or inconsistency of the application of rules and methods for the establishment and enforcement of intellectual property rights outside of the U.S. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries, including EU countries, India, Japan, and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit given that we may have limited remedies available if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents and limit our potential revenue opportunities. Furthermore, patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming

process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent application and prosecution process. 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 other governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. 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 noncompliance can result in abandonment or lapse of a patent or patent application, resulting in loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed or otherwise engaged with universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors.

Although we have policies to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our use of "open source" software could subject our proprietary software to general release, adversely affect our ability to sell our products and services, and subject us to possible litigation.

A portion of the products, services or technologies licensed, developed, and/or distributed by us incorporate so-called "open source" software and we may incorporate open source software into other products, services or technologies in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products or technologies or provide our services that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their products. If an author or other third party that distributes such open source

software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products or provision of our services. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products and services that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with our obligations under license or technology agreements with third parties, we may be required to pay damages and we could lose license rights that are critical to our business.

We license certain intellectual property that is important to our business, and, in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. For example, our agreements with third parties, such as Illumina, include certain non-exclusive license rights that are essential to the operation of our business as it is currently conducted. If we fail to comply with any of the obligations under our license agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from selling our products and services, or inhibit our ability to commercialize future products and services. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. In addition, our rights to certain technologies, including those of Illumina, are licensed to us on a non-exclusive basis. The owners of these non-exclusively licensed technologies are therefore free to license them to third parties, including our competitors, on terms that may be superior to those offered to us, which could place us at a competitive disadvantage. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We, or our licensors, may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we, or our licensors, may have inventorship disputes arise from conflicting obligations of employees, consultants, or others who are involved in developing our products, services, or technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our owned or in-licensed patents, trade secrets, or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products, services, or technologies. Even if we are successful in defending against such claims, litigation could result in 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.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish brand name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Financial and Market Risks and Risks Related to Owning Our Common Stock

Our inability to raise additional capital on acceptable terms in the future may limit our ability to continue to operate our business and further expand our operations.

We may seek to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements to continue executing on our long-term business plan. Additional funding may not be available to us on acceptable terms, or at all.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued may also provide for rights, preferences, or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. 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, if available, could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants,

such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms.

If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or sales and marketing initiatives. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruption to and volatility in the credit and financial markets in the U.S. and worldwide resulting from macroeconomic conditions, actual or perceived changes in interest rates and inflation, geopolitical conflicts (including the Russia-initiated military action against Ukraine). In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to us. While we believe our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements for at least the next 12 months, rising costs and interest rates due to inflation or other economic conditions may cause our capital expenditures and operating expenses to increase more than expected, and we cannot assure you that we will generate sufficient revenue from commercial sales to adequately fund our operating needs or achieve or sustain profitability. If we are unable to raise additional funding on acceptable terms, or at all, or if we consume our existing capital more quickly than expected, it could negatively impact our ability to retain and attract employees and our competitive position, business, financial condition, results of operations, and prospects will be adversely affected.

The market price of our common stock may be volatile or may decline steeply or suddenly regardless of our operating performance, we may not be able to meet investor or analyst expectations, and you may lose all or part of your investment.

The market price of our common stock may fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated fluctuations in our operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research reports by securities analysts or changed recommendations for our stock;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors relating to significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP and Natera, as our largest customers;
- the timing and amount of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business or issues we may face with regulators;
- additions or departures of key management or other personnel;
- inability to obtain additional funding;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments related to our intellectual property or other matters, including litigation;
- health epidemics or pandemics, geopolitical conflicts, inflation, global supply chain issues, regional or national economic slowdowns, recessions, depressions or other economic downturns; and
- other general economic, industry, and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors.

In addition, the stock market in general, and the market for life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies, including in connection with the COVID-19 pandemic, global supply chain challenges, inflation and fears of economic recession, which have resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall

below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are 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 revenue or earnings forecasts that we may provide.

Our quarterly results may fluctuate significantly, which could adversely impact the value of our common stock.

Our quarterly results of operations, including our revenue, gross margin, profitability, and cash flows, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, our quarterly results should not be relied upon as an indication of future performance. Our quarterly financial results may fluctuate as a result of a variety of factors, many of which are outside of our control. For example, Natera and other large customers are not obliged to deliver tissue samples or other specimens to us at any particular time or at all. The rate at which we receive tissue samples or other specimens can vary dramatically from quarter to quarter, and is difficult or impossible for us to accurately forecast. Our receipt and processing of tissue samples and other specimens from our customers leads to our recognition of revenue, and as such the variable rates of delivery of customer samples will lead to variations in our revenue from quarter to quarter. For example, we often see fluctuations in receipt and processing of samples and revenue in the fourth quarter due, in part, to the concentration of holidays in late November and in December, and some of our biopharmaceutical customers have fiscal years ending in December, which we believe may impact the timing of samples or payments provided by such customers. Fluctuations in quarterly results may adversely impact the value of our common stock. Factors that may cause fluctuations in our quarterly financial results include, without limitation, those listed elsewhere in this “Risk Factors” section. We also may face competitive pricing pressures, and we may not be able to maintain our pricing in the future, which would adversely affect our operating results.

Unstable market, economic and geo-political conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions can result in severely diminished liquidity and credit availability, increases in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur, including actual or perceived changes in interest rates and inflation. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon development or commercial initiatives. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions could continue to affect, and potentially materially adversely affect, global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

Insiders may exercise significant control over our company and will be able to influence corporate matters.

Acting together, our directors, executive officers and their affiliates, and holders of greater than five percent of our outstanding common stock are able to exercise significant influence over our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a third party from acquiring control of our company and could adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

Future sales of shares by existing stockholders, or the perception that such sales could occur, could cause our stock price to decline.

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, 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 shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2022, we had 46,707,084 shares of common stock outstanding, all of which shares were eligible as of such date for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, upon issuance, shares of common stock subject to outstanding options under our stock option plans as of December 31, 2022 will become eligible for sale in the public market in

the future, subject to certain legal and contractual limitations. Moreover, certain holders of shares of our common stock have the right to require us to register these shares under the Securities Act pursuant to an investors' rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse effect on the market price of our common stock.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. In addition, our ability to pay cash dividends on our capital stock is limited by our credit agreement and may be prohibited or limited by the terms of any future debt financing arrangement. As a result, any investment returns on our common stock will depend upon increases in the value for our common stock, which are not certain.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

In the future, we may sell common stock, rights to purchase common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, directors, and consultants pursuant to our equity incentive plans. If we sell common stock, rights to purchase common stock, convertible securities, or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. In addition, new investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Holders of our common stock could be adversely affected if we issue preferred stock.

Pursuant to our amended and restated certificate of incorporation, our board of directors is authorized to issue up to 10,000,000 shares of preferred stock without any action on the part of our stockholders. Our board of directors will also have the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, including voting rights, dividend rights, preferences over our common stock with respect to dividends or in the event of a dissolution, liquidation, or winding up, and other terms. In the event that we issue preferred stock in the future that has preferences over our common stock with respect to payment of dividends or upon our liquidation, dissolution, or winding up, or if we issue preferred stock that is convertible into our common stock at greater than a one-to-one ratio, the voting and other rights of the holders of our common stock or the market price of our common stock could be adversely affected.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2022, we had federal and state net operating loss carryforwards of approximately $249.1 million and approximately $229.7 million, respectively. Certain of our federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2031. These net operating loss carryforwards could expire unused and be unavailable to offset future taxable income. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, federal net operating losses incurred in tax years beginning in 2018 and thereafter may be carried forward indefinitely, but the deductibility of such federal net operating losses for tax years beginning after 2020 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, as modified by the CARES Act. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (including certain tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include the following:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- permit the board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- provide that directors may only be removed for cause;
- require super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter, or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws, or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U.S. will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nonetheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

The requirements of being a public company consume substantial resources, may result in litigation and may divert management's attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly and increase demand on our systems and resources, particularly in the event we no longer qualify as a "smaller reporting company" as defined in the Exchange Act. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may be required to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment will result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected. By disclosing information in this document and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

As a public company, it may be increasingly expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. In addition, as a result of our disclosure obligations as a public company, we have reduced strategic flexibility as compared to our competitors that are privately-held companies, and are under pressure to focus on short-term results, which may materially and adversely affect our ability to achieve long-term profitability.

We are a smaller reporting company, and any decision on our part to avail ourselves of certain reduced reporting and disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.

We are a "smaller reporting company" as defined in the Exchange Act. We intend to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including scaled disclosure on executive compensation.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded smaller reporting companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

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

We have implemented disclosure controls and procedures designed to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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 errors or mistakes. 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. As a result, because of these inherent limitations in our control system, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to file required reports in a timely manner and filing reports containing incorrect information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, damage to our reputation, and harm to our financial condition.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be adversely affected.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or any testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal control over financial reporting could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are a non-accelerated filer. For so long as we remain a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters are located in Fremont, California, and comprise 100,000 square feet of space, pursuant to a lease that expires in 2036. The lease includes two options to extend the term for a period of five-years per option, at prevailing market rates. This facility is used for corporate functions and research and development. We intend to move our laboratory operations from Menlo Park, California to the Fremont, California facility in 2023.

We also lease 31,280 square feet of space in Menlo Park, California, pursuant to a lease that expires in 2027. The lease includes an option to extend the term for a period of three years, at prevailing market rates. This facility was previously used as our corporate headquarters. Our CLIA-certified and CAP-accredited laboratory is currently located in the facility.

We believe that our facilities are sufficient to meet our current and foreseeable future needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Item 3. Legal Proceedings.

See the disclosure under the heading "Contingencies" in Note 9 to our consolidated financial statements.

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

Our common stock has been listed on The Nasdaq Global Market under the symbol "PSNL" since June 20, 2019. Prior to our initial public offering, there was no public market for our common stock.

Holders

As of February 14, 2023, there were approximately 65 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have not declared or paid any cash dividend on our common stock. We intend to retain any future earnings and do not expect to pay cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and accompanying notes and other financial information included elsewhere in this Annual Report on Form 10-K. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. You should review the sections titled "Note Regarding Forward-Looking Statements" for a discussion of forward-looking statements and in Part I, Item 1A, "Risk Factors" for a discussion of factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and elsewhere in this Annual Report on Form 10-K.

Overview

We strive to develop some of the most comprehensive and actionable cancer genomic tests in the world to help patients live better and longer lives. We believe we have one of the most discerning technologies to both characterize and monitor cancer – with the aim of driving a new paradigm for cancer management and guiding care from biopsy through the life of the patient. Our assays combine tumor-and-normal profiling with proprietary algorithms to deliver advanced insights even as cancer evolves over time. Our products are designed to detect recurrence at the earliest timepoints, enable selection of targeted therapies based on ultra-comprehensive genomic profiling, and enhance biomarker strategy for drug development.

Today, our platforms are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples in their clinical trials and drug development programs. Our advanced genomic sequencing and analytics also support the development of personalized cancer vaccines and other next-generation cancer immunotherapies. For example, we are providing genomic testing to Moderna in its ongoing clinical trials evaluating a personalized cancer vaccine. In addition, we partner with diagnostics companies by providing our advanced tumor profiling and analysis capabilities as an input to their products. More recently, we launched new diagnostic offerings for the clinical setting and are preparing for future expansion in the clinical diagnostics market. Finally, we have also pursued non-cancer related business opportunities, specifically within the population sequencing market, by providing whole genome sequencing ("WGS") services under contract with the U.S. Department of Veterans Affairs Million Veteran Program ("VA MVP").

As part of one of our new strategies for 2023 and beyond, we are working with a growing number of leading cancer centers and world-class academic research institutions to build and publish the clinical evidence-base to support our products and our key indications. Specifically, because of the high sensitivity of our technology, we aim to focus on three indications in the next 2-3 years: immunotherapy (IO) monitoring, breast cancer, and lung cancer. We have announced collaborations with BC Cancer, Duke University, UCSF, Criterium, and Academic Breast Cancer Consortium that will focus on building the evidence-base for our technology and these indications. If the key opinion leaders ("KOLs") we are collaborating with have a positive experience using our platform, we are optimistic this will support broader use of our platform by other KOLS, as well as clinicians in the future.

Our work in oncology is underpinned by our experience and capacity for next-generation sequencing at scale. We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that our capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases. To date, we have sequenced more than 300,000 human samples, of which more than 160,000 were whole human genomes.

In October 2022, we relocated our corporate headquarters from Menlo Park, California to a new facility in Fremont, California. We signed a 13.5-year lease that extends to 2036 for the 100,000 square foot facility, which is approximately triple the amount of space than our Menlo Park location. The new facility allows for expansion of our laboratory for testing to support pharmaceutical customers and clinical diagnostic testing. In addition, the new space is intended to support the expansion of research and development efforts to bring leading edge products and services to the marketplace. Our Menlo Park office currently continues to house our Clinical Laboratory Improvement Amendments of 1988 ("CLIA")-certified and College of American Pathologists ("CAP")-accredited laboratory and we expect to move our laboratory operations from Menlo Park to the new facility in 2023.

2022 Highlights

Total revenue decreased 24%, or $20.4 million, during 2022 compared to 2021, due primarily to expected lower population sequencing revenue from the VA MVP. Revenue from pharma tests, enterprise, and other customers was $56.6 million in 2022 compared to $39.8 million in 2021, an increase of 42%, driven by higher sales to Natera under our partnership to provide advanced tumor analysis for use in Natera's MRD testing offerings. Revenue from population sequencing was $8.4 million in 2022 compared to $45.7 million in 2021, due to a reduction in the value of annual task orders received from the VA MVP in the past two years.

We announce new product offerings, business developments, and research collaborations at various times during the year. Significant announcements during 2022 included the following:

First Quarter 2022:

- Received our first customer order for NeXT Personal from a large global pharmaceutical customer and processed samples for initial order.

- Announced a collaboration with the Moores Cancer Center at UC San Diego Health, a National Cancer Institute-designated Comprehensive Cancer Center, to support clinical diagnostic testing in patients with advanced solid tumors and hematological malignancies.

Second Quarter 2022:

- Received a new US patent relating to NeXT Personal, signifying its unique place among MRD assays as it combines a highly sensitive measurement of tumor burden with the ability to simultaneously track thousands of tumor variants, both tumor-informed and prespecified, in a single panel.

