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, 2021

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.)
1330 O'Brien Drive **Menlo Park, California**	**94025**
(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	☐

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of June 30, 2021, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $900,300,019 based on the closing price of the shares of common stock on the Nasdaq Global Market. Excludes an aggregate of 8,624,987 shares of the registrant's common stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The number of shares of Registrant's Common Stock outstanding as of February 18, 2022 was 44,950,109.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the Registrant's definitive proxy statement to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the Registrant's 2022 annual meeting of stockholders (the "2022 Proxy Statement").

Auditor Firm ID: 34 Auditor Name: Deloitte & Touche LLP Auditor Location: San Francisco, California, U.S.

PERSONALIS, INC.

Form 10-K
For the Year Ended December 31, 2021

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SPECIAL 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,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “hope,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “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;
- estimates of our total addressable market, future revenue, expenses, capital requirements, and our needs for additional financing;
- our ability to enter into and compete in new markets;
- the impact of the COVID-19 pandemic on our business, our customers’ and suppliers’ businesses and the general economy;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to scale our infrastructure;
- our ability to manage and grow our business by expanding our sales to existing customers or introducing our products to new customers;
- expectations regarding our relationship with the U.S. Department of Veterans Affairs’ Million Veteran Program;
- our ability to establish and maintain intellectual property protection for our 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 in future offerings;
- the volatility of the trading price of our common stock;
- our belief that approval of personalized cancer therapies by the Food and Drug Administration may drive benefits to our business; 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

Personalis' strategy is to develop some of the world's most advanced genetic tests for cancer. Today our tests are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples from their clinical trials. More recently, we have also begun to work with a growing number of leading cancer centers for clinical diagnostic use of our tests. We believe that adoption and publication by these key opinion leaders will develop an advanced standard of care for cancer patients and eventual broad use in a community hospital setting. We believe that our tests can meaningfully improve outcomes for cancer patients, and we estimate that the market opportunity for our tests for therapy selection and monitoring is approximately $30 billion in the U.S.

In December 2021, we launched NeXT Personal, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify minimal residual disease ("MRD") and recurrence in patients previously diagnosed with cancer. NeXT Personal is designed to deliver industry-leading MRD sensitivity down to the 1 part-per-million range, an approximately 10- to 100-fold improvement over other available technologies. NeXT Personal leverages whole genome sequencing of a patient's tumor to identify up to 1,800 specially-selected somatic variants that are subsequently used to create a personalized liquid biopsy panel for each patient. We believe this enables earlier detection across a broader variety of cancers and stages, including typically challenging early stage, low mutational burden, and low-shedding cancers. NeXT Personal is also designed to simultaneously detect and quantify clinically relevant mutations in circulating tumor-derived DNA ("ctDNA") that may be used in the future to help guide therapy, when cancer is detected. These include known targetable cancer mutations, drug resistance mutations, and new variants which can emerge and change over time, especially under therapeutic pressure. We consider this approach not just "tumor-informed", but "comprehensively tumor-informed". Our ultimate goal is not just to detect cancer, but to provide key information over the entire course of the patient's disease. We believe this can be better for patients, more informative for pharmaceutical customers, and a larger business opportunity for us.

Our strategy is to work with world-class medical institutions. To that end, in the fourth quarter of 2021, we announced a collaboration with the Mayo Clinic and in the first quarter of 2022, we announced one with the Moores Cancer Center at UC San Diego Health. In these collaborations, we provide clinical diagnostic testing and research sequencing and analysis services using our tissue-based NeXT Dx test. We have begun to test clinical patient samples and are excited about the opportunity to work with these renowned cancer centers. If we achieve a favorable reimbursement decision for our NeXT Dx test from the Molecular Diagnostic Services Program developed by Palmetto GBA ("MolDx"), we may also generate revenue in the future from some of these collaborations. Given the advanced nature of our NeXT Dx test, we believe it is a good fit for high-end cancer centers, which have a dual mandate for both clinical care and research. If these key opinion leaders have a positive experience using our tests, we are optimistic that this will also support broader use of our platform by other clinicians in the future.

We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases and in support of our NeXT Liquid Biopsy, NeXT Dx Test and NeXT Personal offerings. To date, we have sequenced more than 235,000 human samples, of which more than 145,000 were whole human genomes.

In parallel with the development of our platform technology, we have also pursued business within the population sequencing market, and we have provided whole genome sequencing services under contract with the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP"), which has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. The VA MVP is the largest population sequencing effort in the United States and we have delivered over 140,000 whole human genome sequence datasets to the VA MVP to date. The cumulative value of task orders received from the VA MVP since inception is approximately $186 million, $178.1 million of which we had recognized as revenue as of December 31, 2021. In September 2021, we received a task order from the VA MVP with a value of up to approximately $9.7 million, which was significantly less than in prior years. At that time, we expected the reduced order amount was to be followed by a formal request for proposal ("RFP") process and a potential new contract to be awarded sometime late in the third quarter of 2022. However, recent discussions with our contacts at the VA MVP indicate that there will be no RFP process in 2022. Accordingly, we do not expect to receive any new orders from the VA MVP this year nor to recognize any revenue from the VA MVP beyond the current order and contract. Unless we receive an additional task order and/or enter into a new services agreement with the VA MVP with a value comparable to that of our current contract and historical contracted orders, our revenue from the VA MVP is expected to decline significantly in 2022 and future periods. Given the strong growth we have already experienced in our oncology business in 2021, and the large market opportunity we see in this space, we plan to focus primarily on cancer as we go forward.

In August 2021, we announced that we will relocate our corporate headquarters from Menlo Park to a new facility in Fremont, California and we plan to beginning moving into it in the third quarter of this year. We signed a 13.5-year lease for the 100,000 square foot facility, which is approximately double the amount of space in our current Menlo Park location. The new facility is intended to allow for expansion of our laboratory for clinical testing to support biopharma 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. The new facility will also provide more office space for our selling, general and administrative workforce.

Our current headquarters – housing our Clinical Laboratory Improvement Amendments of 1988 ("CLIA")-certified, College of American Pathologists ("CAP")-accredited laboratory – is located in Menlo Park, CA. 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, universities, non-profits, and government entities.

Personalis: The Genomics Engine for Next-Generation Cancer Therapies

Biopharmaceutical 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 two major classes of next-generation therapeutics: immunotherapies and targeted 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 biopharmaceutical 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.

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 look for the emergence of resistant mutations and to 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 than our initial clinical-trial focused markets. Over time, we expect our biopharmaceutical customers and research collaborators to build evidence of the clinical utility of our platform as a diagnostic for advanced cancer therapies. Separately, we are also acquiring samples and building a database which we expect will hold value for our biopharmaceutical customers and may ultimately allow us to discover new mechanisms of cancer treatment.

Market Opportunities

We estimate the 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 estimate 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 limit our analysis 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 normal clinical care. As part of that standard care, these patients go through therapy selection and eventual monitoring. For therapy selection, we estimate that each of the approximately 2.0 million cancer patients undergoing normal clinical care will have a tissue biopsy sequenced and tested at a cost of approximately $3,000, which is the approved 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. For monitoring, we estimate 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 Test addresses this market for tissue biopsy testing while clinical versions of our products in development may address this liquid-biopsy based monitoring opportunity. Our estimates lead us to project approximately a $22.72 billion potential market opportunity per year for monitoring.

- **Clinical Trial Patients:** For each of the 200,000 pharmaceutical clinical trial patients, we estimate that an initial tissue sample will be sequenced at least once at a cost of $3,000, which is the approved CMS reimbursement rate, and the liquid biopsy sample testing 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 estimate 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 estimate the potential market for population sequencing services is over $2 billion per year. Our whole genome sequencing products address this potential market opportunity.

Our Products and Services

Broadly speaking, we provide proprietary genomic information to customers. Our genomic sequencing and analytics products are focused on the following customer applications: precision oncology, clinical and companion diagnostics, pharma research, and population genomics.

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, clinical-grade, 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 Personal (liquid biopsy offering for personalized tumor tracking for patients), NeXT Dx Test (comprehensive genomic cancer profiling test enabling advanced composite biomarkers for cancer treatment), NeXT SHERPA and NeXT NEOPS (neoantigen prediction capabilities). We are currently investing in the development of additional future product offerings, including NeXT CDx (diagnostic test) and NeXT Database (comprehensive tumor immune-genomics database).

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 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.

An overview of key features and differentiators of our NeXT Platform follows.