Third Quarter 2022:

- Launched a research collaboration with BC Cancer using NeXT Personal to determine the optimal time for ctDNA sampling for MRD detection in colorectal and pancreatic cancers, with the aim of identifying cancer progression before current standard of care tests.

- Announced a research collaboration with Duke University, deploying NeXT Personal to profile and accurately track MRD in patients with advanced gastroesophageal cancer over the course of therapy with the aim of better predicting a patient's immune response to therapy.

- Added two additional patents to our MRD-related IP portfolio, both with priority to January 2013; the new patents describe the detection of cancer and its recurrence by using WGS of a patient's tumor to identify variants for a subsequently used personalized liquid biopsy assay as well as the design of the liquid biopsy assay.

- Appointed Christopher Hall as SVP (subsequently promoted to President) who will lead the company's diagnostic business, bringing 20 years of experience including leading the commercial organization at Veracyte and growing its business to nearly $100M in diagnostic revenue.

- Launched marketing and sales outreach to oncologists to begin generating demand for NeXT Dx, the company's tissue-based clinical test that covers the whole exome and transcriptome and assesses genomic alterations in matched tumor and normal specimens to report variants and help oncologists with decision-making for therapy selection.

- Won an exclusive five-year contract and received the initial order from the VA MVP.

Fourth Quarter 2022:

- Initiated a research collaboration with University Medical Center Hamburg-Eppendorf ("UKE") and its new Fleur-Hiege Center for Skin Cancer Research, where Dr. Klaus Pantel, Dr. Christoffer Gebhardt, and team are using NeXT Personal to track tumor response to immunotherapy ("IO") in patients with melanoma, with the aim of gathering evidence to advance the use of ultra-sensitive MRD detection in routine clinical practice for IO therapy monitoring.

Recent Events

In January 2023, we announced a headcount reduction of up to 30% to reduce expenses and extend our cash runway. The reduction in workforce is expected to be completed in March 2023.

In January 2023, partnered with Criterium and the Academic Breast Cancer Consortium (ABRCC) to conduct a prospective clinical trial to validate the clinical performance of the NeXT Personal assay to evaluate minimal residual disease (MRD) and subsequent recurrence in patients with early-stage, resectable triple negative breast cancer (TNBC).

In February 2023, we announced a partnership with Moderna to provide genomic testing for its upcoming clinical studies evaluating mRNA-4157/V940, an investigational personalized cancer vaccine, jointly developed by Moderna and Merck.

In February 2023, we made a decision to streamline our international operations by closing our operations in China as expeditiously as possible in 2023. We expect to incur one-time charges in connection with the closure, including noncash impairments of property and equipment and a lease asset. Such charges cannot be estimated at this time, but we do not expect such charges to exceed $1.5 million.

Factors Affecting Our Performance

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

- **The continued development of the market for genomic-based tests.** Our performance depends on the willingness of pharmaceutical companies, enterprise customers, and oncologists to continue to seek more comprehensive molecular information to develop more efficacious cancer therapies.

- **Increasing adoption of our products and solutions by existing customers.** Our performance depends on our ability to retain and broaden adoption with existing customers. Because our technology is novel, some customers begin using our platform by initiating pilot studies involving a small number of samples to gain experience with our service. As a result, historically a significant portion of our revenue has come from existing customers. We believe that our ability to convert initial pilots into larger orders from existing customers has the potential to drive substantial long-term revenue. We expect there may be some variation in the number of samples they choose to test each quarter.

- **Adoption of our products and solutions by new customers.** While new customers initially may not account for significant revenue, we believe that they have the potential to grow substantially over the long term as they gain confidence in our service. Our ability to engage new customers is critical to our long-term success. Our publications, posters and presentations at scientific conferences lead to engagement at the scientific level with potential customers who often make the initial decision to gain experience with our platform. Accessing these new customers through scientific engagement and marketing to gain initial buy-in is critical to our success and gives us the opportunity to demonstrate the utility of our platform.

- **Our revenue and cost are affected by the volume of samples we receive from customers from period to period.** The timing and size of sample shipments received after orders have been placed is variable. Since sample shipments can be large, and are often received from a third party, the timing of arrival can be difficult to predict over the short term. Although our long-term performance is not affected, we see quarter-to-quarter volatility due to these factors. Samples arriving later than expected may not be processed in the quarter proposed and result in revenue the following quarter. Since many of our customers request defined turnaround times, we employ project managers to coordinate and manage the complex process from sample receipt to sequencing and delivery of results.

- **Investment in product innovation to support growth.** Investment in research and development, including the development of new products and capabilities is critical to establish and maintain our leading position. We have invested significantly in our NeXT Platform, introducing new products and additional capabilities. We are also collaborating with key opinion leaders from cancer centers, such as Mayo Clinic and UC San Diego Moores Cancer Center, to support the clinical utility of our platform. We believe this work is critical to gaining customer adoption and expect our investments in these efforts to increase.

- **Leverage our operational infrastructure.** We have invested significantly in our sample processing capabilities and commercial infrastructure. With our current operating model and infrastructure, we can increase our production and commercialize new generations of our platform. We expect to grow our revenue and spread our costs over a larger volume of services.

Components of Operating Results

Revenue

We derive our revenue primarily from sales of advanced sequencing and analytics to the following four groups of customers:

- **Pharma tests and services** includes sales of testing services and data analytics for clinical trials and research to pharmaceutical companies in support of their drug development programs.

- **Enterprise sales** includes sales of tumor profiling and diagnostic tests directly to other businesses as an input to their products. Revenue from our partnership with Natera to provide advanced tumor analysis for use in Natera's MRD testing offerings currently makes up substantially all of the revenue in this category.

- **Population sequencing** includes sales of genomic sequencing services and data analytics to support large-scale genetic research programs. Revenue from our partnership with the VA MVP to provide population sequencing accounts for all of the revenue in this category.

- **Other** includes sales of genomic tests and analytics to universities and non-profits. This category also includes sales of diagnostics tests ordered by healthcare providers for cancer patients, which was insignificant in 2022.

Our ability to increase revenue will depend on our ability to further increase sales to these groups of customers and expand our customer base within each group. To do this, we are developing a growing set of state-of-the-art services and products, advancing our operational infrastructure, building our regulatory credentials, focusing our marketing efforts on large pharmaceutical companies, and seeking additional partnerships such as ours with Natera. We sell through a small direct sales force. We also anticipate increasing our revenue in the future through entrance into the clinical diagnostics market and have begun building our regulatory, clinical, and reimbursement capabilities, including hiring a national clinical sales force.

We have one reportable segment from the sale of sequencing and data analysis services. Most of our revenue to date has been derived from sales in the United States.

Costs and Expenses

Cost of Revenue

Cost of revenue consists of raw materials costs, personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), laboratory supplies and consumables, depreciation and maintenance on equipment, and allocated facilities and information technology ("IT") costs. We expect cost of revenue to increase as our revenue grows. We expect variability in our gross margins over the medium term due to fluctuating population sequencing revenue, investments in new capabilities such as automation of laboratory workflows, processing of diagnostic tests for the clinical market while we work to secure reimbursement, and costs related to our new Fremont facility. Over the long-term, we anticipate higher gross margins as growing revenue leads to economies of scale.

Research and Development Expenses

Research and development expenses consist of costs incurred for the research and development of our services and products and costs related to conducting studies and collaborations with partners to validate the clinical utility of our offerings. The expenses primarily consist of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits); laboratory supplies and consumables; costs of processing samples for research, product development, collaborations, and studies; depreciation and maintenance on equipment; and allocated facilities and IT costs. We include in research and development expenses the costs to further develop software we use to operate our laboratory, analyze the data it generates, and automate our operations.

We expense our research and development costs in the period in which they are incurred. We expect to increase our research and development expenses overall as we expand collaborations for clinical validation to secure reimbursement and develop our NeXT Personal test as an LDT for the clinical market, partially offset by cost reductions from our first quarter 2023 reduction in workforce and anticipated savings from our planned discontinuation of operations in China.

Selling, General and Administrative Expenses

Selling expenses consist of personnel costs (salaries, commissions, bonuses, stock-based compensation, payroll taxes, and benefits), customer support expenses, direct marketing expenses, and market research. Our general and administrative expenses include costs for our executive, accounting, finance, legal, and human resources functions. These expenses consist of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), corporate insurance, audit and legal expenses, consulting costs, and allocated facilities and IT costs. We expense all selling, general and administrative costs as incurred.

We expect our selling, general and administrative expenses to decrease significantly in the medium term as a result of the 2023 reduction in workforce, partially offset by investments in our diagnostic sales outreach efforts.

Interest Income and Interest Expense

Interest income consists primarily of interest earned on our cash and cash equivalents and short-term investments. Our interest income increased significantly during 2022 as a result of the higher interest rate environment after the Federal Reserve began taking measures to curb inflation in 2022.

Interest expense in 2022 and 2021 is the recognition of imputed interest on noninterest bearing loans.

Other Income (Expense), Net

Other income (expense), net consists primarily of foreign currency exchange gains and losses, and realized gains or losses associated with sales of marketable securities.

Trend Financial Information

The following selected consolidated financial data should be read in conjunction with the consolidated financial statements and the notes thereto in Item 8 of Part II, “Financial Statements and Supplementary Data”. Historical results are not necessarily indicative of future results.

	Year Ended December 31,				
	2022	2021	2020	2019	2018
Consolidated Statements of Operations:	(in thousands, except share and per share data)				
Revenue	$ 65,047	$ 85,494	$ 78,648	$ 65,207	$ 37,774
Costs and expenses					
Cost of revenue	51,697	53,837	58,534	43,127	25,969
Research and development	64,912	49,312	28,568	22,418	14,304
Selling, general and administrative	63,969	47,698	33,692	22,080	11,271
Total costs and expenses	180,578	150,847	120,794	87,625	51,544
Loss from operations	(115,531)	(65,353)	(42,146)	(22,418)	(13,770)
Interest income	2,396	367	949	1,620	293
Interest expense	(201)	(184)	(2)	(1,133)	(1,894)
Loss on debt extinguishment	—	—	—	(1,704)	(4,658)
Other income (expense), net	61	(42)	(24)	(1,440)	150
Loss before income taxes	(113,275)	(65,212)	(41,223)	(25,075)	(19,879)
Provision for income taxes	40	14	57	9	7
Net loss	$ (113,315)	$ (65,226)	$ (41,280)	$ (25,084)	$ (19,886)
Net loss per share, basic and diluted	$ (2.48)	$ (1.49)	$ (1.20)	$ (1.39)	$ (6.49)
Weighted-average shares outstanding, basic and diluted	45,704,805	43,886,730	34,374,903	18,011,470	3,063,157

	December 31,				
	2022	2021	2020	2019	2018
Consolidated Balance Sheet Data:	(in thousands)				
Cash and cash equivalents, and short-term investments	$ 167,658	$ 287,064	$ 203,290	$ 128,289	$ 19,744
Working capital	166,568	286,918	180,083	89,616	(28,291)
Total assets	292,700	396,528	244,842	157,291	41,670
Total debt	2,596	3,494	—	—	4,996
Long-term obligations	41,430	54,914	9,261	639	804
Total liabilities	74,561	86,227	49,897	50,601	58,654
Redeemable convertible preferred stock	—	—	—	—	89,404
Total stockholders' equity (deficit)	218,139	310,301	194,945	106,690	(106,388)

Results of Operations

This section generally discusses 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussions of 2020 items and year-to-year comparisons between 2021 and 2020 that are not included in this Annual Report on Form 10-K can be found in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2021, which is incorporated by reference herein.

Revenue

The following table shows revenue by customer type (in thousands):

	Years Ended December 31,			Change	
	2022	2021	2020	2022 vs 2021	2021 vs 2020
Pharma tests and services	$ 29,552	$ 30,282	$ 21,396	(2%)	42%
Enterprise sales	26,641	8,774	479	204%	1,732%
Population sequencing	8,443	45,671	56,154	(82%)	(19%)
Other	411	767	619	(46%)	24%
Total revenue	$ 65,047	$ 85,494	$ 78,648	(24%)	9%

The following table shows customers that made up at least 10% of total revenue in each year presented:

	Year Ended December 31,		
	2022	2021	2020
Natera, Inc.	41%	10%	*
VA MVP	13%	53%	71%
Merck & Co., Inc.	11%	*	*

* Less than 10% of revenue

Pharma tests and services

Revenue from pharma tests and services decreased 2%, or $0.7 million, in 2022. This was the result of decreases in certain customer projects, notably declines in ImmunoID NeXT samples processed for research and clinical trial projects for two large pharmaceutical customers; partially offset by increased revenue from other customer projects, notably fulfillment of an ImmunoID NeXT project with a different large pharmaceutical customer, a NeXT Liquid Biopsy project with another large pharmaceutical customer, and an ACE cancer sequencing project for a new customer.

Enterprise sales

Revenue from enterprise sales increased 204%, or $17.9 million, in 2022 primarily due to an increase in the volume of samples we tested for Natera for use in Natera's MRD testing offerings, partially offset by lower selling prices as a result of volume-based tiered pricing. The number of samples processed increased over 300% in 2022 as compared to 2021.

Population sequencing

Population sequencing revenue is made up entirely of sales to the VA MVP. The decrease of 82%, or $37.2 million, in revenue from the VA MVP in 2022 was due to a reduction in the value of annual task orders received from the VA MVP in the past two years. Specifically, we received task orders with values exceeding $36.0 million each year from 2017 to 2019. In 2020, the annual task order received from the VA MVP was $30.9 million, and in 2021 the annual task order received from the VA MVP was $9.7 million. The 2021 task order was the last task order received under our prior contract with the VA MVP, which is now expired. Our conversion of orders into revenue necessarily declined beginning in the fourth quarter of 2021 through the second quarter of 2022, which is when we completed the fulfillment of all outstanding task orders under the prior contract.

In September 2022, we entered into a new contract with the VA MVP to continue providing them WGS services. The performance period under the new contract includes a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. We concurrently received an initial task order with a value of up to $10.0 million, of which we fulfilled $0.9 million during the fourth quarter of 2022. We expect to recognize the remaining $9.1 million unfulfilled portion of the order in 2023.

Other

Other revenue decreased 46%, or $0.4 million, in 2022 due to lower revenue from university research projects.

Costs and Expenses

	Year Ended December 31,			Change	
	2022	2021	2020	2022 vs 2021	2021 vs 2020
		(in thousands)			
Cost of revenue	$ 51,697	$ 53,837	$ 58,534	(4%)	(8%)
Research and development	64,912	49,312	28,568	32%	73%
Selling, general and administrative	63,969	47,698	33,692	34%	42%
Total costs and expenses	$ 180,578	$ 150,847	$ 120,794	20%	25%

Cost of revenue

The decrease in cost of revenue of 4%, or $2.1 million, in 2022 was primarily due to lower revenue levels but also improved contribution margins due to customer mix (non-population sequencing sales generally have higher contribution margins), partially offset by higher fixed laboratory costs and indirect supplies costs (enterprise and pharma customer orders require more supplies to process as compared to population sequencing orders).

Specific components of the decrease were a $12.2 million decrease in raw materials costs due to lower revenue levels plus higher contribution margins, partially offset by a $4.4 million increase in facilities costs and maintenance on lab equipment, a $3.5 million increase in labor costs due to increased headcount, and a $2.2 million increase in laboratory supplies and consumables.

Research and development

The increase in research and development expenses of 32%, or $15.6 million, in 2022 was primarily due to new product and service development, increased hiring to build our clinical offerings, and the cost of testing samples for clinical validation work.

Specific components of the increase were a $7.5 million increase in personnel-related costs primarily related to increased headcount, a $4.1 million increase in sample processing costs incurred in our laboratory for new product development, a $3.0 million increase in IT and fixed facilities costs, and a $1.0 million increase in depreciation and maintenance on research and development equipment.

Selling, general and administrative

The increase in selling, general and administrative expenses of 34%, or $16.3 million, in 2022 was primarily due to expansion of our commercial and clinical diagnostics teams in addition to one-time charges in connection with our former chief executive officer's retirement at the end of 2022.

Specific components of the increase were a $9.6 million increase in personnel-related costs (primarily related to increased headcount but also a $2.0 million one-time charge for severance and equity modifications in connection with our former chief executive officer's retirement at the end of 2022), a $2.6 million increase in professional services (including audit fees and legal expenses), a $2.5 million increase in sales-related and travel expenses, and a $1.6 million increase in facilities costs driven by our new Fremont facility.

Interest Income, Interest Expense and Other Expense, Net

	Year Ended December 31,			Change	
	2022	2021	2020	2022 vs 2021	2021 vs 2020
		(in thousands)			
Interest income	$ 2,396	$ 367	$ 949	553%	(61%)
Interest expense	(201)	(184)	(2)	9%	NM
Other income (expense), net	61	(42)	(24)	NM	75%
Total	$ 2,256	$ 141	$ 923		

Interest income and interest expense

The increase in interest income in 2022 was due to increased yields on our investments. Interest expense in 2022 and 2021 is the recognition of imputed interest on noninterest bearing loans.

Other income (expense), net

Other income (expense), net consisted mainly of foreign currency remeasurements.

Liquidity and Capital Resources

The following tables present selected financial information and cash flow information (in thousands):

	December 31,		
	2022	2021	2020
Cash and cash equivalents, and short-term investments	$ 167,658	$ 287,064	$ 203,290
Property and equipment, net	61,935	19,650	11,834
Contract liabilities	1,264	3,982	21,034
Working capital	166,568	286,918	180,083

	Year Ended December 31,		
	2022	2021	2020
Net cash used in operating activities	$ (70,233)	$ (70,828)	$ (42,653)
Net cash used in investing activities	52,537	(60,069)	(65,143)
Net cash provided by financing activities	1,366	169,700	121,268

From our inception through December 31, 2022, we have funded our operations primarily from $279.0 million in net proceeds from our follow-on equity offerings in August 2020 and January 2021, $144.0 million in net proceeds from our IPO in June 2019, and $89.6 million from issuance of redeemable convertible preferred stock, as well as cash from operations and debt financings. As of December 31, 2022, we had cash and cash equivalents in the amount of $89.1 million and short-term investments in the amount of $78.5 million.

We have incurred net losses since our inception. We anticipate that our current cash and cash equivalents and short-term investments, together with cash provided by operating activities, are sufficient to fund our near-term capital and operating needs for at least the next 12 months.

We have based these future funding requirements on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our services 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 an additional credit facility or another form of third-party funding or seek other debt financing. We filed a prospectus supplement in January 2022 pursuant to which we could offer and sell additional shares of our common stock up to an aggregate amount of $100.0 million through an at-the-market offering program. 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. Additional capital may not be available on reasonable terms, or at all.

Our short-term investments portfolio is primarily invested in highly rated securities, with the primary objective of minimizing the potential risk of principal loss. Our investment policy generally requires securities to be investment grade and limits the amount of credit exposure to any one issuer.

As of December 31, 2022, cash and cash equivalents held by foreign subsidiaries was $0.7 million. Our intent is to indefinitely reinvest funds held outside the United States and our current plans do not demonstrate a need to repatriate them to fund our domestic operations. However, if in the future, we encounter a significant need for liquidity domestically or at a particular location that we cannot fulfill through borrowings, equity offerings, or other internal or external sources, or the cost to bring back the money is not significant from a tax perspective, we may determine that cash repatriations are necessary or desirable. Repatriation could result in additional material taxes. These factors may cause us to have an overall tax rate higher than other companies or higher than our tax rates have been in the past.

During 2022, cash used in operating activities of $70.2 million was a result of $113.3 million of net loss, partially reduced by non-cash expenses of $32.5 million (the most significant non-cash expenses were $19.4 million of stock-based compensation and $8.4 million of depreciation and amortization) and a net positive change in working capital of $10.6 million (primarily due to $13.2 million cash receipts in connection with our Fremont facility lease incentives and a $3.1 million increase in accounts payable, partially offset by a $3.0 million increase in inventory and a $2.7 million reduction in outstanding customer prepayments as we fulfilled the related revenue contracts).

During 2022, cash provided by investing activities was $52.5 million due to $102.4 million of net proceeds from short-term investments partially offset by $49.9 million in property and equipment purchases. Cash provided by financing activities of $1.4 million during the same period consisted of $2.5 million proceeds from stock option exercises and purchases under our ESPP and $1.2 million proceeds from noninterest bearing loans, partially offset by $2.3 million repayments of noninterest bearing loans.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist primarily of variable costs of revenue, operating expenditures, capital expenditures, property leases, and other. We plan to fund our material cash requirements with our existing cash and cash equivalents and short-term investments, which amounted to $167.7 million as of December 31, 2022, as well as anticipated cash receipts from customers. To fund our material cash requirements in the short- and long-term, we may also seek to sell additional common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing.

Variable costs of revenue. From time to time in the ordinary course of business, we enter into agreements with vendors for the purchase of raw materials, laboratory supplies and consumables to be used in the sequencing of customer samples. However, we generally do not have binding and enforceable purchase orders beyond the short term, and the timing and magnitude of purchase orders beyond such period is difficult to accurately project. We currently expect spend in this area to increase in 2023 to support expected higher levels of revenue.

Operating expenditures. Our primary use of cash relates to paying employees, spend on professional services, spend related to research and development projects, and other costs related to our research and development, selling, general and administrative functions. We currently expect to decrease our spend in these areas as a result of our first quarter 2023 workforce reduction. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Capital expenditures. Capital expenditures are expected to decrease significantly after 2022 as we have substantially completed the one-time build-out of our new headquarters and laboratory facility in Fremont, California as of the end of 2022. Going forward, our capital expenditures are expected to consist primarily of laboratory equipment and computer equipment. We currently expect capital expenditures to be between $4 million to $6 million in each of the years 2023, 2024, and 2025.

Property leases. Our noncancelable operating lease payments were $83.8 million as of December 31, 2022. The timing of these future payments, by year, can be found in Part II, Item 8 of this Annual Report on Form 10-K in the Notes to Consolidated Financial Statements in Note 7, Leases.

Other. As of December, 2022, we had three noninterest bearing loans to finance the purchase of $6.9 million of computer hardware, internal use software licenses, and related ongoing support. In connection with the loans, we made payments of $2.3 million in 2022. Remaining payments of $2.3 million and $0.4 million due in 2023 and 2024, respectively. Further discussion of these transactions can be found in Part I, Item 1 of this Annual Report on Form 10-K in the Notes to Consolidated Financial Statements in Note 6, Loans.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. Our estimates are based on our 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 may differ from these estimates under different assumptions or conditions.

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably possible could materially impact the financial statements. We believe that the assumptions and estimates associated with revenue recognition, stock-based compensation, and leases have the greatest potential impact on our consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

Revenue Recognition

We generate our revenue from selling sequencing and data analysis services. We agree to provide services to our customers through a contract, which may be in the form of a combination of a signed agreement, statement of work and/or a purchase order.

We have evaluated the performance obligations contained in contracts with customers to determine whether any of the performance obligations are distinct, such that the customers can benefit from the obligations on their own, and whether the obligations can be separately identifiable from other obligations in the contract. For the significant majority of our contracts to date, the customer orders a specified quantity of a sequencing; therefore, the delivery of the ordered quantity per the purchase order is accounted for as one performance obligation. Our contracts include only one performance obligation—the delivery of the sequencing and data analysis services to the customer.

Fees for our sequencing and data analysis services are predominantly based on a fixed price per sample. The fixed prices identified in the arrangements only change if a pricing amendment is agreed with a customer. In limited cases we provide our customers a discount if samples received above a certain volume are purchased. In such cases, the discount applies prospectively. We have analyzed such discounts if they represent a material right provided to a customer. We have concluded that such discounts generally do not represent a material right provided to a customer since they are not deemed to be incremental to the pricing offered to the customer or are not enforceable options to acquire additional goods. As a result, these discounts do not constitute a material right and do not meet the definition of a separate performance obligation, except in limited instances. We do not offer retrospective discounts or rebates. Accordingly, all of the transaction price, net of any discounts, is allocated to one performance obligation. Therefore, upon delivery of the services, there are no remaining performance obligations.

Contracts that contain multiple distinct performance obligations would require an allocation of the transaction price to each performance obligation based on a relative stand-alone selling price basis. Sometimes we deliver sequencing results in two or more batches; however, since the quantity delivered per batch of each individual test per sales order in these instances is in the same ratio as in the original sales order, allocating the transaction price on a relative stand-alone selling price basis would have no impact on the revenue recognized in any period presented.

We recognize revenue when control of the promised services is transferred to our customers. Management has determined that customers obtain control when the sequencing and data analysis service results are delivered to customers. Revenue is recorded net of sales or other transaction taxes collected from clients and remitted to taxing authorities.

A customer contract liability will arise when we receive payments from a customer related to an executed contract in advance of our provision of sequencing and data analysis services to such customer. We record a customer contract liability for performance obligations outstanding related to payments received in advance for customer deposits. We expect to satisfy these remaining performance obligations and recognize the related revenue upon providing sequencing and data analysis services.

All of our revenue and trade receivables are generated from contracts with customers.

Payment Terms

Payment terms and conditions vary by contract and customer. Our standard payment terms are typically 90 days or less from the invoice date. In instances where the timing of our revenue recognition differs from the timing of its invoicing, we have determined that our contracts do not include a significant financing component. The primary purposes of our invoicing terms are to provide customers with simplified and predictable ways of purchasing our services and provide payment protection for us.

Stock-Based Compensation

For options granted to employees, non-employees, and directors, stock-based compensation is measured at grant date based on the fair value of the award. We determine the grant-date fair value of options using the Black-Scholes option-pricing model, except for certain performance-based awards for which an alternative valuation method may be used. We determine the fair value of restricted stock unit awards using the closing market price of the Company’s common stock on the date of grant. The grant-date fair value of awards is amortized over the employees’ requisite service period on a straight-line basis, or the non-employees’ vesting period as the goods are received or services rendered. Forfeitures are accounted for as they occur. Additionally, our ESPP is deemed to be a compensatory plan and therefore is included in stock-based compensation expense.

Estimating the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option-pricing model, is affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

- *Expected Term*—The expected term assumption represents the weighted-average period that the stock-based awards are expected to be outstanding. We have elected to use the "simplified method" for estimating the expected term of the options, which is an available method if there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting tranche for awards with graded vesting. The midpoint of the vesting date and the contractual expiration date is used as the expected term under this method. For awards with multiple vesting tranches, the assumed period for each tranche is computed separately and then averaged together to determine the expected term for the award.

- *Expected Volatility*—For all stock options granted to date, expected volatility was estimated based on an average historical stock price volatility of a peer group of publicly traded companies as we did not have sufficient trading history for our own common stock. For purposes of identifying these peer companies, we considered the industry, stage of development, size, and financial leverage of potential comparable companies.

- *Expected Dividend Yield*—The Black-Scholes option-pricing valuation model calls for a single expected dividend yield as an input. We currently have no history or expectation of paying cash dividends on our common stock.

- *Risk-Free Interest Rate*—The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the award.

Incremental Borrowing Rate

Lease liabilities are recognized at the present value of the fixed lease payments, reduced by landlord incentives, using a discount rate based on the Company's current borrowing rate at the lease commencement date (the incremental borrowing rate), unless the rate implicit in the lease is readily determinable.

In August 2021, we entered into a 13.5-year lease for our new corporate headquarters in Fremont, California. We estimated our incremental borrowing rate as the rate implicit in the lease was not readily determinable. To determine the incremental borrowing rate, we estimated our credit rating by comparing certain financial ratios and metrics of the Company to those of other issuers with publicly-available credit ratings from Standard & Poor's (S&P). We then adjusted yields from publicly traded corporate bonds of companies of similar size and credit rating over a term approximating the term of our lease for the nature of the collateral. Our concluded incremental borrowing rate for this lease was 5.8%, which resulted in a lease liability and right-of-use asset of $44.7 million.