Comprehensive tumor and immune genomics from a single limited sample:

- Sequencing and analyzing all of the approximately 20,000 human genes generates more comprehensive molecular information than current tumor tissue and liquid biopsy panels focused on roughly 50 to 500 genes
- Covers a much broader set of biomarkers for new immunotherapies and traditional targeted therapies
- Analysis of both tumor DNA and RNA expression
- Analysis of both tumor and normal tissue
- Analysis of non-human species such as oncoviruses
- NeXT Liquid Biopsy targets approximately 20,000 genes and enables testing at multiple time points
- Proprietary technology enables superior sequencing quality and advanced analytics

Makes single, comprehensive tumor molecular profiling practical for cancer patients:

- Tumor and immune molecular profiling from one limited tumor sample
- Engineered to be cost-effective and scalable, with rapid turnaround times, making it suitable for large-scale profiling of cancer patients
- Overcomes the need for fragmented tumor testing
- One platform for both research and clinical use

Platform anticipates future cancer biomarkers that will come with evolving science:

- NeXT overcomes the limitations of small panels that become out of date when new genetic biomarkers or therapeutic targets are identified
- Comprehensive coverage of all genes, DNA and RNA, tumor and normal tissue, and immune biology enables our platform to accommodate new genetic biomarkers and signatures as they are published

Generates comprehensive, harmonized data across patients to enable large-scale database creation and insight:

- Comprehensive profiling for large cohorts of patients leads to more useful databases for biopharmaceutical customers using our platform and our internal database
- Opportunity for integration with other sources of real-world data such as electronic health records to generate real-world evidence that may be used by biopharmaceutical customers to inform and accelerate therapeutic development
- Data harmonization, analytics, and machine learning maximize therapeutic insight
- Comprehensive nature of the platform provides long-lasting data relevance, yielding new insights over time as new biomarkers are identified

Our NeXT Platform technology can analyze cell-free DNA ("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. 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, we expect to monitor changes in tumor genetics that arise in response to therapy through serial measurements using cfDNA samples collected across multiple time points. In 2020, we launched our first liquid biopsy assay designed to analyze all human genes so as to detect potential neoantigens and tumor escape mechanisms that arise under therapeutic pressure. Although we believe our cfDNA test will offer new insights, we believe it will be most useful for our biopharmaceutical customers alongside our primary tumor biopsy product, given that a tumor biopsy is required to analyze gene expression and elucidate tumor-infiltrating lymphocytes which are critical to understanding cancer's interaction with the immune system.

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, 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.

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. Unlike typical liquid biopsy panel approaches focused on roughly only 50 to 500 driver genes, our NeXT Liquid Biopsy is designed to sequence all of the approximately 20,000 genes in the human genome. Our broader liquid biopsy approach will help biopharmaceutical customers identify biological changes across multiple time points for each patient in their trials that they would otherwise miss with the current, narrowly focused liquid biopsy panels. We also believe broader coverage will enable better neoantigen prediction, broader biomarker coverage, and higher potential to identify new drug targets.

We anticipate that our exome-scale NeXT Liquid Biopsy approach will have many applications, including monitoring of tumor response to therapy over many time points, detecting new genetic variants from evolution of the tumor under therapeutic pressure, detecting acquired mechanisms of resistance, and identifying neoantigens.

NeXT Personal is an advanced, tumor-informed liquid biopsy assay developed to deliver industry-leading MRD sensitivity in the range of 1-3 parts per million, representing a 10- to 100-fold improvement over other 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 detection methods for ctDNA have rapidly advanced, the limited sensitivity of these detection methods reduces its 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.

Our NeXT Dx Test is a comprehensive genomic cancer profiling test enabling advanced composite biomarkers for cancer treatment and provides a path from translational research to CDx on our NeXT Platform. The NeXT Dx Test helps oncologists identify potential therapies and clinical trial options for cancer patients. NeXT Dx Test is one of the first cancer diagnostic platforms to profile approximately 20,000 genes in both the tumor exome and transcriptome, providing a comprehensive genomic testing solution that goes beyond many existing cancer diagnostic panels that focus on only a few hundred genes. The NeXT Dx Test includes advanced analytics to provide a diagnostic report on genetic alterations in medically-important cancer genes, as well as emerging immunotherapy composite biomarkers of medical importance. Additionally, immunotherapy-related biomarkers such as microsatellite instability ("MSI") status and tumor mutational burden ("TMB") are included in the clinical report.

The NeXT Dx Test is a laboratory-developed test performed at our CAP-accredited and CLIA'88-certified laboratory that is optimized for formalin-fixed, paraffin-embedded tumor samples. The test utilizes ImmunoID NeXT, our clinical-grade, next-generation sequencing and analysis platform, to report base substitutions, insertions/deletions, gene fusions, and copy number alterations in cancer driver genes of clinical significance. Additionally, MSI status is reported based on five canonical loci (BAT25, BAT26, NR-21, NR-24, and NR-27), and TMB status is reported by leveraging the exome-wide analysis of non-synonymous somatic mutations. Based on the tumor's molecular profile, the report delivers relevant therapy recommendations and appropriate clinical trial matches. Each case is reviewed by a team of board-certified molecular geneticists and genetic counselors. Test results are electronically delivered to the ordering clinician.

In December 2020, we announced the launch of our Systematic HLA Epitope Ranking Pan Algorithm ("SHERPA"), our proprietary, machine learning-based tool for the comprehensive identification and characterization of cancer neoantigens. Integrated into our NeXT Platform, SHERPA enables the development of new neoantigen-based diagnostic biomarkers and novel personalized therapies. Trained on a proprietary immunopeptidomics dataset derived from engineered cell lines, SHERPA improves neoantigen presentation prediction compared to other *in silico* methods. With this advancement, SHERPA can enable more predictive biomarkers for cancer therapy as well as facilitate the development of neoantigen-targeting, personalized cancer therapies.

While most conventional *in silico* methods generally only assess the potential MHC-binding affinity and stability of identified peptides, SHERPA goes a step further by incorporating features relating to the antigen processing machinery and RNA abundance to generate a presentation rank for each detected peptide. We believe this will aid in determining the relative likelihood of a given neoantigen being presented and undergoing immunosurveillance. A large drug development customer of ours has leveraged SHERPA to characterize immune response to precision genetic therapeutics in patients with rare diseases, demonstrating the applicability of this machine learning tool in disease areas beyond cancer.

Our proprietary Neoantigen Presentation Score ("NEOPS"), also launched in December 2020, is one example of a SHERPA-derived composite biomarker that has shown promise in predicting immunotherapy response in cancer patients. NEOPS combines analysis from our state-of-the-art tumor neoantigen prediction tool, SHERPA, with mechanisms of immune evasion to better predict response to cancer therapy. NEOPS combines the tumor genomic and immune-related analytics of our NeXT Platform to create a composite biomarker that can be more effective in predicting immunotherapy response than other, simpler biomarkers.

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 in connection with our NeXT Platform products has grown rapidly in recent years, accounting for only a minimal proportion of revenue prior to 2020 but now accounting for over two-thirds of revenue for the year ended December 31, 2021, excluding revenue from the VA MVP (discussed below).

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.

The substantial majority of our revenue since inception, excluding revenue from the VA MVP (discussed below) and our growing revenue from our NeXT Platform described above, were derived from ACE Platform products.

Whole Genome Sequencing

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 the largest population sequencing effort 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. To date, we have been contracted to deliver over 140,000 genome sequence data sets to the VA MVP. 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 whole genome sequencing also optimally positions us for what we anticipate to be the longer-term strategic direction of the cancer genomics industry, which may include whole genome sequencing of tumors.

The VA MVP program has accounted for a substantial amount of our revenue in recent years, 53% in 2021, 71% in 2020, and 67% in 2019. In September 2021, we received a task order from the VA MVP with a value of up to approximately $9.7 million, which was significantly less than in prior years. At that time, we expected the reduced order amount was to be followed by a formal RFP process and a potential new contract to be awarded sometime late in the third quarter of 2022. However, recent discussions with our contacts at the VA MVP indicate that there will be no RFP process in 2022. Accordingly, we do not expect to receive any new orders from the VA MVP this year nor to recognize any revenue from the VA MVP beyond the current order and contract. Unless we receive an additional task order and/or enter into a new services agreement with the VA MVP with a value comparable to that of our current contract and historical contracted orders, our revenue from the VA MVP is expected to decline significantly in 2022 and future periods.

Personalis is Valuable to Biopharmaceutical Companies

We believe that our platform is valuable to our customers because:

- **Our tumor and immune molecular profiling capabilities provide an unprecedented breadth of data from a single limited tumor sample.** We provide information on all of the approximately 20,000 human genes, as well as gene expression, the immune system, and other elements of cancer biology, in contrast to other currently marketed panels that cover a limited range of roughly 50 to 500 genes and do not focus on immune cells. The commercial success of immunotherapy drugs has demonstrated the need to better understand the immune system. Unfortunately, development of new therapies in this category has been challenged by difficulties understanding the precise interaction between cancer and the immune system. Since our platform provides comprehensive insights on tumor and immune biology, including in both innate and adaptive immune cells, we believe it will enable drug companies to better understand the biological effect of therapeutics in patients.
- **Our platform enhances the opportunity to conduct translational research by analyzing tumor tissues from patients in clinical trials, rather than animal models or in vitro cancer cell lines, which have historically limited cancer research.** While conventional pre-clinical model systems, such as animal models and cancer cell lines, have been instrumental in early-stage cancer research and drug development, translation of results to the clinic has been limited and remains a significant barrier to progress, in part because these models do not sufficiently reflect the complexity of human cancer and the human immune system. Over recent years, tools used to study tissue from patients have improved and the utilization of tissue from trials has increased. We believe our platform represents the next step in this transition by further enabling biopharmaceutical companies to address the historical limitations of analyzing patient tissue comprehensively.
- **Our enterprise-grade operational infrastructure is scalable, enables rapid turnaround times, and is tailored to meet the unique workflow needs of our customers.** 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. Moreover, we believe our infrastructure provides customers with visibility and control over processes, ensures consistency across all components used for the duration of each clinical trial, is fully traceable for compliance purposes, and allows us to scale while maintaining rapid turnaround times.
- **We offer a complementary liquid biopsy test, which also offers broad 20,000-gene coverage versus more narrowly focused liquid biopsy tests that are currently available.** As with a tissue biopsy, we analyze all of the approximately 20,000 human genes. We are not aware of any other company developing a cfDNA platform that analyzes all of the approximately 20,000 human 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, we expect to monitor changes in tumor genetics that arise in response to therapy through serial measurements using cfDNA samples collected across multiple time points. Our liquid biopsy assay is designed to monitor known neoantigens and detect novel neoantigens and tumor escape mechanisms that arise under therapeutic pressure.