In September 2022, the lease commencement date for our new facility in Fremont, California was delayed from the original intended date due to delays in the completion of the work necessary for the Company to move into the facility, which resulted in a reassessment of the lease term and consequently a remeasurement of the lease liability and corresponding adjustment to the carrying amount of the right-of-use asset based on the updated incremental borrowing rate. We estimated our incremental borrowing rate by using the same method described above and concluded that the incremental borrowing rate for the remeasured lease was 10.5%. The lease reassessment resulted in a $12.9 million reduction to right-of-use assets in 2022. The increase in our estimated borrowing rate between August 2021 and September 2022 mostly reflects the higher interest rate environment in 2022 as compared to 2021.

Recent Accounting Pronouncements

See the sections titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" and "—Recent Accounting Pronouncements Not Yet Adopted" in Note 2 to our consolidated financial statements for additional information.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company", we are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

PERSONALIS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

PERSONALIS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 89,128	$ 105,585
Short-term investments	78,530	181,479
Accounts receivable, net	16,642	18,468
Inventory and other deferred costs	8,591	5,610
Prepaid expenses and other current assets	6,808	7,089
Total current assets	199,699	318,231
Property and equipment, net	61,935	19,650
Operating lease right-of-use assets	26,480	53,822
Other long-term assets	4,586	4,825
Total assets	$ 292,700	$ 396,528
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 12,854	$ 9,221
Accrued and other current liabilities	19,013	18,110
Contract liabilities	1,264	3,982
Total current liabilities	33,131	31,313
Long-term operating lease liabilities	41,041	52,797
Other long-term liabilities	389	2,117
Total liabilities	74,561	86,227
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value — 10,000,000 shares authorized; none issued	—	—
Common stock, $0.0001 par value — 200,000,000 shares authorized; 46,707,084 and 44,904,512 shares issued and outstanding at December 31, 2022 and 2021, respectively	5	4
Additional paid-in capital	579,456	557,558
Accumulated other comprehensive loss	(912)	(166)
Accumulated deficit	(360,410)	(247,095)
Total stockholders' equity	218,139	310,301
Total liabilities and stockholders' equity	$ 292,700	$ 396,528

See notes to consolidated financial statements.

PERSONALIS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,		
	2022	2021	2020
Revenue	$ 65,047	$ 85,494	$ 78,648
Costs and expenses			
Cost of revenue	51,697	53,837	58,534
Research and development	64,912	49,312	28,568
Selling, general and administrative	63,969	47,698	33,692
Total costs and expenses	180,578	150,847	120,794
Loss from operations	(115,531)	(65,353)	(42,146)
Interest income	2,396	367	949
Interest expense	(201)	(184)	(2)
Other income (expense), net	61	(42)	(24)
Loss before income taxes	(113,275)	(65,212)	(41,223)
Provision for income taxes	40	14	57
Net loss	$ (113,315)	$ (65,226)	$ (41,280)
Net loss per share, basic and diluted	$ (2.48)	$ (1.49)	$ (1.20)
Weighted-average shares outstanding, basic and diluted	45,704,805	43,886,730	34,374,903

See notes to consolidated financial statements.

PERSONALIS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (113,315)	$ (65,226)	$ (41,280)
Other comprehensive income (loss), net of tax			
Foreign currency translation adjustment	(277)	49	12
Change in unrealized gain (loss) on available-for-sale debt securities	(469)	(237)	16
Comprehensive loss	$ (114,061)	$ (65,414)	$ (41,252)

See notes to consolidated financial statements.

PERSONALIS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2019	31,243,029	$ 3	$ 247,282	$ (6)	$ (140,589)	$ 106,690
Proceeds from follow-on offering, net of offering costs	6,578,947	1	117,064	—	—	117,065
Exercise of common stock warrants	79,772	—	—	—	—	—
Proceeds from exercise of stock options	908,691	—	2,789	—	—	2,789
Proceeds from ESPP purchases	164,164	—	1,415	—	—	1,415
Restricted stock units vested	130,945	—	—	—	—	—
Stock-based compensation	—	—	8,238	—	—	8,238
Foreign currency translation adjustment	—	—	—	12	—	12
Unrealized gain on available-for-sale debt securities	—	—	—	16	—	16
Net loss	—	—	—	—	(41,280)	(41,280)
Balance—December 31, 2020	39,105,548	4	376,788	22	(181,869)	194,945
Proceeds from follow-on offering, net of offering costs	4,542,500	—	161,916	—	—	161,916
Proceeds from exercise of stock options	862,056	—	2,096	—	—	2,096
Proceeds from ESPP purchases	128,289	—	2,380	—	—	2,380
Restricted stock units vested	266,119	—	—	—	—	—
Stock-based compensation	—	—	14,378	—	—	14,378
Foreign currency translation adjustment	—	—	—	49	—	49
Unrealized loss on available-for-sale debt securities	—	—	—	(237)	—	(237)
Net loss	—	—	—	—	(65,226)	(65,226)
Balance—December 31, 2021	44,904,512	4	557,558	(166)	(247,095)	310,301
Proceeds from exercise of stock options	488,187	1	1,010	—	—	1,011
Proceeds from ESPP purchases	416,514	—	1,455	—	—	1,455
Restricted stock units vested	897,871	—	—	—	—	—
Stock-based compensation	—	—	19,433	—	—	19,433
Foreign currency translation adjustment	—	—	—	(277)	—	(277)
Unrealized loss on available-for-sale debt securities	—	—	—	(469)	—	(469)
Net loss	—	—	—	—	(113,315)	(113,315)
Balance—December 31, 2022	46,707,084	$ 5	$ 579,456	$ (912)	$ (360,410)	$ 218,139

See notes to consolidated financial statements

PERSONALIS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net loss	$ (113,315)	$ (65,226)	$ (41,280)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock-based compensation expense	19,433	14,378	8,238
Depreciation and amortization	8,432	6,014	5,758
Noncash operating lease cost	4,446	2,950	1,409
Amortization of premium on short-term investments	57	2,031	391
Other	103	169	60
Changes in operating assets and liabilities			
Accounts receivable	1,825	(12,118)	(3,049)
Inventory and other deferred costs	(2,982)	29	(1,076)
Prepaid expenses and other assets	484	(2,658)	(2,312)
Accounts payable	3,089	(1,457)	751
Accrued and other current liabilities	(1,479)	3,365	3,529
Contract liabilities	(2,718)	(17,052)	(14,942)
Operating lease liabilities	12,811	(962)	(850)
Other long-term liabilities	(419)	(291)	720
Net cash used in operating activities	(70,233)	(70,828)	(42,653)
Cash flows from investing activities:			
Purchases of available-for-sale debt securities	(121,490)	(267,128)	(161,775)
Proceeds from maturities of available-for-sale debt securities	223,923	213,083	99,878
Proceeds from sales of available-for-sale debt securities	—	5,059	—
Purchases of property and equipment	(49,896)	(11,083)	(3,246)
Net cash provided by (used in) investing activities	52,537	(60,069)	(65,143)
Cash flows from financing activities:			
Proceeds from public offerings, net of underwriting discounts and commissions	—	162,258	117,500
Payments of costs related to public offerings	—	(342)	(435)
Proceeds from loans	1,194	5,167	—
Repayments of loans	(2,293)	(1,857)	—
Proceeds from exercise of equity awards	2,465	4,474	4,203
Net cash provided by financing activities	1,366	169,700	121,268
Effect of exchange rates on cash, cash equivalents and restricted cash	(127)	47	7
Net change in cash, cash equivalents and restricted cash	(16,457)	38,850	13,479
Cash, cash equivalents and restricted cash, beginning of period	107,375	68,525	55,046
Cash, cash equivalents and restricted cash, end of period	$ 90,918	$ 107,375	$ 68,525
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:			
Cash and cash equivalents	$ 89,128	$ 105,585	$ 68,525
Restricted cash, included in other long-term assets	1,790	1,790	—
Total cash, cash equivalents and restricted cash	$ 90,918	$ 107,375	$ 68,525
Supplemental cash flow information:			
Cash paid for interest	$ —	$ —	$ —
Cash paid for income taxes, net of refunds	47	39	35
Acquisition of property and equipment included in accounts payable and accrued liabilities	3,917	3,006	282

See notes to consolidated financial statements.

PERSONALIS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Company and Nature of Business

Personalis, Inc. (the "Company") is a provider of advanced genomic tests for cancer. The Company also provides sequencing and data analysis services to support population sequencing initiatives. The Company's genomic tests are sold primarily to pharmaceutical companies, biopharmaceutical companies, diagnostics companies, universities, non-profits, and government entities, while services for population sequencing initiatives are sold primarily to government entities. The principal markets for the Company's services are in the United States and Europe.

The Company was incorporated in Delaware in February 2011 and began operations in September 2011. The Company formed a wholly owned subsidiary, Personalis (UK) Ltd., in August 2013 and a wholly owned subsidiary, Shanghai Personalis Biotechnology Co., Ltd., which is referred to as "Personalis (Shanghai) Ltd" herein, in October 2020. The Company operates and manages its business as one reportable operating segment, which is the sale of sequencing and data analysis services.

The Company has incurred losses to date and expects to incur additional losses for the foreseeable future. The Company continues to invest the majority of its resources in the development and growth of its business, including investments in product development and sales and marketing efforts. The Company's activities have been financed to date primarily through the sale of its equity securities and cash from operations.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding annual reporting. The consolidated financial statements include the accounts of Personalis, Inc. and its wholly owned subsidiaries, Personalis (UK) Ltd. and Personalis (Shanghai) Ltd. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The estimates include, but are not limited to, useful lives assigned to long-lived assets, discount rates for lease accounting, the valuation of stock options, the valuation of stock-based awards, and provisions for income taxes and contingencies. Actual results could differ from these estimates, and such differences could be material to the Company's consolidated financial position and results of operations.

Follow-On and At-the-Market Equity Offerings

In August 2020, the Company completed a follow-on equity offering in which it issued and sold 6,578,947 shares of its common stock at a public offering price of $19.00 per share. The Company received net proceeds of $117.5 million after deducting underwriting discounts and commissions. The Company also incurred $0.4 million of offering costs, including legal, accounting, printing and other offering-related costs.

In January 2021, the Company completed a follow-on equity offering in which it issued and sold 3,950,000 shares of its common stock at a public offering price of $38.00 per share. The Company received net proceeds of $141.1 million after deducting underwriting discounts and commissions. The underwriters of the offering exercised their option to purchase an additional 592,500 shares shortly thereafter, resulting in additional net proceeds of $21.2 million after deducting underwriting discounts and commissions. The Company also incurred $0.3 million of offering costs, including legal, accounting, printing and other offering-related costs.

In December 2021, the Company entered into an At-the-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG") under which it may offer and sell its common stock having aggregate sales proceeds of up to $100.0 million from time to time through BTIG as its sales agent. BTIG will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay BTIG a commission of up to 3% of the gross sales proceeds of any common stock sold through BTIC under the Sales Agreement. The Company is not obligated to make any sales of common stock under the Sales Agreement. No shares of the Company's common stock have been offered or sold under the Sales Agreement.

Concentration of Credit Risk and Other Risks and Uncertainties

The Company is subject to credit risk from its portfolio of cash and cash equivalents. The Company's cash and cash equivalents are deposited with high-quality financial institutions. Deposits at these institutions may, at times, exceed federally insured limits. Management believes these financial institutions are financially sound and, accordingly, that minimal credit risk exists.

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 are as follows: preservation of principal; liquidity of investments sufficient to meet cash flow requirements; avoidance of inappropriate concentration and credit risk; competitive after-tax rate of returns; and fiduciary control of cash and investments. Under its investment policy, the Company limits the amounts invested in such securities by credit rating, maturity, investment type, and issuer. As a result, management believes that these financial instruments do not expose the Company to any significant concentrations of credit risk.

The Company purchases various reagents and sequencing materials from sole source suppliers. Any extended interruption in the supply of these materials could result in the Company's inability to secure sufficient materials to conduct business and meet customer demand.

The Company routinely assesses the creditworthiness of its customers and does not require collateral. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company maintains an allowance for doubtful accounts, which was $0.1 million as of December 31, 2022 and 2021. The Company had no bad debt expense in any of the periods presented.

Significant customers are those that represent more than 10% of the Company's total revenue or accounts receivable balance at each respective balance sheet date. For each significant customer, revenue as a percentage of total revenue and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue			Accounts Receivable	
	Year Ended December 31,			December 31,	
	2022	2021	2020	2022	2021
Natera, Inc.	41%	10%	*	43%	39%
VA MVP	13%	53%	71%	*	*
Merck & Co., Inc.	11%	*	*	*	15%
AbbVie Inc.	*	*	*	*	18%
GSK plc	*	*	*	12%	*
Pfizer Inc.	*	*	*	10%	*

* Less than 10% of revenue or accounts receivable

Revenue Recognition

The Company applies the revenue recognition guidance in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("Topic 606").

Revenue Recognition

The revenue guidance provides a five-step framework through which revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company concludes are within the scope of Topic 606, management performs the following five steps: (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract(s); (iii) determines the transaction price, including whether there are any constraints on variable consideration; (iv) allocates the transaction price to the performance obligations; and (v) recognizes revenue when (or as) the Company satisfies a performance obligation. At contract inception, once a contract is determined to be within the scope of the new revenue standard, the Company assesses whether individual goods or services promised within each contract are distinct and, therefore, represent separate performance obligations.

The Company derives revenue from the sale of sequencing and data analysis services. The Company's contracts are in the form of a combination of signed agreements, statements of work, and/or purchase orders. The Company accounts for a contract with a customer when there is approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance, and it is probable that the Company will collect substantially all of the consideration to which it will be entitled.

The sequencing and data analysis services are the only distinct services that meet the definition of a performance obligation and are accounted for as one performance obligation under Topic 606. The Company recognizes revenue from such services at the point in time when control of the test results is transferred to the customer. The Company has elected to exclude all sales and value added taxes from the measurement of the transaction price. Sequencing and data analysis services are based on a fixed price per test.

Payment terms and conditions vary by contract and customer. The Company's standard payment terms are typically 90 days or less from the invoice date. In instances where the timing of the Company's revenue recognition differs from the timing of its invoicing, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised services to the customer will be one year or less. After assessing each of its revenue-generating arrangements to determine whether a significant financing component exists, the Company concluded that a significant financing component does not exist in any of its arrangements. The primary purpose of the Company's invoicing terms is to provide customers with simplified and predictable ways of purchasing the Company's services and to provide payment protection for the Company.

Practical Expedients and Exemptions

As a practical expedient, the Company recognizes the incremental costs of obtaining contracts, such as sales commissions, as an expense when incurred since the amortization period of the asset the Company otherwise would have recognized is one year or less. Sales commissions are recorded within selling, general, and administrative expenses in the consolidated statements of operations.

Cost of Revenue

Cost of revenue consists of raw materials costs, personnel costs (salaries, bonuses, benefits, payroll taxes, and stock-based compensation), laboratory supplies and consumables, depreciation and maintenance on equipment, and allocated facilities and information technology ("IT") costs.

Research and Development Expenses

The Company charges research and development costs to expenses as incurred, including lab and automation development costs. The expenses primarily consist of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits); laboratory supplies and consumables; costs of processing samples for research, product development, collaborations, and studies; depreciation and maintenance on equipment; and allocated facilities and IT costs.

Stock-Based Compensation

For options granted to employees, non-employees, and directors, stock-based compensation is measured at grant date based on the fair value of the award. The Company determines the grant-date fair value of options using the Black-Scholes option-pricing model, except for certain performance-based awards for which an alternative valuation method may be used. The Company determines the fair value of restricted stock unit awards using the closing market price of the Company's common stock on the date of grant. The grant-date fair value of awards is amortized over the employees' requisite service period on a straight-line basis, or the non-employees' vesting period as the goods are received or services rendered. Forfeitures are accounted for as they occur. Additionally, the Company's 2019 Employee Stock Purchase Plan (the "ESPP") is deemed to be a compensatory plan and therefore is included in stock-based compensation expense.

Inputs used in Black-Scholes option-pricing models to measure fair value of options are summarized as follows:

Expected Term. The expected term is calculated using the simplified method, which is available if there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting tranche for awards with graded vesting. The midpoint of the vesting date and the contractual expiration date is used as the expected term under this method. For awards with multiple vesting tranches, the assumed period for each tranche is computed separately and then averaged together to determine the expected term for the award.

Expected Volatility. The Company used an average historical stock price volatility of a peer group of publicly traded companies to be representative of its expected future stock price volatility, as the Company did not have sufficient trading history for its common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size, and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-Free Interest Rate. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with remaining terms equivalent to the expected term of a stock award.

Expected Dividend Rate. The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

Foreign Currency Translation

The Company considers the functional currencies of its foreign subsidiaries to be the local currency. Assets and liabilities recorded in foreign currencies are translated at the exchange rate as of the balance sheet date, and costs and expenses are translated at average exchange rates in effect during the period. Equity transactions are translated using historical exchange rates. The effects of foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive income (loss) in the consolidated balance sheets.

Comprehensive Loss

Comprehensive loss includes all changes in equity (net assets) during the period from nonowner sources. The Company's comprehensive loss consists of its net loss, its cumulative translation adjustments, and its unrealized gains or losses on available-for-sale debt securities.

Income Taxes

The Company uses the asset and liability method under ASC Topic 740, Income Taxes, in accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expenses or benefits are the result of changes in the deferred tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets where it is more likely than not that the deferred tax assets will not be realized.

ASC Topic 740 clarifies the accounting for uncertainty in income taxes recognized in the financial statements. ASC Topic 740 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon audit, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. ASC Topic 740 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the consolidated statements of operations. Accrued interest and penalties are included within the related liability line in the consolidated balance sheets.

The Company considers undistributed earnings of its foreign subsidiaries to be indefinitely reinvested and, accordingly, no U.S. income taxes have been provided thereon.

Cash and Cash Equivalents

Cash equivalents consist of highly liquid investments with 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 cash, U.S. Treasury bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. Government, its agencies or instrumentalities, and repurchase agreements secured by such obligations or cash. Cash equivalents also include commercial paper and U.S. Treasury bills, which are marketable debt securities recorded at fair value and accounted for in the same manner as other marketable debt securities described below.

Short-term Investments

The Company's investments in marketable debt securities are classified as available-for-sale and recorded at fair value. Investments with original maturities of greater than three months and remaining maturities of less than one year are classified as short-term investments. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Short-term investments primarily consist of U.S. agency bonds, commercial paper, corporate bonds, asset-backed securities, U.S. Treasury bills, and non-U.S. Government notes.

Unrealized gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity. Any discount or premium arising at purchase is accreted or amortized to interest income or expense. Realized gains and losses and declines in fair value, if any, judged to be other than temporary are reported in other income (expense), net. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity is reclassified out of stockholders' equity on a specific-identification basis and recorded in earnings for the period.

The Company periodically evaluates whether declines in fair values of its investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly-available information that may affect the value of the marketable security, duration and severity of the decline in value, and management's strategy and intentions for holding the marketable security. To date, the Company has not recorded any impairment charges on its marketable securities related to other-than-temporary declines in market value.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. Observable inputs reflect market data obtained from independent sources while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques used to measure fair value is briefly summarized as follows:

Level 1 — Unadjusted quoted prices in active markets that are accessible to the reporting entity at the measurement date for identical assets and liabilities.

Level 2 — Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability. Level 2 inputs include the following:

- Quoted prices for similar assets and liabilities in active markets.
- Quoted prices for identical or similar assets or liabilities in markets that are not active.
- Observable inputs other than quoted prices that are used in the valuation of the assets or liabilities (e.g., interest rate and yield curve quotes at commonly quoted intervals).
- Inputs that are derived principally from or are corroborated by observable market data by correlation or other means.

Level 3 — Unobservable inputs for the assets or liabilities (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Accounts Receivable, Net

Trade accounts receivable are recorded at the invoiced amount and are noninterest bearing. At each reporting period, management reviews all outstanding customer balances to determine if the facts and circumstances of each customer relationship indicate the need for a reserve. A reserve is recorded when it is probable that a loss has been incurred based on past events and conditions existing at the date of the financial statements, and the loss is reasonably estimated.

Inventory and Other Deferred Costs

Inventory, consisting of supplies used in fulfilling customer contracts, are valued at the lower of cost or net realizable value. Cost is determined using actual costs, on a first-in, first-out basis.

Other deferred costs relate to work in process for costs incurred on customer contracts that have not been completed or recognized as revenue. Other deferred costs represent materials used in sequencing services, labor, and overhead allocations.

Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation and amortization, and are depreciated on a straight-line basis over the estimated useful lives of the related assets, which is generally three to five years for computer equipment, two years for software, three years for furniture and equipment, and five years for machinery and equipment. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Upon retirement or sale, the cost and related accumulated depreciation and amortization are removed from the consolidated balance sheet, and the resulting gain or loss is reflected in the consolidated statements of operations. Maintenance and repairs that are not considered improvements and do not extend the useful lives of the assets are charged to expense as incurred.

Construction-in-process assets consist primarily of computer equipment and machinery and equipment that have not yet been placed in service. These assets are stated at cost and are not depreciated. Once the assets are placed into service, assets are reclassified to the appropriate asset class based on their nature and depreciated in accordance with the useful lives above.

Leases

The Company categorizes leases with contractual terms longer than 12 months as either operating or finance leases. Finance leases are generally those leases that allow the Company to substantially utilize or pay for the entire asset over its estimated life. All other leases are categorized as operating leases. As of December 31, 2022, the Company had no finance leases.

Certain lease contracts include obligations to pay for other services, such as maintenance. The Company elected to account for these other services as a component of the lease (i.e., the Company elected the practical expedient not to separate lease and non-lease components).

Lease liabilities are recognized at the present value of the fixed lease payments using a discount rate based on the Company's current borrowing rate at the lease commencement date, adjusted for various factors including level of collateralization and term (the "incremental borrowing rate"), unless the rate implicit in the lease is readily determinable. The current portion of lease liabilities is included in "Accrued and other current liabilities." Lease assets are recognized based on the initial present value of the fixed lease payments plus any direct costs from executing the leases and any lease prepayments. Lease assets are presented as "Operating lease right-of-use assets" as a long-term asset. Leasehold improvements are capitalized at cost and amortized over the lesser of their expected useful life

or the lease term. Costs associated with operating lease assets are recognized on a straight-line basis within operating expenses over the term of the lease.

The Company has made an accounting policy election not to recognize right-of-use assets and lease liabilities that arise from leases with a term of 12 months or less. Fixed lease payments are recognized as an expense on a straight-line basis over the lease term. Variable lease costs are amounts owed by us to a lessor that are not fixed, such as reimbursement for common area maintenance, operating expenses, utilities, or other costs that are subject to fluctuation from period to period. The Company has also elected to include expenses related to leases with a term of one month or less in the short-term lease cost disclosure.

Recent Accounting Pronouncements

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables. The accounting update also made minor changes to the impairment model for available-for-sale debt securities. The Company will adopt the new guidance as of the beginning of the first quarter of 2023 by means of a cumulative-effect adjustment to opening retained earnings and does not expect adoption to have a material impact on the consolidated financial statements.

Note 3. Revenue

The Company disaggregates revenue by the following four customer types:

- **Pharma tests and services** includes sales of testing services and data analytics for clinical trials and research to pharmaceutical companies in support of their drug development programs. Individual contracts typically contemplate a single project and involve a wide range of tests and analytics deliverables from the Company that are suitable for each particular project.

- **Enterprise sales** includes sales of tumor profiling and diagnostic tests directly to other businesses as an input to their products. The Company is typically contracted to deliver a limited number of tests and analytics deliverables, but in high volume over time, and may offer tiered pricing. Revenue from the Company's partnership with Natera to provide advanced tumor analysis for use in Natera's MRD testing offerings makes up substantially all of the revenue in this category.

- **Population sequencing** includes sales of genomic sequencing services and data analytics to support large-scale genetic research programs. The Company is typically contracted to deliver a similar type of test and analytic across a large volume of samples, and has historically received partial prepayment prior to performance. Revenue from the Company's partnership with the VA MVP to provide population sequencing accounts for all of the revenue in this category.

- **Other** includes sales of genomic tests and analytics to universities and non-profits.

The following table presents the Company's revenue disaggregated by customer type (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Pharma tests and services	$ 29,552	$ 30,282	$ 21,396
Enterprise sales	26,641	8,774	479
Population sequencing	8,443	45,671	56,154
Other	411	767	619
Total revenue	$ 65,047	$ 85,494	$ 78,648

Revenue from countries outside of the United States, based on the billing addresses of customers, represented 9%, 8%, and 5% of the Company's revenue for the years ended December 31, 2022, 2021 and 2020, respectively.

Contract Assets and Liabilities

Contract assets as of December 31, 2022 and 2021 were immaterial.

Amounts collected in advance of services being provided are deferred as current liabilities in the consolidated balance sheets. The associated revenue is recognized and the contract liability is reduced as contracted services are subsequently performed. The balance of contract liabilities was $1.3 million and $4.0 million as of December 31, 2022 and 2021, respectively. Revenue recognized in 2022, 2021, and 2020 that were included in the contract liability balance at the beginning of each reporting period were $3.5 million, $19.1 million, and $33.8 million, respectively.

Note 4. Balance Sheet Details

Inventory and other deferred costs consist of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 6,384	$ 4,081
Other deferred costs	2,207	1,529
Total inventory and other deferred costs	$ 8,591	$ 5,610

Property and equipment, net consists of the following (in thousands):

	December 31,	
	2022	2021
Machinery and equipment	$ 21,537	$ 15,877
Computer equipment	17,803	13,286
Computer software costs	3,010	2,213
Furniture and fixtures	2,152	517
Construction in progress	3,989	5,393
Leasehold improvements	40,370	1,357
Total	88,861	38,643
Less: accumulated depreciation and amortization	(26,926)	(18,993)
Property and equipment, net	$ 61,935	$ 19,650

Depreciation and amortization expense for the years ended December 31, 2022, 2021, and 2020 was $8.4 million, $6.0 million, and $5.8 million, respectively.

Restricted cash. The Company's restricted cash is pledged as collateral for a standby letter of credit related to a property lease. The balance of restricted cash was $1.8 million as of December 31, 2022 and 2021, and is included in other long-term assets.

Accrued and other current liabilities consist of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation	$ 9,008	$ 10,673
Operating lease liabilities	5,391	3,728
Loans—current portion (Note 6)	2,218	1,806
Accrued liabilities	1,700	883
Employee ESPP contributions	543	517
Customer deposits	30	382
Accrued taxes	123	121
Total accrued and other current liabilities	$ 19,013	$ 18,110

Note 5. Fair Value Measurements

The following tables show the Company's financial assets and liabilities measured at fair value on a recurring basis and the level of inputs used in such measurements as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 5,615	$ —	$ —	$ 5,615	
Money market funds	31,401	—	—	31,401	Level 1
Commercial paper	47,135	—	(15)	47,120	Level 2
U.S. government securities	4,991	1	—	4,992	Level 2
Total cash and cash equivalents	89,142	1	(15)	89,128	
Short-term investments:					
Commercial paper	13,097	—	(51)	13,046	Level 2
U.S. agency securities	9,445	—	(105)	9,340	Level 2
U.S. government securities	56,658	1	(515)	56,144	Level 2
Total short-term investments	79,200	1	(671)	78,530	
Total assets measured at fair value	$ 168,342	$ 2	$ (686)	$ 167,658	

	December 31, 2021				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 6,094	$ —	$ —	$ 6,094	
Money market funds	49,488	—	—	49,488	Level 1
Commercial paper	50,005	—	(2)	50,003	Level 2
Total cash and cash equivalents	105,587	—	(2)	105,585	
Short-term investments:					
Commercial paper	18,068	—	(2)	18,066	Level 2
U.S. government securities	50,040	—	(15)	50,025	Level 2
Corporate debt securities	18,059	—	(7)	18,052	Level 2
U.S. agency securities	19,738	—	(35)	19,703	Level 2
Asset-backed securities	75,787	—	(154)	75,633	Level 2
Total short-term investments	181,692	—	(213)	181,479	
Total assets measured at fair value	$ 287,279	$ —	$ (215)	$ 287,064	

Realized gains or losses on marketable debt securities are immaterial for the periods presented. No security has been in an unrealized loss position for 12 months or greater. The Company determined that it did have the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. As of December 31, 2022, the Company does not consider any of its marketable debt securities to be other-than-temporarily impaired. The Company's marketable debt securities at December 31, 2022 have maturities due in one year or less.