Our Strategy

Our mission is to transform the development of next-generation cancer therapies by providing more comprehensive molecular data about each patient's cancer and immune response. To achieve this mission, our strategy is to:

- **Drive continued adoption of our NeXT Platform offerings—ImmunoID Next, NeXT Liquid Biopsy, NeXT Dx, and NeXT Personal—with existing and new customers.**
- **Continue to enhance and display clinical utility of the NeXT Platform through collaborations.**
- **Invest in clinical, regulatory, and reimbursement infrastructure for NeXT Dx and NeXT Personal (MRD and ongoing patient management).**
- **Focus our early diagnostic commercialization efforts on world-class cancer centers, which have a dual mandate for patient care and advanced clinical research.**
- **Complete build-out of new facility in Fremont, California, which will expand our operational capacity and support future growth.**
- **Expand footprint in China and develop relationships with the local scientific and regulatory community.**

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 this capacity is already larger than the sequencing capacities of most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases and in support of our NeXT Liquid Biopsy. To date, we have sequenced more than 220,000 human samples, of which more than 145,000 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 in place certain agreements and purchase arrangements with Illumina to satisfy the 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 that our platform could be essential to the composition and manufacture of any personalized cancer therapy 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 uses our NeXT Platform achieves regulatory approval, we believe that our commercial opportunity may increase substantially.

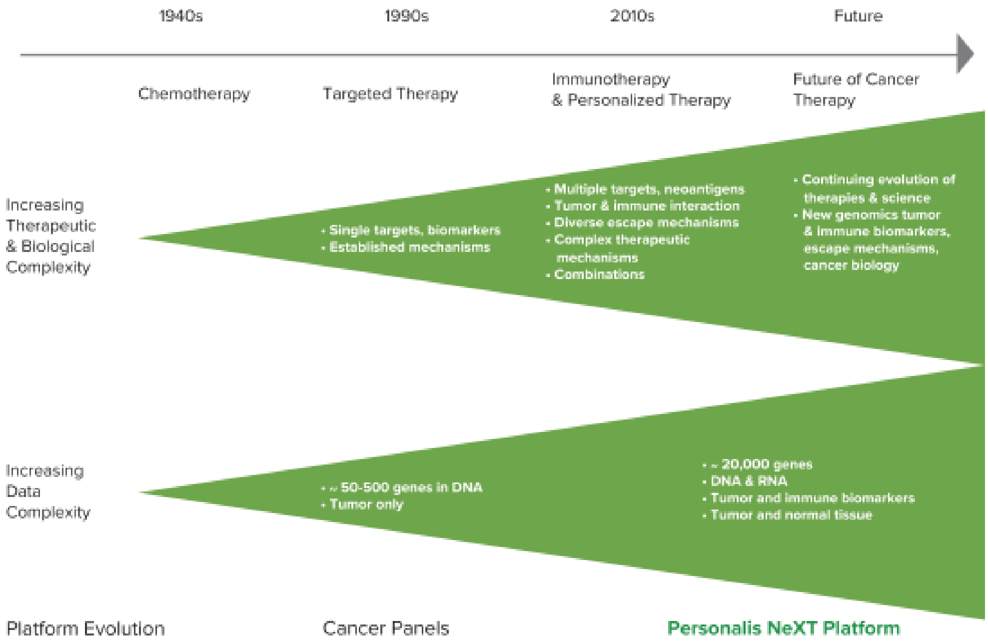
We leverage our proprietary software, laboratory automation and protocols, and other operational and technological know-how to power our NeXT Platform.

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 tumor 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 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 (the "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. The threefold increase in probability of FDA approval from Phase I clinical trial for therapies with biomarkers across all diseases and therapeutic types 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, 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

Most current 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 panels today, whether tissue or liquid biopsy based, typically sequence 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 current 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. Due to the limited coverage of most cancer panels, they may miss 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 in the United States and Europe through our targeted sales organization. We have also recently begun efforts to commercialize our products in China. In 2021, we derived 92% of our revenue from our customers in the United States. 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.

As the clinical utility of advanced biomarkers is further established, we expect there to be a patient-centered diagnostic opportunity whereby some patients would be guided to personalized therapies. We believe that our platform's ability to support biomarkers for a broad range of therapeutics positions us to be a leader in therapy selection for patients.

Our Customers

Our cancer genomic services are sold primarily to pharmaceutical companies, biopharmaceutical companies, biotechnology companies, 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 2021, we had two customers account for 10% or more of our revenue: VA MVP at 53% and Natera, Inc. ("Natera") at 10%. In 2020, VA MVP accounted for 71% of our revenue and no other customer accounted for 10% or more. In 2019, we had two customers account for 10% or more of our revenue: VA MVP at 67% and Pfizer Inc. at 13%.

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, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, 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, Inc. ("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, Mount Sinai Genomics, Inc. which does business under the name Sema4, Natera, NanoString Technologies, Inc., NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Predicine, Inc., Roche Molecular Systems, 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 integrity 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, 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, particularly other novel assay technologies which may be applicable in cancer cases 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 technology, including claims directed to methods for enriching sample nucleic acids based on differences in GC-content, molecular size, presence of genetic variations or rearrangements, epigenetic modifications, and species-origin (e.g., human and non-human);
- hybrid exome-genome technologies, including claims directed to methods for combining exome and genome sequencing data generated from a sample to identify polymorphisms;
- liquid biopsy methods, including claims directed to methods of analyzing sequenced cell-free and leukocyte-derived nucleic acids in a blood sample to identify a tissue source, or recommend a drug treatment;
- clinical interpretation methods, including claims directed to methods of ranking genes associated with a phenotype and inheritance pattern; and
- personalized genetic testing assays, including claims directed to methods for using sequencing data to create a personalized genetic test to monitor cancer progression, or the recurrence of disease.

As of December 31, 2021, we own sixteen issued U.S. and foreign patents in China, the European Union, and the United Kingdom and several pending U.S. and foreign patent applications. 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 2041.

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 test, is uncertain. If we decide to seek reimbursement for our NeXT Dx test 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 Centers for Medicare & Medicaid Services (“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. We maintain a current license with the New York State Department of Health for our laboratory. 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 (the “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.

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. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. In addition, Congress and the Biden administration are considering other health reform initiatives, such as the Build Back Better Plan. 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 through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% 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 impact overall 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, or 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. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019. 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. Further, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

Material Agreements

VA MVP Agreement

On September 28, 2017, we entered into a contract with the VA for the VA MVP to provide them with a combination of whole genome sequencing services (the “VA MVP Agreement”). The performance period for the services includes a base period of one year (September 2017 through August 2018), with three one-year renewal option periods that may be exercised upon discretion of the VA MVP. Each task order issued against the VA MVP Agreement has a separate period of performance and is subject to the terms and conditions of the VA MVP Agreement. Funds are obligated by the VA MVP under each task order based on actual needs. We received contracted orders from the VA MVP in September 2017, 2018, 2019, 2020, and 2021. The current contract does not include a renewal option. For us to provide additional services to the VA MVP after completion of the current contract, we would need to receive an additional task order and/or enter into a new services agreement with the VA MVP, neither of which had occurred as of the date of filing this Annual Report.

All materials and samples utilized during the course of the VA MVP Agreement and all data first produced or delivered under the VA MVP Agreement are the sole property of the VA MVP. Under the VA MVP Agreement, 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 Agreement, or any part thereof, at its sole convenience. Subject to the terms of the VA MVP Agreement, 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 Agreement, 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.

In September 2021, we received a task order from the VA MVP with a value of up to approximately $9.7 million, which was significantly less than in prior years. At that time, we expected the reduced order amount was to be followed by a formal RFP process and a potential new contract to be awarded sometime late in the third quarter of 2022. However, recent discussions with our contacts at the VA MVP indicate that there will be no RFP process in 2022. Accordingly, we are not planning on receiving any new orders from the VA MVP this year or expecting to recognize any revenue from the VA MVP beyond the current order and contract.

Agreements with Illumina

On November 1, 2017, we entered into a master services subcontract agreement (the “Subcontract Agreement”) with Illumina. Under the terms of the Subcontract Agreement, we engaged Illumina as our subcontractor to perform certain genotyping services (the “Services”) on our behalf pursuant to written purchase orders in fulfillment of our VA MVP Agreement. The price for Illumina’s Services set forth in the Subcontract Agreement is effective through March 2022, or later if the VA MVP Agreement is extended.

The Subcontract Agreement extends through the last day of the VA MVP Agreement, currently March 2022 but as may be extended, unless it is otherwise terminated early pursuant to its terms. All or part of the Subcontract Agreement may be terminated at our convenience in the event that the VA MVP terminates the VA MVP Agreement or terminates the part of the VA MVP Agreement that affects the Services provided by Illumina. Each party may terminate the Subcontract Agreement for default in the event that the other party materially fails to perform any of the provisions of the Subcontract Agreement, materially fails to make progress so as to endanger performance of the Subcontract Agreement in accordance with its terms, or becomes financially or legally incapable of completing the work and does not provide a plan of correction or recovery within the provided period of time to cure such failure. The Subcontract Agreement may be renewed for subsequent one-year terms as agreed by the parties subject to a four-year limit.