Note 6. Loans

Equipment and Software Loans

In April 2021, the Company entered into a payment agreement with a financing entity to finance the purchase of $2.4 million of certain internal use software licenses and related software maintenance from a vendor. The financing entity and vendor are not related. The Company is obligated to repay the financed amount in three equal payments of $0.8 million in May 2021, May 2022, and May 2023. The payment agreement is noninterest bearing and the Company concluded that such interest rate (zero) did not represent fair and adequate compensation to the financing entity for the use of the related funds. Accordingly, the Company approximated the rate at which it could obtain financing of a similar nature from other sources at the date of the transaction. The resulting imputed interest rate was 7% and was used to establish the present value of the payment agreement. The discount is recognized as interest expense in the consolidated statements of operations over the life of the payment agreement.

The Company entered into two more payment agreements in April 2021 and July 2022, with the same financing entity, to finance the purchase of $3.1 million of computer hardware and related hardware maintenance and $1.3 million of internal use software licenses and related ongoing support, respectively. The Company is required to pay three equal payments of $1.0 million in July 2021, June 2022, and June 2023 for the first agreement, and three equal payments of $0.4 million in September 2022, September 2023, and September 2024 for the second agreement. The nature of these agreements and resulting accounting treatment are the same as the payment agreement described in the preceding paragraph, except the imputed interest rate was 9% for the July 2022 agreement.

The total initial present value of the payment agreements was $6.4 million and presented as proceeds from loans in the consolidated statements of cash flows. Such proceeds were used to purchase equipment, software, and related maintenance and are reflected as cash outflows in the investing and operating activities sections in the consolidated statements of cash flows. Repayments are presented as financing cash outflows in the consolidated statements of cash flows. Interest expense for the years ended December 31, 2022 and 2021 was $0.2 million each. Amounts outstanding under the payment agreements are as follows (in thousands):

	December 31,	
	2022	2021
Principal	$ 2,730	$ 3,714
Less: unamortized discount	(134)	(220)
Total carrying amount	2,596	3,494
Less: current portion (included in accrued and other current liabilities)	(2,218)	(1,806)
Long-term portion (included in other long-term liabilities)	$ 378	$ 1,688

Note 7. Leases

In 2015, the Company entered into a noncancelable operating lease for approximately 31,280 square feet of space used for its current laboratory operations. In 2020, the lease term was extended through November 2027 and includes an option to extend the term for a period of three years at prevailing market rates. The Company determined the extension option is not reasonably certain to be exercised. The lease contains a leasehold improvement incentive and escalating rent payments. In 2021, the Company amended the

lease to expand the leased premises by an additional 14,710 square feet of space (the “Expansion Lease”). The Expansion Lease expired at the end of December 2022 and was not extended.

In 2019, the Company entered into a noncancelable three-year operating lease for a co-located data center space. In 2022, the lease term was extended through September 2025 and includes an option to extend the term for a period of three years immediately following the expiration of the term. The Company determined the extension option is not reasonably certain to be exercised.

In 2021, the Company entered into a noncancelable operating lease for approximately 100,000 square feet of space in Fremont, California to be used as the Company’s corporate headquarters and expanded laboratory facility. The lease term is 13.5 years and commenced in October 2022. The Company gained early access to the premises upon entering the lease for the purpose of constructing and installing tenant improvements, for which the landlord agreed to contribute up to $15.5 million, $13.2 million of which has been received through December 31, 2022. Such contributions become payable only upon approval by the landlord of applications for payment and are accounted for as lease incentives once the Company has incurred costs and the amounts qualify for reimbursement by the landlord. The lease incentives are then recognized as reductions to lease expense over the remainder of the lease term. The lease expires at the end of March 2036 and includes two options to extend the term for a period of five-years per option at prevailing market rates. The Company determined the extension options are not reasonably certain to be exercised. The lease also contains escalating rent payments. Due to delays in the completion of the work necessary for the Company to move into the facility, the lease commencement date was delayed from the original intended date. This change in circumstances during the third quarter of 2022 triggered a reassessment of the lease term and consequently a remeasurement of the lease liability and corresponding adjustment to the carrying amount of the right-of-use asset.

The Company also has a noncancelable operating lease for approximately 5,100 square feet of space in Shanghai, China used for its China operations, which expires at the end of June 2024, as well as various other short-term leases.

Components of lease cost were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Lease cost			
Operating lease cost	$ 8,530	$ 5,009	$ 2,295
Short-term lease cost	122	364	227
Variable lease cost	1,411	1,152	748
Total lease cost	$ 10,063	$ 6,525	$ 3,270

As of December 31, 2022, the Company’s operating leases had a weighted-average remaining lease term of 11.1 years and a weighted-average discount rate of 10.5%. The Company’s discount rates are based on estimates of its incremental borrowing rate, as the discount rates implicit in the Company’s lease cannot be readily determined. Future lease payments under operating leases as of December 31, 2022 were as follows (in thousands):

	Amount
2023	$ 5,711
2024	7,895
2025	7,808
2026	7,168
2027	7,189
2028 and thereafter	48,013
Total future minimum lease payments	83,784
Less: imputed interest	(37,352)
Present value of future minimum lease payments	46,432
Less: current portion of operating lease liability (included in accrued and other current liabilities)	(5,391)
Long-term operating lease liabilities	$ 41,041

Cash paid for operating lease liabilities, included in cash flows from operating activities in the consolidated statements of cash flows, for the years ended December 31, 2022, 2021 and 2020, was $4.4 million, $3.3 million and $1.7 million, respectively. Right-of-use assets obtained in exchange for new operating lease liabilities, during 2022, 2021 and 2020, were $3.1 million, $46.5 million and $9.8 million, respectively. Additionally, the remeasurement of the Fremont headquarters lease liability in the third quarter of 2022 resulted in a $12.9 million reduction to right-of-use assets.

Note 8. Stock-Based Compensation

2011 Equity Incentive Plan

In 2011, the Company established its 2011 Equity Incentive Plan (the "2011 Plan") that provided for the granting of stock options to employees and nonemployees of the Company. Under the 2011 Plan, the Company had the ability to issue incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, and restricted stock unit awards ("RSUs"). Options under the 2011 Plan could be granted for periods of up to 10 years. The ISOs could be granted at a price per share not less than the fair value at the date of grant.

2019 Equity Incentive Plan

The Company's board of directors adopted and the Company's stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") in May 2019 and June 2019, respectively. The 2019 Plan became effective in June 2019 in connection with the Company's IPO, and no further grants will be made under the 2011 Plan. Shares reserved and remaining available for issuance under the 2011 Plan were added to the 2019 Plan reserve upon its effectiveness.

The 2019 Plan provides for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, RSUs, performance-based stock awards, and other forms of equity compensation. Additionally, the 2019 Plan provides for the grant of performance cash awards. ISOs may be granted only to the Company's employees and to any of the Company's parent or subsidiary corporation's employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of the Company and any of the Company's affiliates. The exercise price of a stock option generally cannot be less than 100% of the fair market value of the Company's common stock on the date of grant. Options under the 2019 Plan may be granted for periods of up to 10 years.

2020 Inducement Plan

The Compensation Committee of the Company's board of directors adopted the 2020 Inducement Plan (the "Inducement Plan") in May 2020, which became effective upon adoption. The Inducement Plan was adopted without stockholder approval, as permitted by the Nasdaq Stock Market rules. The Inducement Plan provides for the grant of equity-based awards, including NSOs, stock appreciation rights, restricted stock awards, RSUs, performance-based stock awards, and other forms of equity compensation, and its terms are substantially similar to the stockholder-approved 2019 Plan. In accordance with relevant Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals entry into employment with the Company.

2019 Employee Stock Purchase Plan

The Company's board of directors adopted and the Company's stockholders approved the 2019 Employee Stock Purchase Plan (the "ESPP") in May 2019 and June 2019, respectively. Subject to any plan limitations, the ESPP allows eligible employees to contribute, normally through payroll deductions, up to 15% 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 1 and November 1 of each year.

Shares of common stock available for issuance under the Company's equity incentive plans at December 31, 2022 were as follows:

	December 31, 2022
Outstanding stock awards	8,493,614
Reserved for future award grants	1,958,949
Reserved for future ESPP	615,879
Total common stock reserved for stock awards	11,068,442

Stock Option Activity

A summary of the Company's stock option activity (excluding performance-based stock option activity summarized further below) under the 2011 Plan, 2019 Plan, and Inducement Plan for the years ended December 31, 2022, 2021, and 2020 is as follows:

	Outstanding Options			
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance—December 31, 2019	4,731,435	$ 4.94	6.60	$ 29,730
Options granted	1,357,741	12.05		
Options exercised	(908,691)	3.07		
Options forfeited or expired	(232,179)	7.87		
Balance—December 31, 2020	4,948,306	$ 7.10	6.71	$ 146,044
Options granted	1,026,276	21.26		
Options exercised	(862,056)	2.43		
Options forfeited or expired	(110,107)	13.88		
Balance—December 31, 2021	5,002,419	$ 10.66	6.89	$ 28,308
Options granted	1,429,295	4.80		
Options exercised	(488,187)	2.07		
Options forfeited or expired	(492,395)	10.57		
Balance—December 31, 2022	5,451,132	$ 9.90	5.31	$ 7
Options vested and exercisable as of December 31, 2022	3,740,205	$ 9.03	3.76	$ 7

Options granted to new hires generally vest over a four-year period, with 25% vesting at the end of one year and the remaining vesting monthly thereafter. Options granted as merit awards generally vest monthly over a three- or four-year period.

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $1.98 on December 31, 2022 and the exercise prices of the underlying stock options. Out-of-the money stock options are excluded from the aggregate intrinsic value.

The weighted-average grant date fair value of options granted was $3.21, $13.14, and $7.17 per share for the years ended December 31, 2022, 2021, and 2020, respectively. As of December 31, 2022, the unrecognized stock-based compensation of unvested options was $10.3 million, which is expected to be recognized over a weighted-average period of 2.4 years.

Valuation of Stock Options

The Company estimated the fair value of stock options (excluding performance-based stock options discussed below) using the Black-Scholes option-pricing model. The fair value of stock options is recognized on a straight-line basis over the requisite service periods of the awards. The fair value of stock options was estimated using the following range of assumptions:

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	5.50 - 6.08	5.50 - 6.27	5.50 - 6.40
Volatility	68.37 - 77.68%	67.97 - 69.90%	61.74 - 68.18%
Risk-free interest rate	1.62 - 4.23%	0.62 - 1.39%	0.36 - 1.66%
Dividend yield	–%	–%	–%

Performance-Based Stock Option Activity

In March 2020, the Company's board of directors granted the Company's then Chief Executive Officer a performance-based stock option ("PSO") to purchase 421,000 shares of common stock. The PSO was subject to the Chief Executive Officer's continued service to the Company through the date of vesting and, if the performance condition were not met within 10 years from the date of grant, the PSO would be canceled. The shares subject to the PSO would vest in full if the Company's average market capitalization is equal to or greater than $1 billion over a 30 calendar day period. Upon a change in control, the vesting of the shares subject to the PSO would accelerate on a pro rata basis based on the price per share in such change in control transaction multiplied by the price per share at such time divided by $1 billion, with up to 100% of the shares eligible for such accelerated vesting. During the last quarter of 2020, the Company's average market capitalization was equal to or greater than $1 billion over a 30 calendar day period and the PSO vested in full.

A summary of the Company's performance-based stock option activity under the 2019 Plan for the years ended December 31, 2022, 2021 and 2020 is as follows:

	Outstanding Performance-Based Options			
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance—December 31, 2019	—	$ —	—	$ —
Options granted	421,000	5.10		
Options exercised	—			
Options cancelled	—			
Balance—December 31, 2020	421,000	$ 5.10	9.21	$ 13,266
No activities	—			
Balance—December 31, 2021	421,000	$ 5.10	8.21	$ 3,861
No activities	—			
Balance—December 31, 2022	421,000	$ 5.10	1.00	$ —
Options vested and exercisable as of December 31, 2022	421,000	$ 5.10	1.00	$ —

As of December 31, 2022, there is no remaining unrecognized stock-based compensation cost.

Valuation of Performance-Based Stock Options

The Company estimated the fair value of the PSO using a Monte Carlo Model and the following assumptions and estimates:

	2020
Performance period (in years)	10.00
Derived service period (in years)	4.55
Volatility	63.60%
Risk-free interest rate	1.02%
Dividend yield	–%
Estimated fair value (per share)	$ 3.31

Restricted Stock Units Activity and Valuation

A summary of the Company's RSU activity under the 2019 Plan and Inducement Plan for the years ended December 31, 2022, 2021 and 2020 is as follows:

	Unvested Restricted Stock Units		
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Fair Value
Balance—December 31, 2019	120,000	$ 8.86	$ 1,308
RSUs granted	648,000	9.93	
RSUs vested	(130,945)	7.09	2,991
RSUs forfeited	(17,837)	6.83	
Balance—December 31, 2020	619,218	$ 10.41	$ 22,670
RSUs granted	1,387,656	18.05	
RSUs vested	(266,119)	10.93	5,521
RSUs forfeited	(61,059)	18.45	
Balance—December 31, 2021	1,679,696	$ 16.35	$ 23,969
RSUs granted	2,071,201	4.86	
RSUs vested	(897,871)	11.74	3,189
RSUs forfeited	(231,544)	10.94	
Balance—December 31, 2022	2,621,482	$ 9.33	$ 5,191

The Company grants RSUs to employees to receive shares of the Company's common stock. The RSUs awarded are subject to each individual's continued service to the Company through each applicable vesting date. RSUs granted to new hires generally vest annually over a four-year period. RSUs granted as merit awards generally vest semi-annually over a three- or four-year period. The Company accounts for the fair value of RSUs using the closing market price of the Company's common stock on the date of grant.

The aggregate fair value of unvested RSUs is calculated using the closing price of the Company's common stock of $1.98 on December 31, 2022. As of December 31, 2022, the unrecognized stock-based compensation cost of unvested RSUs was $21.9 million, which is expected to be recognized over a weighted-average period of 2.6 years.

The Company's default tax withholding method for RSUs is the sell-to-cover method, in which shares with a market value equivalent to the tax withholding obligation are sold on behalf of the holder of the RSUs upon vesting and settlement to cover the tax withholding liability and the cash proceeds from such sales are remitted by the Company to taxing authorities.

ESPP Activity and Valuation

During the years ended December 31, 2022, 2021 and 2020, 416,514, 128,289 and 164,164 shares of common stock were purchased under the ESPP, respectively. The fair value of stock purchase rights granted under the ESPP was estimated using the following range of assumptions:

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	0.49 - 0.5	0.49	0.49 - 0.5
Volatility	82.35 - 112.07%	55.92 - 74.88%	65.15 - 102.10%
Risk-free interest rate	1.49 - 4.58%	0.04 - 0.06%	0.11 - 0.12%
Dividend yield	–%	–%	–%
Fair value	$1.26 - $2.23	$6.30 - $8.21	$4.29 - $8.12

Stock-based Compensation Expense

The following is a summary of stock-based compensation expense by function (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	$ 1,922	$ 1,414	$ 854
Research and development	5,256	4,064	1,773
Selling, general and administrative	12,255	8,900	5,611
Total stock-based compensation expense	$ 19,433	$ 14,378	$ 8,238

The following is a summary of stock-based compensation expense by award type (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Stock options	$ 8,560	$ 8,585	$ 4,729
Performance-based stock options	—	—	1,392
RSUs	9,990	4,765	1,401
ESPP	883	1,028	716
Total stock-based compensation expense	$ 19,433	$ 14,378	$ 8,238

Note 9. Commitments and Contingencies

Contingencies

On August 2, 2022, the Company filed a complaint in the U.S. District Court for the District of Colorado against Foresight Diagnostics Inc. ("Foresight") for patent infringement. The complaint is based on the Company's U.S. Patent No. 10,450,611 (the "'611 Patent"), entitled "Personalized Genetic Testing," our U.S. Patent No. 11,299,783 (the "'783 Patent"), entitled "Methods and Systems For Genetic Analysis," and our U.S. Patent No. 11,384,394 (the "'394 Patent"), entitled "Methods and Systems for Genetic Analysis." The '611 Patent was granted on October 22, 2019 and relates to methods for personalized genetic testing by performance of sequencing assays on biological samples. The '783 Patent was granted on April 12, 2022 and relates to methods for sample processing and data analysis by performance of sequencing assays on biological samples that can aid in the diagnosis, monitoring, treatment, and prevention of one or more diseases. The '394 Patent was granted on July 12, 2022 and relates to methods for sample processing and analysis to aid in the diagnosis, monitoring, treatment, and prevention of disease. On August 17, 2022, the Company filed an amended complaint for patent infringement against Foresight. The amended complaint added our U.S. Patent No. 11,408,033 (the "'033 Patent"), entitled "Methods and Systems for Genetic Analysis." The '033 Patent was granted on August 9, 2022 and relates to methods for sample processing and analysis to aid in the diagnosis, monitoring, treatment, and prevention of disease. The Company is seeking remedies

including injunctive relief, damages and costs. On October 12, 2022, Foresight filed its answer and counterclaims in the matter, alleging and seeking declaratory judgement that its solid tumor recurrence test does not infringe the Company's asserted patents and that the claims of our asserted patents are invalid and/or unenforceable. On November 2, 2022, the Company filed its answer to Foresight's counterclaims. The Company believes the assertions in Foresight's counterclaims are without merit and intends to vigorously defend against these counterclaims.

Between November 30, 2022 and February 11, 2023, Foresight filed four *inter partes* review petitions with the USPTO, seeking to invalidate the four patents that we are asserting against Foresight in our patent infringement action. Also on November 30, 2022, Foresight filed a motion to stay our patent infringement action in the U.S. District Court for the District of Colorado pending the resolution of the *inter partes* review proceedings that Foresight has requested. On December 21, 2022, we filed our opposition to Foresight's motion to stay, and on December 29, 2022 Foresight filed its reply in support of the stay. On January 5, 2023, the Court held a hearing on Foresight's motion and on January 24, 2023, the Court granted Foresight's motion to stay our patent infringement action pending the resolution of the *inter partes* review proceedings. The USPTO has yet to issue a decision regarding whether it will institute the *inter partes* reviews.

Litigation is inherently unpredictable, and, except for events that have already occurred, it is too early in the foregoing proceedings to predict the outcome of these proceedings, or any impact they may have on us. As such, the estimated financial effect associated with this complaint cannot be made as of the date of filing of this Annual Report on Form 10-K. Litigation is a significant ongoing expense with an uncertain outcome and may in the future be a material expense for us. Management believes this investment is important to protect our intellectual property position, even recognizing the uncertainty of the outcome.

The Company is also subject to claims and assessments from time to time in the ordinary course of business. Accruals for litigation and loss contingencies are reflected in the consolidated financial statements based on management's assessment, including the advice of legal counsel, of the expected outcome of litigation or other dispute resolution proceedings and/or the expected resolution of contingencies. Liabilities for estimated losses are accrued if the potential losses from any claims or legal proceedings are considered probable and the amounts can be reasonably estimated. Significant judgment is required in both the determination of probability of loss and the determination as to whether the amount can be reasonably estimated. Accruals are based only on information available at the time of the assessment due to the uncertain nature of such matters. As additional information becomes available, management reassesses potential liabilities related to pending claims and litigation and may revise its previous estimates, which could materially affect the Company's consolidated results of operations in a given period. Except for the matter described in the first paragraph of this Note 9, as of December 31, 2022, the Company was not involved in any material adverse legal proceedings.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

Note 10. Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed using net loss and the weighted-average number of common shares outstanding plus potentially dilutive common shares outstanding during the period. Potentially dilutive common shares include the assumed exercise of outstanding in-the-money stock options and common stock warrants, assumed release of outstanding RSUs, and assumed issuance of common stock under the ESPP using the treasury stock method. The Company incurred net losses in the periods presented, and as a result, potential common shares from stock options, RSUs, and the assumed release of outstanding shares under the ESPP were not included in the diluted shares used to calculate net loss per share, as their inclusion would have been anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (113,315)	$ (65,226)	$ (41,280)
Weighted-average common shares outstanding—basic and diluted	45,704,805	43,886,730	34,374,903
Net loss per common share—basic and diluted	$ (2.48)	$ (1.49)	$ (1.20)

The following table sets forth the potentially dilutive shares excluded from the computation of diluted net loss per common share because their effect was anti-dilutive:

	Year Ended December 31,		
	2022	2021	2020
Options to purchase common stock	5,872,132	5,423,419	5,369,306
Unvested RSUs	2,621,482	1,679,696	619,218
ESPP	627,740	87,367	58,802
Total	9,121,354	7,190,482	6,047,326

Note 11. Income Taxes

For financial reporting purposes, loss before income taxes includes the following components (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ (113,558)	$ (65,415)	$ (41,404)
Foreign	283	203	181
Loss before income taxes	$ (113,275)	$ (65,212)	$ (41,223)

Provision for Income Taxes

The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Current:			
Federal	$ —	$ —	$ —
State	5	—	26
Foreign	66	43	31
Total current	71	43	57
Deferred:			
Foreign	(31)	(29)	—
Total deferred	(31)	(29)	—
Provision for income taxes	$ 40	$ 14	$ 57

Income tax provision related to continuing operations differ from the amounts computed by applying the statutory income tax rate of 21% to pretax loss in 2022, 2021, and 2020 as follows:

	Year Ended December 31,		
	2022	2021	2020
Expected tax (benefit) at federal statutory rate	(21%)	(21%)	(21%)
Effect of:			
State taxes	(6%)	(9%)	(10%)
Change in valuation allowance	28%	36%	38%
Stock-based compensation	1%	(3%)	(4%)
Research and development credit	(2%)	(3%)	(3%)
Other	–%	–%	–%
Effective tax rate	–%	–%	–%

Tax Law Changes

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), which includes several U.S. income tax provisions related to, among other things, net operating loss carrybacks, alternative minimum tax credits, modifications to interest expense limitations, and an option to defer payroll tax payments for a limited period. Based on the guidance in the CARES Act, the Company deferred the payment of $0.7 million of certain payroll taxes, of which $0.3 million was paid in 2021 and the remaining balance was paid in 2022. The other provisions of the CARES Act did not have a significant impact on the Company’s consolidated financial statements.

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and 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 for federal and state income taxes are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 72,408	$ 61,219
Research and development credits	16,824	12,127
Capitalized research and development	11,972	—
Deferred revenue	38	164
Accruals and reserves	1,914	2,846
Stock-based compensation	5,197	4,435
Operating lease liabilities	13,455	16,406
Other intangibles	267	321
Other	236	115
Total gross deferred tax assets	122,311	97,633
Less: valuation allowance	(114,483)	(81,628)
Total deferred tax assets	7,828	16,005
Deferred tax liabilities:		
Property and equipment	(108)	(356)
Operating lease right-of-use assets	(7,659)	(15,620)
Total deferred tax liabilities	(7,767)	(15,976)
Net deferred tax assets	$ 61	$ 29

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Because of the Company's lack of U.S. earnings history, the net U.S. deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $32.9 million and $24.8 million during the years ended December 31, 2022 and 2021, respectively.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2022, the Company had a net operating loss carryforward for federal income tax purposes of approximately $249.1 million, of which $86.1 million will begin to expire in 2031. The Company had a total state net operating loss carryforward of approximately $229.7 million, which will begin to expire in 2031. Utilization of some of the federal and state net operating loss and credit carryforwards are subject to annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits before utilization.

As of December 31, 2022, the Company has federal credits of approximately $8.6 million, which will begin to expire in 2031 and state research credits of approximately $8.2 million, which have no expiration date. These tax credits are subject to the same limitations discussed above.

Unrecognized Tax Benefits

The Company has incurred net operating losses since inception and does not have any significant unrecognized tax benefits. The Company's policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the consolidated statements of operations. If the Company is eventually able to recognize its uncertain positions, the effective tax rate would be reduced. The Company currently has a full valuation allowance against its net deferred tax assets, which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future. Any adjustments to the Company's uncertain tax positions would result in an adjustment of net operating loss or tax credit carryforwards rather than resulting in a cash outlay.

The Company files U.S. federal income tax returns and various state income tax returns. Because of net operating losses and research credit carryovers, substantially all the Company's tax years remain open to examination.

The Company has the following activity relating to unrecognized tax benefits (in thousands):

	December 31,	
	2022	2021
Beginning balance	$ 3,066	$ 2,148
Gross increase—tax position in current period	1,174	918
Ending balance	$ 4,240	$ 3,066

Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next 12 months due to tax examination changes, settlement activities, expirations of statute of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar activities, the Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months. During the years ended December 31, 2022, 2021, and 2020, no interest or penalties were required to be recognized relating to unrecognized tax benefits.

Note 12. Subsequent Events

In January 2023, the Board of Directors of the Company approved a reduction in the Company's workforce of approximately 30% to reduce operating costs and improve operating efficiency. The reduction in workforce is expected to be completed in the first quarter of 2023. The Company estimates that it will incur charges of approximately $3 million for severance payments and employee benefits, most of which will be recognized in the first quarter of 2023. Substantially all of the estimated charges are expected to result in future cash expenditures.

In February 2023, Company management made a decision to streamline its international operations by closing its operations in China as expeditiously as possible in 2023. The Company expects to incur one-time charges in connection with the closure, including noncash impairments of property and equipment and a lease asset. Such charges cannot be estimated at this time, but the Company does not expect such charges to exceed $1.5 million.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Personalis, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Personalis, Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholder's equity and cash flows, for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ DELOITTE & TOUCHE LLP

Austin, Texas
February 23, 2023

We have served as the Company's auditor since 2018.

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 interim chief executive officer ("CEO") and chief financial officer ("CFO") has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our CEO and CFO have concluded that as of December 31, 2022, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosures.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the 1934 Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

Our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting for so long as we qualify as a non-accelerated filer.

Changes in Internal Control

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) of the Exchange Act. An evaluation was also performed under the supervision and with the participation of our management, including our CEO and our CFO, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except for the principal occupation, business experience, and education of each of our executive officers and directors set forth further below, the information required by this Item is set forth under the headings “Executive Officers,” “Security Ownership of Certain Beneficial Owners and Management,” “Delinquent Section 16(a) Reports,” “Corporate Governance and Board of Directors Matters,” and “Proposal No. 1 Election of Directors—Information About Our Continuing Directors” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022 in connection with the solicitation of proxies for the Company’s 2023 annual meeting of stockholders, and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available on our website (investors.personalis.com) under "Corporate Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on the website address and location specified above.

The principal occupation, business experience, and education of each of our executive officers and directors are set forth below.

Executive Officers

Aaron Tachibana. Mr. Tachibana has served as our Chief Financial Officer since March 2019; in July 2021, he was promoted Senior Vice President and Chief Financial Officer; and in December 2022, he was promoted to interim Chief Executive Officer while continuing to serve as Senior Vice President and Chief Financial Officer. From August 2015 to September 2018, Mr. Tachibana served as Chief Financial Officer at Lumentum Holdings Inc., a designer and manufacturer of optical and photonic products. From November 2013 to July 2015, Mr. Tachibana served as Vice President, Finance and Corporate Controller at JDS Uniphase Corp., subsequently renamed Viavi Solutions Inc., a network test, measurement, and assurance technology company. From March 2010 to October 2013, Mr. Tachibana served as Chief Financial Officer at Pericom Semiconductor Corp., a supplier of high-performance connectivity and timing solutions. Mr. Tachibana holds a B.S. in Business Administration and Finance from San Jose State University.

Christopher Hall. Mr. Hall has served as our President since December 2022 and before that served as our Senior Vice President and Head, Diagnostics Business since joining our company in October 2022. From October 2020 to July 2022, Mr. Hall served as Chief Executive Officer of Naring Health, Inc., a medical research services company. From February 2010 to July 2019, Mr. Hall served as President, Chief Operating Officer, and Chief Commercial Officer at Veracyte, Inc., a publicly traded global diagnostics company. Mr. Hall holds a B.A. in Political Science and Economics from DePauw University and an M.B.A. from Harvard Business School.