On March 26, 2019, we entered into a pricing agreement with Illumina, which provides pricing terms for the NovaSeq™ 5000/6000 S4 Reagent Kit (each, a “Kit”). The pricing agreement had a purchase commitment of $1.7 million by June 30, 2019 to purchase these Kits, which we fulfilled in the ordinary course of business. The term of the pricing agreement extends through December 31, 2022.

From time to time, we receive quotations for supply of genetic analysis products from Illumina that provide for pricing terms on Illumina products outside of those discussed above.

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
- 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, 2021, we had 326 employees, of which 325 were full-time employees. Of these full-time employees, 149 were in research and development, 74 in laboratory operations, 55 in commercial operations and 47 in general and administrative functions. 311 of our full-time employees are located in the United States, six are located in Europe and eight are located in China. As of December 31, 2021, more than 50% 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.

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, 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. 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.

- Our operations and employees face risks related to health crises, such as the ongoing COVID-19 pandemic, 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.

- 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 our largest customers, the VA MVP and Natera.

- 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.

- Expansion into China and other international markets will subject us to increased regulatory oversight and regulatory, economic, social, health and political uncertainties.

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.

- The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability.

- 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. If we decide to 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 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 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.
- As of December 31, 2021, we were still eligible to use the scaled disclosures of a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.
- 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 as our costs increase, 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, 2021, 2020, and 2019 we had net losses of $65.2 million, $41.3 million, and $25.1 million, respectively. As of December 31, 2021, we had an accumulated deficit of $247.1 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.

Our operations and employees face risks related to health crises, such as the ongoing COVID-19 pandemic, 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, such as the ongoing COVID-19 pandemic, that could cause significant disruption in the operations of our customers and third-party suppliers upon whom we rely. Our laboratory facilities (other than the facilities being developed for our use in Shanghai, China), 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 have been impacted by the ongoing COVID-19 pandemic. For example, the previous shelter-in-place order and health orders have 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 continue to cause such effects on our operations. The COVID-19 pandemic has disrupted, and may continue to disrupt, the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we are aware of increased demand in the market for certain consumables used in COVID-19 test kits and vaccines. We use such 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 if other supply chain issues arise as a result of the COVID-19 pandemic. Several of our customers, including the VA MVP, have been 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.

While authorities in many areas have lifted or relaxed pandemic-related restrictions, in some cases they have subsequently re-imposed various restrictions after observing an increased rate of COVID-19 cases as the global COVID-19 pandemic continues to rapidly evolve and to present serious health risks. There is no guarantee when or if all such restrictions and recommendations will be eliminated, such that we and our customers, manufacturers and suppliers will be able to safely resume operations consistent with our pre-COVID-19 operations. The full extent of the impact of the COVID-19 pandemic on our business, operations and plans remains uncertain and will depend on future developments that cannot be predicted at this time. Such developments include the continued spread of the Delta and Omicron variants in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants that may prove especially contagious or virulent, the ultimate duration of the pandemic and the resulting impact on our business and other third parties with whom we do business, and the effectiveness of actions taken globally to contain and treat the disease.

While vaccines for COVID-19 have been developed and administered, and the spread of COVID-19 may eventually be contained or mitigated, we cannot predict the timing of the vaccine roll-out globally (including boosters to vaccinations), the percentage of the population that becomes vaccinated, or the efficacy of such vaccines against Delta, Omicron or other variants, and we do not yet know how businesses, advertisers, or our partners will operate in a post COVID-19 environment. In addition, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business. The ultimate impact of the COVID-19 pandemic or a similar health epidemic on our business, operations, or the global economy as a whole remains highly uncertain, but a continued and prolonged public health crisis could have a material negative impact on our business, financial condition, and operating results.

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 result in our customers or potential customers deciding 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, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, 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, Mount Sinai Genomics, Inc. which does business under the name Sema4, Natera, NanoString Technologies, Inc., NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Predicine, Inc., Roche Molecular Systems, 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 2021, revenue under our agreement accounted for 10% 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 U.S. Food and Drug Administration (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 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 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 our largest customers, the VA MVP and Natera.

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 53%, 71% and 67% of our revenue for the years ended December 31, 2021, 2020 and 2019, respectively. Our top five customers, including the VA MVP, accounted for 84%, 87% and 90% of our revenue for the years ended December 31, 2021, 2020 and 2019, 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 the VA MVP terminates our services for convenience, which it is permitted to do, such termination would 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 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, if the VA MVP conducts a competitive bid process for the next contract and we do not win, or if the VA MVP does not award any such contract on a timely basis or at all, our business, financial condition, revenue and other operating results, and cash flows will be materially harmed.

We currently derive 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. The current contract does not include a renewal option. For us to provide additional services to the VA MVP after completion of the current contract, we would need to receive an additional task order and/or enter into a new services agreement with the VA MVP, neither of which had occurred as of the date of filing this annual report.

The VA MVP may initiate a competitive bidding process for its next DNA sequencing and data analysis services contract, if any. However, there may not be any such potential bidding process or new contract awarded on a timely basis or at all, we may not win any such potential new contract in any such potential bidding process, the value of any such potential new contract or the VA MVP contracted orders thereunder may be lower than our current contract and historical contracted orders from the VA MVP, and/or the scope or nature of the services required under such new contract may change such that we are unable to serve the VA MVP in the future.

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 for our services among other factors. For example, the VA MVP contracted order received in September 2020 had a value of up to approximately $31 million, whereas the VA MVP contracted order received in September 2021 has a value of up to approximately $9.7 million, which represents a substantial decline. Unless we receive an additional task order and/or enter into a new services agreement with the VA MVP with a value comparable to that of our current contract and historical contracted orders, our revenue from the VA MVP will decline significantly in the future.

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. If the priorities of the VA, the VA MVP, or the U.S. government have changed or change in the future, including in response to the COVID-19 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), our business, financial condition, revenue and other operating results and cash flows will be materially harmed. The success of our business and our future operating results are significantly dependent on the VA MVP's continued demand and receipt of funding for use of our services and the terms of our sales to the VA MVP, including the price per sample, the number of samples and the timing of the VA MVP's deliveries of samples. Furthermore, we only recognize revenue under our VA MVP contract upon the receipt and processing of samples, and the timing and number of VA MVP samples we receive 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 and, even if we win a potential new VA MVP contract and order with a value comparable to that of the September 2020 contracted order, the revenue we recognize under such potential new contract and order may be less than the revenue we recognized during the 2020-2021 contract year. The timing and number of VA MVP samples may also have been or be negatively affected by the current COVID-19 pandemic. 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 value of the September 2021 VA MVP contracted order 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, and the COVID-19 pandemic may also negatively impact the value of any potential new VA MVP contract or order.

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.

On February 17, 2021, we announced that we had entered into a partnership in the field of personalized oncology with Natera, pairing our NeXT tumor profiling and diagnostic 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, during 2021, revenue under our agreement accounted for 10% 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.

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 the COVID-19 pandemic), failures in their clinical trials, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control.

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.

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 the 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. Our Subcontract Agreement with Illumina is set to expire in March 2022, and our various pricing agreements with Illumina are set to expire on various dates up to December 2022. 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 an extension to our agreements 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, the COVID-19 pandemic has disrupted, and may continue to disrupt, Illumina's ability to perform under our Subcontract Agreement and fulfill our purchase orders for reagents or other materials in a timely manner and the pandemic has also disrupted, and may continue to disrupt, the ability of our other suppliers to fulfill our purchase orders in a timely manner or at all. Our suppliers could cease supplying these materials and equipment at any time, 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 File that we have filed with the FDA, which is focused on the technology, quality management, and validation of our platform, specifically on its use for the development of personalized immunotherapies, is predicated on our use of specified equipment and processes, including Illumina sequencers and related equipment. The detailed information in the Device Master File is not shared with our customers, but with our permission they can reference our FDA file number 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 File 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 File, 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 hiring additional personnel and 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, we do not have any clinical reference or research and development laboratory facilities other than our facilities in Menlo Park, California and the facilities being developed for our use in Shanghai, China and planned future facilities in Fremont, California. 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. Additionally, as a result of the ongoing COVID-19 pandemic, we have limited access to our office and laboratory facilities in Menlo Park to protect the health and safety of our employees and to comply with applicable state and local orders. Northern California has recently experienced serious fires 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. The limited access to our laboratory facilities as a result of the COVID-19 pandemic has resulted, and may in the future result, 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. 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, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses 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 planned opening of our new headquarters and laboratory facilities in Fremont, California could divert management's attention and disrupt our ongoing business.

We plan to relocate our corporate headquarters to an existing building located in Fremont, California that was leased in August 2021. We also plan to build and operate new laboratory facilities in the building. These efforts will involve significant tenant improvements, construction and regulatory compliance activities to be undertaken, including state licensure and CLIA certification for such laboratory facilities. Such efforts may distract management from current operations, disrupt planned research, development or regulatory compliance activities, and 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.