Richard Chen, M.D., M.S. Dr. Chen was promoted to Senior Vice President, R&D, and Chief Medical Officer in July 2021. Dr. Chen previously served as our Chief Scientific Officer since November 2011. Since September 2011, Dr. Chen has served on the clinical faculty at Stanford University School of Medicine. In August 1997, Dr. Chen co-founded Ingenuity Systems, a genomic data software company. Dr. Chen holds a B.S. in Computer Science from Stanford University, an M.S. in Medical Informatics from Stanford University School of Medicine, and an M.D. from Stanford University School of Medicine.

Stephen Moore. Mr. Moore has served as our Vice President and General Counsel since April 2020 and as Corporate Secretary since May 2020. From October 2014 to April 2020, Mr. Moore served as General Counsel and Corporate Secretary at Pacific Biosciences of California, Inc., a publicly traded advanced genomics company. From January 2010 to October 2014, Mr. Moore served in other roles at Pacific Biosciences of California, Inc., including Associate General Counsel and Senior Director of Commercial Legal Affairs, and Vice President, Legal Affairs. From June 2007 to December 2009, Mr. Moore served as General Counsel and Corporate Secretary at Navigenics, Inc., a consumer genomics company. From January 1999 to June 2007, Mr. Moore held various positions at Affymetrix, Inc., a microarray company, including Associate General Counsel. Mr. Moore holds a B.A. in Political Science from San Jose State University and a J.D. from University of California, Davis.

Independent Directors

Olivia K. Bloom. Ms. Bloom has served on our Board of Directors since March 2022. Ms. Bloom has served as Executive Vice President, Finance since February 2014, Chief Financial Officer since December 2012 and Treasurer since February 2011 at Geron Corporation, a publicly traded clinical stage biopharmaceutical company. Ms. Bloom also previously held various other positions at Geron, including Senior Vice President, Finance from December 2012 to February 2014, Chief Accounting Officer from September 2010 to December 2012 and Vice President, Finance from January 2007 to December 2012. Ms. Bloom joined Geron in 1994 as a Senior Financial Analyst and from 1996 to 2011 served as Controller. Ms. Bloom started her career in public accounting at KPMG International Limited and became a Certified Public Accountant in 1994. Ms. Bloom holds a B.S. in Business Administration from the University of California, Berkeley. Ms. Bloom was selected to serve on our Board of Directors because of her expertise in finance and accounting and experience working for and with publicly-traded life science companies.

A. Blaine Bowman. Mr. Bowman has served on our Board of Directors since May 2019. Beginning in 2006, Mr. Bowman served on the board of directors of Solexa, Inc., a DNA sequencing company, until its sale to Illumina, Inc., a publicly traded biotechnology company and leader in DNA sequencing in January 2007, after which Mr. Bowman continued to serve on the board of directors of Illumina,

Inc. until May 2018. From March 1977 to August 2005, Mr. Bowman served in various roles at Dionex Corporation, a publicly traded manufacturer of analytical instruments, including Chairman of the board of directors, President, and Chief Executive Officer, and he served on the board of directors until its sale to Thermo Fisher Scientific Inc. in May 2011. From July 2012 to December 2015, Mr. Bowman served on the board of directors of Altera Corporation, a publicly traded programmable logic devices company. Mr. Bowman holds a B.S. in Physics from Brigham Young University and an M.B.A. from the Stanford Graduate School of Business. Mr. Bowman was selected to serve on our Board of Directors because of his experience in executive roles and his experience serving on the boards of directors of various instrumentation and biotechnology companies.

Alan Colowick, M.D. Dr. Colowick has served on our Board of Directors since May 2019. Dr. Colowick has served on the board of directors of Harpoon Therapeutics, Inc., a publicly traded clinical stage immunotherapy company, since March 2021. Dr. Colowick has also served on the board of directors of AC Immune SA, a publicly traded clinical stage biopharmaceutical company, since March 2021. From May 2017 to January 2021, Dr. Colowick served as a Partner at Sofinnova Investment, Inc., a clinical stage life sciences venture capital firm. From February 2010 to April 2017, Dr. Colowick held various positions, including Executive Vice President, at Celgene Corporation, a pharmaceutical company. From February 2008 to January 2010, Dr. Colowick served as the Chief Executive Officer of Gloucester Pharmaceuticals Inc., an early stage cancer pharmaceutical company, until its acquisition by Celgene Corporation in January 2010. From October 2006 to February 2008, Dr. Colowick served as President, Oncology at Geron Corporation, a publicly traded clinical stage biopharmaceutical company. Earlier in his career, Dr. Colowick served in various capacities at Amgen Inc., a biopharmaceutical company. Dr. Colowick previously served on the boards of directors of Principia Biopharma, Inc., a publicly traded biopharmaceutical company, from February 2017 to September 2020, Achaogen, Inc., a publicly traded biopharmaceutical company, from August 2015 to August 2017, and Dimension Therapeutics, Inc., a publicly traded biopharmaceutical company, from August 2015 to November 2017. Dr. Colowick holds a B.S. in Molecular Biology from the University of Colorado, an M.D. from Stanford University School of Medicine, and an M.P.H. from the Harvard School of Public Health. Dr. Colowick was selected to serve on our Board of Directors because of his educational background in science and medicine and experience in developing oncology therapeutics, as well as financial understanding of the biotechnology industry gained from his investing experience.

Karin Eastham. Ms. Eastham has served on our Board of Directors since September 2019. Ms. Eastham has served on the boards of directors of Nektar Therapeutics, Inc., a publicly traded biopharmaceutical company, since September 2018, Veracyte, Inc., a publicly traded genomic diagnostics company, since December 2012, and Geron Corporation, a publicly traded clinical stage biopharmaceutical company, since March 2009. Ms. Eastham served as a member of the board of directors of Illumina, Inc., a publicly traded biotechnology company and leader in DNA sequencing, from August 2004 to May 2019. From May 2004 to September 2008, Ms. Eastham served as Executive Vice President and Chief Operating Officer, and as a member of the Board of Trustees, of the Burnham Institute for Medical Research, a non-profit corporation engaged in biomedical research. Ms. Eastham holds a B.S. in Accounting and an M.B.A. from Indiana University and is a Certified Public Accountant (inactive). Ms. Eastham was selected to serve on our Board of Directors because of her expertise in financial and operations management and experience serving on the boards of publicly-traded life science companies.

Kenneth Ludlum. Mr. Ludlum has served on our Board of Directors since July 2015. Mr. Ludlum has served on the board of directors of IRIDEX Corporation, a publicly traded medical technology company, since April 2019. From January 2002 to June 2020, Mr. Ludlum served on the board of directors of Natus Medical Inc., a publicly traded medical device and equipment company. From February 2014 to April 2016, Mr. Ludlum served as Chief Financial Officer at CareDx, Inc., a molecular diagnostics company, and prior to that Mr. Ludlum served as a Chief Financial Officer for other publicly traded companies. Mr. Ludlum holds a B.S. in Business Administration from Lehigh University and an M.B.A. from Columbia Business School. Mr. Ludlum was selected to serve on our Board of Directors because of his experience working for and with publicly-traded healthcare, medical device, biotechnology, and diagnostic companies and his expertise in finance, accounting, and general management.

Woodrow A. Myers, Jr., M.D. Dr. Myers has served on our Board of Directors since March 2021. Dr. Myers has served as an advisor of public and political affairs to Sera Prognostics Inc., a publicly traded health diagnostics company, since November 2021. From May 2007 to December 2018, Dr. Myers served on the board of directors of Express Scripts Inc., a publicly traded health care company. From January 2018 to February 2019, Dr. Myers served as Chief Medical Officer and Chief Healthcare Strategist for Blue Cross Blue Shield of Arizona. Since December 2015, Dr. Myers has served as Managing Director of Myers Ventures LLC, a healthcare consulting company. Dr. Myers holds a B.S. in Biology from Stanford University, an M.B.A. from Stanford Graduate School of Business, and an M.D. from Harvard Medical School. Dr. Myers was selected to serve on our Board of Directors because of his extensive experience in the healthcare industry, including in government and health policy roles.

Lonnie Shoff. Ms. Shoff has served on our Board of Directors since August 2022. Ms. Shoff has served as President of Antech and Sound Diagnostics, a business unit of Mars Petcare, since April 2020. From September 2016 to April 2020, Ms. Shoff served as President of the Clinical Diagnostics Division at Thermo Fisher Scientific Inc. From September 2009 to May 2016, Ms. Shoff held various positions at Henry Schein, a publicly traded health care product distributor, including Chief Executive Officer of the Global Animal Health and Strategic Partnership Group and President of the Global Healthcare Specialty Group. Ms. Shoff also held positions of increasing responsibility including the Senior Vice President & General Manager of Molecular Diagnostic and Applied Science at Roche, a Swiss multinational healthcare company, from August 1988 to September 2009. Ms. Shoff holds a B.S. in Biology from Purdue University.

Item 11. Executive Compensation.

The information required by this Item is set forth under the headings “Director Compensation,” “Executive Compensation,” and “Compensation Committee Interlocks and Insider Participation” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022, 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 is set forth under the headings “Equity Compensation Plans at December 31, 2022” and “Security Ownership of Certain Beneficial Owners and Management” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

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

The information required by this Item is set forth under the headings “Corporate Governance and Board of Directors Matters” and “Transactions with Related Persons and Indemnification” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is set forth under the headings “Principal Accountant Fees and Services” and “Pre-Approval Procedures” under the proposal “Ratification of Selection of Independent Registered Public Accounting Firm” in the Company’s 2023 Proxy Statement to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements and Schedules

The financial statements are set forth under Item 8 of this Annual Report on Form 10-K, as indexed below. Financial statement schedules have been omitted since they either are not required, not applicable, or the information is otherwise included.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

(b) Exhibits

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38943	3.1	6/24/2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38943	3.1	10/31/2022
4.1	Description of Securities of Personalis, Inc.	10-K	001-38943	4.1	2/25/2021
4.2	Form of Common Stock Certificate of the Registrant.	S-1/A	333-231703	4.1	6/7/2019
4.3	Amended and Restated Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated December 16, 2014.	S-1	333-231703	4.2	5/23/2019
10.1#	Personalis, Inc. 2011 Equity Incentive Plan, as amended, and forms of agreements thereunder.	S-1	333-231703	10.1	5/23/2019
10.2#	Personalis, Inc. 2019 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-231703	10.2	6/7/2019
10.3#	Personalis, Inc. 2019 Employee Stock Purchase Plan.	S-1/A	333-231703	10.3	6/7/2019
10.4#	Form of Indemnification Agreement entered into by and between the Registrant and each director and executive officer.	S-1/A	333-231703	10.4	6/7/2019
10.5#	Employment Terms Letter, by and between Dr. Richard Chen and the Registrant, dated June 2, 2019.	S-1/A	333-231703	10.7	6/7/2019
10.6#	Employment Terms Letter, by and between Aaron Tachibana and the Registrant, dated June 2, 2019.	S-1/A	333-231703	10.8	6/7/2019
10.7	Lease, by and between MENLO PREHC I, LLC, MENLO PREPI I, LLC, TPI INVESTORS 9, LLC and the Registrant, dated February 2, 2015.	S-1	333-231703	10.9	5/23/2019
10.8	First Amendment to Lease, by and between MENLO PREPI I, LLC and TPI INVESTORS 9, LLC and the Registrant, dated April 8, 2020.	10-Q	001-38943	10.1	8/6/2020
10.9#	Personalis, Inc. 2020 Inducement Plan and forms of agreements thereunder.	S-8	333-238080	99.1	5/7/2020
10.10	Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated August 25, 2021.	10-Q	001-38943	10.1	11/4/2021
10.11	Amendment No. 1 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated December 8, 2021.	10-K	001-38943	10.16	2/24/2022
10.12‡	At-the-Market Sales Agreement, dated December 30, 2021, by and between the Registrant and BTIG, LLC.	8-K	001-38943	1.1	12/30/2021
10.13#	Amended Personalis, Inc. Non-Employee Director Compensation Policy, dated February 17, 2022.	10-K	001-38943	10.18	2/24/2022
10.14#	Amended and Restated Executive Severance Agreement, by and between Dr. Richard Chen and the Registrant, dated February 23, 2022.	10-K	001-38943	10.20	2/24/2022
10.15#	Amended and Restated Executive Severance Agreement, by and between Aaron Tachibana and the Registrant, dated February 23, 2022.	10-K	001-38943	10.21	2/24/2022
10.16	Amendment No. 2 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated June 9, 2022.	10-Q	001-38943	10.1	8/3/2022
10.17‡	Contract No. 36C24E22D0031, by and between the U.S. Department of Veterans Affairs and the Registrant, dated September 30, 2022.	10-Q	001-38943	10.1	11/2/2022
10.18#	Separation Agreement, dated December 14, 2022, between John West and the Registrant.	8-K	001-38943	10.1	12/14/2022
10.19	Amendment No. 3 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated December 19, 2022.				
21.1	Subsidiaries of the Registrant as of December 31, 2022.				
23.1	Consent of Independent Registered Public Accounting Firm.				
24.1	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K).				
31.1	Certification of Principal Executive and 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 Principal Executive and Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				

101	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.
104	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.

# Indicates management contract or compensatory plan or arrangement.

† The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

‡ Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K because such schedules and exhibits do not contain information which is material to an investment or voting decision or which is not otherwise disclosed in the filed agreements. The Company will furnish the omitted schedules and exhibits to the SEC upon request by the SEC.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of 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.

Date: February 23, 2023

Personalis, Inc.

By: /s/ Aaron Tachibana
Aaron Tachibana
Interim Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Aaron Tachibana, 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:

Name and Signature	Title	Date
/s/ Aaron Tachibana **Aaron Tachibana**	Interim Chief Executive Officer and Chief Financial Officer *(Principal Executive Officer and Principal Financial and Accounting Officer)*	February 23, 2023
/s/ A. Blaine Bowman **A. Blaine Bowman**	Director	February 23, 2023
/s/ Alan Colowick **Alan Colowick, M.D.**	Director	February 23, 2023
/s/ Karin Eastham **Karin Eastham**	Director	February 23, 2023
/s/ Kenneth Ludlum **Kenneth Ludlum**	Director	February 23, 2023
/s/ Lonnie Shoff **Lonnie Shoff**	Director	February 23, 2023
/s/ Olivia Bloom **Olivia Bloom**	Director	February 23, 2023
/s/ Woodrow A. Myers, Jr. **Woodrow A. Myers, Jr., M.D.**	Director	February 23, 2023