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 EEA (and Northern Ireland) the new European Union (“EU”) In Vitro Diagnostic Device Regulation (the “IVDR”) entered into force on May 25, 2017, replacing the In-Vitro Diagnostic Directive (the “IVDD”) (and national legislation that implemented the IVDD in member states) as the primary legislation governing IVDs. Most requirements under the IVDR will not apply until the end of a transition period which is expected to occur on May 26, 2022. The IVDR broadens the scope of the regulation of IVDs and, among other things, tightens the requirements for clinical evidence and conformity assessment, increases transparency requirements, and introduces a requirement for a unique device identifier for every IVD. Under the IVDR there are four classes of IVDs, referred to as classes A, B, C, and D. IVDs are placed into a class based on their perceived risk to the patient and wider public. The main requirements of the IVDR apply regardless of the class which the relevant device falls into, and class A devices (including instruments and specimen receptacles) are the only devices that can be self-certified as meeting the requirements of the IVDR. The IVDR explicitly includes software used for diagnostic purposes in its scope. The IVDR requires pre-registration and post-market data collection to ensure that the device meets the relevant requirements. It is also notable that 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. The IVDR will not apply to Great Britain (England, Wales and Scotland). These additional regulatory requirements are likely to increase the cost and time required in order to obtain regulatory approval for products in the EEA where such approval was already necessary, and in certain cases will introduce a new requirement to obtain regulatory approval where one did not exist under the IVDD arrangements. Further, the IVDR may result in devices being classified in a higher risk category than would have been the case under the existing IVDD arrangements.

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.

Physicians, hospitals, and third-party payors often are slow to adopt new products, 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, including John West, our Chief Executive Officer, Richard Chen, our Chief Medical Officer, and Aaron Tachibana, our Chief Financial Officer. The collective efforts of each of these persons 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, or if one or more of these key employees were to become unable to perform his or her duties due to contracting COVID-19, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. 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. 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.

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 planned future facilities 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 the Mayo Clinic, MapKure, LLC ("MapKure"), which is jointly-owned by BeiGene, Ltd. and SpringWorks Therapeutics, Inc., and Moores Cancer Center at UC San Diego Health) 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 planned expansion into China entails substantial risks*.**

In June 2020, we announced 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. Our expansion and investment plans are subject to substantial risks which may include, but are not limited to: the inability to protect our intellectual property rights under Chinese law, which may not offer as high a level of protection as U.S. law; unexpectedly long negotiation periods with Chinese suppliers and customers; quality issues related to supplies sourced from local vendors; unexpectedly high labor costs due to a tight labor supply; foreign investment restrictions, including those that restrict foreign investment in the development and application of gene diagnosis and treatment technologies (which we believe prevent us from directly offering our NeXT Dx test, or other diagnostic tests based on our NeXT Platform, to patients in China); and difficulty in repatriating funds and selling or transferring assets. Our investments in China also expose us to additional foreign currency exchange risk. In addition, as tensions have escalated between the U.S. and China, we believe there is an enhanced risk that our planned investments in China may be subject to unforeseen risks or restrictions, which may include expropriation of the investments by the Chinese government or new restrictions imposed by the U.S. government on the export of necessary goods or technologies to our Shanghai subsidiary. These and other risks may result in our not realizing a return on, or losing some, or all, of our planned investments in China, which could have a material adverse effect on our financial condition and financial performance.

Personal privacy, cyber security, and data protection are becoming increasingly significant issues in China. For example, the State Council of the People's Republic of China adopted the Regulations of the People's Republic of China on Administration of Human Genetic Resources, which went into effect on July 1, 2019. The regulations establish a framework for the collection, preservation, utilization, and supply abroad of human genetic resources of China. The regulations also establish a framework for the use of data and other information generated from use of human genetic resources of China. The regulations also provide that foreign organizations, individuals and entities established or controlled by them are prohibited to collect or preserve China's human genetic resources or transport them abroad. Due to the lack of detailed interpretations and implementations, it is not clear whether the agency in China responsible for enforcing the regulations will grant the necessary approvals for use by us and our partners of our NeXT Platform or our other current or future products in research or clinical projects involving China's human genetic resources or information generated therefrom. For example, we understand that the initial application by one of our pharmaceutical customers for such a project approval was previously rejected by such agency in China for reasons relating to data retention by our customer and sharing of rights to research results with our customer's collaborator in China. Although it is our understanding that the agency's decision was not based on the use of our NeXT Platform in the project, and that the agency subsequently approved applications by our customer for this project and another project also involving the use of our NeXT Platform, we are supporting and expect in the future to support the preparation of multiple such applications, and there is no guarantee that any such additional applications will be approved by such agency in the future. The Chinese government separately has various regulations relating to the collection, use, storage, disclosure, and security of data, among other things, including the new Personal Information Protection Law ("PIPL") passed by the Standing Committee of China's National People's Congress on August 20, 2021, which took effect on November 1, 2021 and contains provisions similar to those of the General Data Protection Regulation (EU) 2016/679 ("GDPR") adopted by the EU, including extraterritorial reach, restrictions on data transfer, compliance obligations and sanctions for non-compliance. We cannot assure you that we will be able to comply with all these regulatory requirements. Any failure to comply with relevant regulations and policies could result in significant cost and liability to us and could adversely affect our business and results of operations. For example, the consequences for failing to comply with the PIPL could potentially include monetary penalties, business suspension and revocation of business licenses. Any additional new regulations or the amendment or modification of previously implemented regulations, or the failure to receive any necessary approvals for use of our products in connection with such projects, could require us and our partners to change our business plans and incur additional costs, and could limit our ability to generate revenue in China.

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. For example, in June 2020, we announced our intention to expand into China. 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 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 U.S. Food and Drug Administration, and/or CLIA requirements for quality laboratory testing.

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 products 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 laboratory developed tests ("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. We 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. 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.

Additionally, the Centers for Medicare & Medicaid Services ("CMS"), and certain state agencies regulate the performance of LDTs (as authorized under CLIA and state law, respectively). Our tests are developed in compliance with CLIA requirements. However, if our laboratory fails to comply with the prescribed quality requirements for laboratory testing or other requirements for CLIA, we could lose CLIA certification. That in turn would impact our ability to operate our laboratory and provide results to our customers, which could negatively impact our business operations. The IVDR includes limited exemptions for LDTs, but such exemptions only apply to laboratories that are part of health institutions established in the EEA, and so any services undertaken outside of the EEA (for example at our facilities in the U.S.) will not be covered by such exemptions. In any event, such exemptions are limited in their scope, and only apply if a number of conditions are met, including that the health institution justifies that the "target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market" and do not cover devices that are manufactured on an "industrial scale". Even where an exemption is applicable, such IVDs will still be subject to certain requirements under the IVDR. It is therefore unlikely that our tests will benefit from any exemption on the basis of being LDTs and will have to comply with the IVDR in full if we offer such tests to customers in the EEA (and Northern Ireland) (whether directly or via intermediaries).

If the FDA determines that our services are subject to enforcement as medical devices, we could incur substantial costs and time delays associated with satisfying statutory and regulatory requirements such as pre-market clearance or approval 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 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 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 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 product development costs, delay commercialization of any future products, and interrupt sales of our current 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 GCPs, which are regulations and guidelines enforced by the FDA, for products 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.

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.

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 products. If premarket review is required for some or all of our products, the FDA may require that we stop selling our products pending clearance or approval, which would negatively impact our business. Even if our products are allowed to remain on the market prior to clearance or approval, demand for our products may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our services, or from other services or products now in development.

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 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.

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

We are subject to 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. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

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 product-specific basis by New York as an out-of-state laboratory, and our products, as LDTs, must be approved by the New York State Department of Health (the "NYDOH") on a product-by-product 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 may 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 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. Penalties under the IVDR are devolved to national governments, but the IVDR requires that such measures are "effective, proportionate, and dissuasive." Initial indications suggest that penalties for breaches of the IVDR are likely to include fines and, potentially, prison sentences.

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 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 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 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 security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our services, compromise sensitive information related to our business, harm our reputation, trigger breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business.

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 proprietary, confidential, and sensitive information, including PHI, personally identifiable information ("PII"), credit card and other financial information, intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We depend on information technology and telecommunications systems for significant elements of our operations and we have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit, and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors, as we have outsourced elements of our operations to third parties and as a result a number of third-party vendors and other contractors and consultants have access to our proprietary, confidential, and sensitive information. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place.

We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of business-critical information, including research and development information, patient data, commercial information, and business and financial information. Despite the precautionary 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 the first quarter of 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 disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

Notwithstanding the implementation of security measures, given the size and complexity of our internal information technology systems and those of our third-party vendors and other contractors and consultants, and the increasing amounts of proprietary, confidential, and sensitive information that they maintain, such information technology systems are potentially vulnerable to breakdown, service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third-party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure, or that of our third-party partners, or lead to data leakage. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. 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), 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, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, 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. Similarly, 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.

The risk of a security breach or disruption, particularly through accidental actions or omissions by trusted insiders, cyber-attacks or cyber intrusions, including by computer hackers, threat actors, viruses, sophisticated nation states, and nation-state-supported actors, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased; in particular, during the COVID-19 pandemic we have observed an increase in attempted attacks against our data systems. Additionally, in connection with the ongoing COVID-19 pandemic, most of our personnel are working remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more personnel accessing sensitive and critical information from remote locations.

We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, hostile foreign governments or agencies, or cybersecurity researchers. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our services and technologies could be delayed. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. 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. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, 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.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen. Any of the previously identified or similar threats could cause a security incident or other interruption, which could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our proprietary, confidential, or sensitive information. 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 privacy, data protection, or data security obligations may require us to implement and maintain certain measures to protect our information technology systems and sensitive information.

We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our services and technologies could be delayed. Furthermore, significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Any such access, breach, or other loss of information could result in legal claims or proceedings, liability under domestic or foreign privacy, data protection, and data security laws such as HIPAA and HITECH, and penalties. Applicable privacy, data protection, or data security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Notice of certain security breaches must be made to affected individuals, the Secretary of HHS, and for extensive breaches, notice may need to be made to the media or state attorneys general. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. 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.

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm.

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, we 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. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. Similarly, the California Consumer Privacy Act ("CCPA") allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures. The CCPA also allows for statutory fines for noncompliance of up to $7,500 per violation. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as PHI or PII, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional liabilities.

The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability.

We are subject to numerous domestic and foreign laws and regulations regarding privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations and may be inconsistent among countries, or conflict with other rules. We are also subject to policies, industry standards, and the terms of our contractual obligations to customers and third parties related to privacy, data protection, and data security. The actual or perceived failure by us, our customers, our vendors, or other relevant third parties to address or comply with these laws, regulations, and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, reduce the use of our services, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

For example, the EU adopted the GDPR, which imposes onerous and comprehensive privacy, data protection, and data security obligations onto data controllers and processors, including, as applicable, contractual privacy, data protection, and data security commitments, expanded disclosures to data subjects about how their personal information is used, honoring individuals' data protection rights, limitations on retention of personal information, additional requirements pertaining to sensitive information (such as health data) and pseudonymized (i.e., key-coded) data, data breach notification requirements, and higher standards for obtaining consent from data subjects. Penalties for non-compliance with the GDPR can be significant and include fines in the amount of the greater of €20 million or 4% of global turnover and restrictions or prohibitions on data processing, which could limit our ability to do business in the EU, reduce demand for our services, and adversely impact our business and results of operations. The GDPR also provides that EU member states may introduce further conditions, including limitations, to make their own further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share European data, or could cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices.

In addition, in January 2021, following its exit from the EU, the UK implemented its own version of the GDPR (the "UK GDPR"), which currently imposes substantively similar obligations as the GDPR and provides for fines of up £17.5 million or 4% of global turnover, whichever is greater, for non-compliance. In addition, an actual or asserted violation of the GDPR or UK GDPR could result in regulatory investigations, reputational damage, orders to cease or change our processing of our data, enforcement notices and/or assessment notices (for a compulsory audit). We also may face civil claims, including representative actions and other class action-type litigation (where individuals have suffered harm), potentially resulting in our paying significant compensation or damages, or incurring other significant liabilities, as well as associated costs, diversion of internal resources, and reputational harm.

The relationship between the UK and the EU in relation to certain aspects of privacy, data protection, and data security laws is subject to some uncertainty. For example, on June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the UK ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal information flows from the European Economic Area ("EEA") to the UK. This adequacy determination will automatically expire in June 2025 unless the European Commission renews or extends it and may be modified or revoked in the interim. We cannot predict how the UK GDPR and other UK data protection laws or regulations may develop, including as compared to the GDPR, nor can we predict the effects of divergent laws and related guidance. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure, particularly if the GDPR and UK GDPR develop in conflicting or otherwise divergent ways.

Further, European and UK privacy, data protection, and data security laws, including the GDPR and the UK GDPR, generally restrict the transfer of personal information from the UK, EEA and Switzerland to the U.S. and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. There is uncertainty on how to implement such safeguards and how to conduct such transfers in compliance with the GDPR and UK GDPR, and certain safeguards may not be available or applicable with respect to some or all of the personal information processing activities necessary to research, develop and market our products and services. The European Commission recently released a set of Standard Contractual Clauses ("SCCs") that is designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, the SCCs are a valid mechanism to transfer personal data outside of the EEA. The SCCs, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the transferred personal information. Moreover, due to potential legal challenges, there is uncertainty regarding whether the SCCs will remain a valid mechanism for transfers of personal information out of the EEA. Similarly, the UK's Information Commissioner's Office has released a draft international data transfer agreement ("IDTA") governing data transfers much like the SCCs. If we are unable to implement a valid solution for personal information transfers to the U.S. and other countries, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe to the U.S. or other countries may decrease demand for our products and services as our customers that are subject to the GDPR or UK GDPR may seek alternatives that do not involve personal information transfers out of Europe. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses and the IDTA.

Similar laws have been proposed in other foreign jurisdictions in which we do, or expect to do, business. For example, the PIPL was adopted in China on August 20, 2021, and it went into effect on November 1, 2021. The PIPL shares certain similarities with the GDPR, including extraterritorial application, requirements for data minimization, data localization, and purpose limitation, and obligations to provide certain notices to and honor data subject rights from individuals located in the PRC. The PIPL allows for fines of up to 50 million yuan or 5% of a covered company's revenue in the prior year. The PIPL, and other new and evolving laws and regulations relating to privacy, data protection, and data security in China and other relevant foreign jurisdictions, increase our risk exposure, and may require us to modify our operations, may limit our ability to collect, retain, store, use, share, disclose, transfer, disseminate, and otherwise process personal information, may require additional investment of resources in compliance programs, and could result in increased compliance costs or changes in our ongoing or planned business practices, policies or strategies.

In the United States, federal, state, and local governments have enacted numerous privacy, data protection, and data security laws, including data breach notification laws, personal data 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. The CCPA, which took effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. It allows for statutory fines for noncompliance (up to $7,500 per violation). 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. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy, data protection and data security legislation in the U.S., which could increase our potential liability and adversely affect our business. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA imposes additional obligations relating to consumer data on companies doing business in California beginning January 1, 2022 and enforcement beginning July 1, 2023. The CPRA significantly modifies the CCPA and will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law.

The enactment of the CCPA has led a wave of similar legislative developments in other states in the U.S., which creates the potential for a patchwork of overlapping but different state laws and could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business, financial condition and results of operations. For example, in March 2021, Virginia enacted the Virginia Consumer Data Protection Act, a comprehensive privacy, data protection, and data security statute that becomes effective on January 1, 2023 (at the same time as the CPRA) and shares similarities with the CCPA, the CPRA, and legislation proposed in other states. In June 2021, Colorado enacted a similar law, the Colorado Privacy Act, which becomes effective on July 1, 2023. Many other states are considering proposed comprehensive data privacy legislation and all 50 states have passed some form of legislation relating to privacy or cybersecurity (for example, all 50 states have enacted laws requiring disclosure of certain personal information breaches). Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information. At the federal level, the United States Congress is considering various proposals for comprehensive federal privacy, data protection, and data security legislation and, while no such law currently exists, we are subject to applicable existing federal laws and regulations, such as the rules and regulations promulgated under the authority of the Federal Trade Commission, which regulates unfair or deceptive acts or practices, including with respect to privacy, data protection, and data security. These state statutes, and other similar state or federal laws, may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Additionally, many laws and regulations relating to privacy and the collection, storing, sharing, use, disclosure, and other processing or protection of certain types of data are subject to varying degrees of enforcement and new and changing interpretations by courts. These laws and other changes in laws or regulations relating to privacy, data protection, and data security, particularly any new or modified laws or regulations, or changes to the interpretation or enforcement of such laws or regulations, that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer, or disclosure, could greatly increase our operating costs, or require changes to our operations.

Compliance with U.S. and foreign privacy, data protection, and data security laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require 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. Given that we do not typically obtain direct consent from such data subjects and we do not audit our customers to ensure that they have obtained the necessary consents required by law, the failure of our customers to obtain consents that are valid under applicable law could result in our own non-compliance with privacy laws. Such failure to 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 privacy, data protection, and data 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.

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 and similar state laws, 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;

- 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 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 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 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;

- 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 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, 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 Foreign Corrupt Practices Act of 1977, as amended (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.

If we decide to 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 test, is uncertain. If we decide to seek reimbursement for our NeXT Dx test 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. 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 products are less safe, less effective, or less cost-effective than existing or later-introduced 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.

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 remain 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. 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. 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 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 in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicate payments will vary from 1% in 2022 to up to 3% 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. 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 APMs and 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 impact overall 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 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, or 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. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019.

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. Further, it is possible that additional governmental action is taken to address the COVID-19 pandemic. 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.

The 2017 tax reform law, as modified by 2020 tax legislation, and possible future 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. President Biden is considering further repeals and/or replacement of the Tax Cuts and Jobs Act which may affect us. On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspended the use of California net operating losses and limited the use of California research tax credits for tax years beginning in 2020 and before 2023, although California legislation enacted in early February 2022 ends the suspension and limitation for tax year 2022. On December 27, 2020, the Consolidated Appropriations Act, a coronavirus relief package that extended and expanded various tax provisions, was signed into law. 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, 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, commonly referred to as "Brexit" could lead to 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. A deal that outlines the future trading relationship between the U.K. and the EU was agreed in December 2020 and has been approved by each EU member state and the U.K.

While the deal provides for, in most cases, tariff-free trade of goods between the U.K. and the EU, there are additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. For example, a UKCA mark will be required to sell medical devices to customers in Great Britain, rather than a CE mark.

Should the U.K. or Great Britain further diverge from the EU from a regulatory perspective (for example, by not mirroring the provisions of the IVDR), tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) 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 impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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 infringement, misappropriation or other violations of other 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 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 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 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 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. 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 2041. 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 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 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 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 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 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 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 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 may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may also infringe our patents or the patents of our licensing partners. 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 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 product or the 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, 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 products may compete with our 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 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 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 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. 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 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 expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations, and research and development activities. Additionally, if we decide to grow our business by developing in vitro diagnostic tests, our capital expenditures and operating expenses would significantly increase. We may seek to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements. 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 the ongoing COVID-19 pandemic. 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 of significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP, as our largest customer;
- 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;
- the long-term macroeconomic effects of the COVID-19 pandemic, including potential global, regional or national economic slowdowns, recessions, depressions or other economic downturns; and
- 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 very recently in connection with the ongoing COVID-19 pandemic, which has 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, the VA MVP 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.

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, 2021, we had 44,904,512 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, 2021 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, 2021, we had federal and state net operating loss carryforwards of approximately $222.5 million and approximately $166.3 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 in future years 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. In addition, for California income tax purposes, California net operating losses and California research tax credits were suspended and limited, respectively, for tax years beginning after 2019 but before 2023, although California legislation enacted in early February 2022 ends the suspension and limitation for tax year 2022.

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 after we are no longer 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.

As of December 31, 2021, we were still eligible to use the scaled disclosures of a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.

Our status as a “smaller reporting company,” as defined in the Exchange Act, ended on December 31, 2021, because we had at least $700 million of equity securities held by non-affiliates on June 30, 2021. Pursuant to the rules, we are still eligible to use the scaled disclosures in this Annual Report on Form 10-K and we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K.

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 in this filing. 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.

Assessing our processes, procedures and staffing in order to maintain and improve our internal control over financial reporting is an ongoing process. For the year ended December 31, 2020, management became obligated to comply for the first time with Section 404 of the Sarbanes-Oxley Act of 2002 (SOX), which requires issuing a report that assesses the effectiveness of our internal control over financial reporting. Also, for the year ended December 31, 2021, an attestation report relating to the effectiveness of our internal control over financial reporting has been issued for the first time by our external auditor, Deloitte & Touche LLP.

Certain of our customers prepay us for a portion of the services that they expect to order from us in the future and we may be required to refund some or all of those prepayments if a customer cancels its contract with us or reduces the level of services that it expects to receive.

Certain of our customers prepay us for a portion of the services that they expect to order from us before they place purchase orders and we deliver those services. In some cases, this prepayment can be substantial and may be paid months or a year or more in advance of these customers providing samples to us and before our delivery of the services to which some or all of the deposit relates. As of December 31, 2021, we had approximately $3.8 million in customer deposits, including $3.3 million from one customer. However, as of that date, we had $287.1 million of cash and cash equivalents, and short-term investments. We are generally not required by our contracts to retain these deposits in cash or otherwise and we have generally used these deposits to make capital expenditures and fund our operations. When a customer that has prepaid us for future services cancels its contract with us, reduces the level of services that it expects to receive, or we determine that a prepayment is no longer necessary, we will repay that customer’s deposit. We may not have the cash or other available resources to satisfy that repayment obligation. Even if we are able to satisfy the repayment obligation from available resources, we may need to seek additional sources of capital to fund our operations, which funding may not be available when needed or on acceptable terms. In either of those circumstances, our business, financial condition, results of operations, and reputation would be materially and adversely affected. Furthermore, in the future, customers may elect not to prepay us for our services in which case we would have to find other sources of funding for our capital expenditures and operations, which would be costly relative to the aforementioned cost-free customer deposit funding and which may not be available when needed or on acceptable terms.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters are located in Menlo Park, California, and comprise approximately 46,000 square feet of space, pursuant to a lease that expires in 2027 (14,710 square feet of such space is under a separate lease that expires at the end of 2022). This lease includes an option to extend for an additional three years, at market rates that prevail at the time of our election to extend. Our CLIA-certified and CAP-accredited laboratory is located in this facility.

In August 2021, we announced that we will relocate our corporate headquarters from Menlo Park to a new facility in Fremont, California. We signed a 13.5-year lease that expires in 2035 for the 100,000 square foot facility. This lease includes two options to extend the term for a period of five-years per option at market rates that prevail at the time of our election to extend. The new facility is intended to allow for expansion of our CLIA-certified and CAP-accredited laboratory as well as provide additional space for our growing workforce.

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.

None.

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 18, 2022, there were approximately 71 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 the related 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 "Special 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 analysis and elsewhere in this Annual Report on Form 10-K.

Overview

Personalis' strategy is to develop some of the world's most advanced genetic tests for cancer. Today our tests are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples from their clinical trials. More recently, we have also begun to work with a growing number of leading cancer centers for clinical diagnostic use of our tests. We believe that adoption and publication by these key opinion leaders will develop an advanced standard of care for cancer patients and eventual broad use in a community hospital setting. We believe that our tests can meaningfully improve outcomes for cancer patients, and we estimate that the market opportunity for our tests for therapy selection and monitoring is approximately $30 billion in the U.S.

In December 2021, we launched NeXT Personal, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify MRD and recurrence in patients previously diagnosed with cancer. NeXT Personal is designed to deliver industry-leading MRD sensitivity down to the 1 part-per-million range, an approximately 10- to 100-fold improvement over other available technologies. NeXT Personal leverages whole genome sequencing of a patient's tumor to identify up to 1,800 specially-selected somatic variants that are subsequently used to create a personalized liquid biopsy panel for each patient. We believe this enables earlier detection across a broader variety of cancers and stages, including typically challenging early stage, low mutational burden, and low-shedding cancers. NeXT Personal is also designed to simultaneously detect and quantify clinically relevant mutations in ctDNA that may be used in the future to help guide therapy, when cancer is detected. These include known targetable cancer mutations, drug resistance mutations, and new variants which can emerge and change over time, especially under therapeutic pressure. We consider this approach not just "tumor-informed", but "comprehensively tumor-informed". Our ultimate goal is not just to detect cancer, but to provide key information over the entire course of the patient's disease. We believe this can be better for patients, more informative for pharmaceutical customers, and a larger business opportunity for us.

Our strategy is to work with world-class medical institutions. To that end, in the fourth quarter of 2021, we announced a collaboration with the Mayo Clinic and in the first quarter of 2022, we announced one with the Moores Cancer Center at UC San Diego Health. In these collaborations, we provide clinical diagnostic testing and research sequencing and analysis services using our tissue-based NeXT Dx test. We have begun to test clinical patient samples and are excited about the opportunity to work with these renowned cancer centers. If we achieve a favorable reimbursement decision for our NeXT Dx test from MolDx, we may also generate revenue in the future from some of these collaborations. Given the advanced nature of our NeXT Dx test, we believe it is a good fit for high-end cancer centers, which have a dual mandate for both clinical care and research. If these key opinion leaders have a positive experience using our tests, we are optimistic that this will also support broader use of our platform by other clinicians in the future.

We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases and in support of our NeXT Liquid Biopsy, NeXT Dx Test and NeXT Personal offerings. To date, we have sequenced more than 235,000 human samples, of which more than 145,000 were whole human genomes.

In parallel with the development of our platform technology, we have also pursued business within the population sequencing market, and we have provided whole genome sequencing services under contract with the VA MVP, which has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. The VA MVP is the largest population sequencing effort in the United States and we have delivered over 140,000 whole human genome sequence datasets to the VA MVP to date. The cumulative value of task orders received from the VA MVP since inception is approximately $186 million, $178.1 million of which we had recognized as revenue as of December 31, 2021. In September 2021, we received a task order from the VA MVP with a value of up to approximately $9.7 million, which was significantly less than in prior years. At that time, we expected the reduced order amount was to be followed by a formal RFP process and a potential new contract to be awarded sometime late in the third quarter of 2022. However, recent discussions with our contacts at the VA MVP indicate that there will be no RFP process in 2022. Accordingly, we do not expect to receive any new orders from the VA MVP this year nor to recognize any revenue from the VA MVP beyond the current order and contract. Unless we receive an additional task order and/or enter into a new services agreement with the VA MVP with a value comparable to that of our current contract and historical contracted orders, our revenue from the VA MVP is expected to decline significantly in 2022 and future periods. Given the strong growth we have already experienced in our oncology business in 2021, and the large market opportunity we see in this space, we plan to focus primarily on cancer as we go forward.

In August 2021, we announced that we will relocate our corporate headquarters from Menlo Park to a new facility in Fremont, California and we plan to beginning moving into it in the third quarter of this year. We signed a 13.5-year lease for the 100,000 square foot facility, which is approximately double the amount of space in our current Menlo Park location. The new facility is intended to allow for expansion of our laboratory for clinical testing to support biopharma 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. The new facility will also provide more office space for our selling, general and administrative workforce.

Our operations have been impacted by the ongoing COVID-19 pandemic. For example, the previous shelter-in-place order and health orders have 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 continue to cause such effects on our operations. The COVID-19 pandemic has also disrupted, and may continue to disrupt, the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we are aware of increased demand in the market for certain consumables used in COVID-19 test kits and vaccines. We use such 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. Several of our customers, including the VA MVP, were delayed in sending us samples in the prior year 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 and samples to us in the future.

While authorities in many areas have lifted or relaxed pandemic-related restrictions, in some cases they have subsequently re-imposed various restrictions after observing an increased rate of COVID-19 cases as the global COVID-19 pandemic continues to rapidly evolve and to present serious health risks. There is no guarantee when or if all such restrictions and recommendations will be eliminated, such that we and our customers, manufacturers and suppliers will be able to safely resume operations consistent with our pre-COVID-19 operations. The full extent of the impact of the COVID-19 pandemic on our business, operations and plans remains uncertain and will depend on future developments that cannot be predicted at this time. Such developments include the continued spread of the Omicron variant in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants that may prove especially contagious or virulent, the ultimate duration of the pandemic and the resulting impact on our business and other third parties with whom we do business, and the effectiveness of actions taken globally to contain and treat the disease.

A continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

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 biopharmaceutical customers 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 in the past two years, including NeXT Liquid Biopsy (exome-wide liquid biopsy platform), NeXT Dx Test (comprehensive genomic cancer profiling test enabling advanced composite biomarkers for cancer treatment), NeXT SHERPA and NeXT NEOPS (neoantigen prediction capabilities), and NeXT Personal (liquid biopsy offering for personalized tumor tracking for patients). We are currently investing in the development of future new product offerings, including NeXT CDx (diagnostic test) and NeXT Database (comprehensive tumor immune-genomics database). 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, and will continue to invest, 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, but as our volumes continue to increase we will ultimately need to invest in additional production capabilities. We expect to grow our revenue and spread our costs over a larger volume of services. In addition, we may invest significant amounts in infrastructure to support new products resulting from our research and development activities.

Components of Operating Results

Revenue

We derive our revenue primarily from sequencing and data analysis services to support the development of next-generation cancer therapies and to support large-scale genetic research programs. We support our customers by providing high-accuracy, validated genomic sequencing and advanced analytics. Many of these analytics are related to state-of-the-art biomarkers, including those relevant to immuno-oncology therapeutics such as checkpoint inhibitors.

Our revenue is primarily generated through contracts with companies in the pharmaceutical industry, healthcare organizations, and government entities. Our ability to increase revenue will depend on our ability to further penetrate this market. To do this, we are developing a growing set of state-of-the-art products, advancing our operational infrastructure, expanding our international presence, building our regulatory credentials, and expanding our targeted marketing efforts. We sell through a small direct sales force.

Since 2018, we derived a substantial portion of our revenue from sales of our DNA sequencing and data analysis services to the VA MVP. However, we do not anticipate deriving such substantial portions of our revenue from the VA MVP in future periods. Our contract with the VA MVP does not include specific testing turnaround times. Therefore, we have the ability to modulate the volume of samples processed for the VA MVP up or down to complement sample volumes from all other customers, which can vary from period to period.

We have one reportable segment from the sale of sequencing and data analysis services. Substantially all 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, and in the short term cost of revenue may outpace revenue growth as we invest in expanding our laboratory capacity, including additional costs associated with our future laboratory in Fremont, California. Over time the cost per sample processed is expected to decrease due to economies of scale we may gain as volume increases, automation initiatives, and other cost reductions.

Research and Development Expenses

Research and development expenses consist of costs incurred for the research and development of our products. These expenses consist primarily of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), laboratory supplies and consumables, costs of processing samples for research purposes, 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. These expenses also include costs associated with our collaborations, which we expect to increase over time.

We expense our research and development costs in the period in which they are incurred. We expect to increase our research and development expenses as we continue to develop new products and incur additional costs associated with our future headquarters in Fremont, California.

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 expenses will continue to increase in absolute dollars, primarily driven by our efforts to expand our commercial capability and to expand our brand awareness and customer base through targeted marketing initiatives with an increased presence both within and outside the United States. We expect general and administrative expenses to increase as we scale our operations and incur additional costs associated with ramping up our new headquarters facility in Fremont, California.

Interest Income and Interest Expense

Interest income consists primarily of interest earned on our cash and cash equivalents and short-term investments. Interest income increased significantly beginning in the second half of 2019 as a result of us investing proceeds from the initial public offering of our common stock in June 2019 (our "IPO"). Since the first quarter of 2020, our interest income has been adversely impacted by declines in yields on debt securities. Interest expense in 2021 is the recognition of imputed interest on noninterest bearing loans. Interest expense in 2019 and prior years consisted of cash and non-cash interest costs related to previously outstanding loans.

Loss on Debt Extinguishment

We incurred a loss on debt extinguishment in 2018 resulting from changes in the maturity dates of convertible notes issued in 2017. We also incurred a loss on debt extinguishment in 2019 upon the payoff of the Growth Capital Loan. See Note 6 to our consolidated financial statements included elsewhere in this annual report.

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. In 2019, other income (expense), net also consisted of changes in fair value of a convertible preferred stock warrant liability. We expect our foreign currency gains and losses to continue to fluctuate in the future due to changes in foreign currency exchange rates.

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,				
	2021	2020	2019	2018	2017
Consolidated Statements of Operations:	(in thousands, except share and per share data)				
Revenue	$ 85,494	$ 78,648	$ 65,207	$ 37,774	$ 9,393
Costs and expenses					
Cost of revenue	53,837	58,534	43,127	25,969	11,736
Research and development	49,312	28,568	22,418	14,304	9,919
Selling, general and administrative	47,698	33,692	22,080	11,271	9,901
Total costs and expenses	150,847	120,794	87,625	51,544	31,556
Loss from operations	(65,353)	(42,146)	(22,418)	(13,770)	(22,163)
Interest income	367	949	1,620	293	100
Interest expense	(184)	(2)	(1,133)	(1,894)	(1,303)
Loss on debt extinguishment	—	—	(1,704)	(4,658)	—
Other income (expense), net	(42)	(24)	(1,440)	150	(227)
Loss before income taxes	(65,212)	(41,223)	(25,075)	(19,879)	(23,593)
Provision for income taxes	14	57	9	7	5
Net loss	$ (65,226)	$ (41,280)	$ (25,084)	$ (19,886)	$ (23,598)
Net loss per share, basic and diluted	$ (1.49)	$ (1.20)	$ (1.39)	$ (6.49)	$ (7.78)
Weighted-average shares outstanding, basic and diluted	43,886,730	34,374,903	18,011,470	3,063,157	3,031,636

	December 31,				
	2021	2020	2019	2018	2017
Consolidated Balance Sheet Data:	(in thousands)				
Cash and cash equivalents, and short-term investments	$ 287,064	$ 203,290	$ 128,289	$ 19,744	$ 22,617
Working capital	286,918	180,083	89,616	(28,291)	(22,262)
Total assets	396,528	244,842	157,291	41,670	33,563
Total debt	3,494	—	—	4,996	17,506
Long-term obligations	54,914	9,261	639	804	1,183
Total liabilities	86,227	49,897	50,601	58,654	50,171
Redeemable convertible preferred stock	—	—	—	89,404	75,995
Total stockholders' equity (deficit)	310,301	194,945	106,690	(106,388)	(92,603)

Results of Operations

This section generally discusses 2021 and 2020 items and year-to-year comparisons between 2021 and 2020. Discussions of 2019 items and year-to-year comparisons between 2020 and 2019 that are not included in this 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, 2020.

Revenue

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

	Years Ended December 31,			Change	
	2021	2020	2019	2021 vs 2020	2020 vs 2019
VA MVP	$ 45,671	$ 56,154	$ 43,545	-19%	29%
All other customers	39,823	22,494	21,662	77%	4%
Total revenue	$ 85,494	$ 78,648	$ 65,207	9%	21%

The following table shows concentration of revenue by customer:

	Year Ended December 31,		
	2021	2020	2019
VA MVP	53%	71%	67%
Natera, Inc.	10%	*	*
Pfizer Inc.	*	*	13%

* Less than 10% of revenue

VA MVP

The decrease of $10.5 million in revenue from the VA MVP in 2021 was primarily due to a decrease in the volume of samples we tested in the period. As of December 31, 2021, we had a remaining backlog of $7.6 million under our current contract with the VA MVP, including the task order received in September 2021. We expect to convert such amount into revenue during the first three quarters of 2022.

The recognition of significant revenue from the VA MVP in future periods after the completion of our current backlog is contingent on receipt of a new contract. The VA MVP may not award us a new contract. Further, the value of any such potential new contract may be lower than our current contract and historical contracted orders from the VA MVP, and/or the scope or nature of the services required under any such new contract may change such that we are unable to serve the VA MVP in the future. The task order received in September 2021 had a value of up to approximately $9.7 million, which represents a substantial decline compared to historical contracted orders. At that time, we expected the reduced order amount was to be followed by a formal RFP process and a potential new contract to be awarded sometime late in the third quarter of 2022. However, recent discussions with our contacts at the VA MVP indicate that there will not be an RFP process in 2022. Accordingly, we are not planning on receiving any new orders from the VA MVP this year or expecting to recognize any revenue beyond the current order and contract. Unless we receive an additional task order and/or enter into a new services agreement with the VA MVP with a value comparable to that of our current contract and historical contracted orders, our revenue from the VA MVP will decline significantly in 2022 and future periods.

All other customers

The increase of $17.3 million in revenue from all other customers in 2021 was driven primarily by strong demand from large pharmaceutical customers for our NeXT Platform products, which resulted in an increase in the volume of samples we tested during 2021. Revenue from Natera contributed $8.6 million of the increase due to increased sample receipts under our agreement to provide advanced tumor analysis for use in Natera's MRD testing offerings. Revenue derived from our NeXT Platform products, which includes revenue from Natera, was $27.9 million in 2021, compared to $8.2 million in 2020, an increase of $19.7 million.

Based on the relatively large dollar value of orders received from all other customers throughout fiscal 2021, we anticipate that revenue from all other customers will make up the majority of our total revenue in fiscal year 2022.

Costs and Expenses

	Year Ended December 31,			Change	
	2021	2020	2019	2021 vs 2020	2020 vs 2019
		(in thousands)			
Cost of revenue	$ 53,837	$ 58,534	$ 43,127	-8%	36%
Research and development	49,312	28,568	22,418	73%	27%
Selling, general and administrative	47,698	33,692	22,080	42%	53%
Total costs and expenses	$ 150,847	$ 120,794	$ 87,625	25%	38%

Cost of revenue

The decrease in cost of revenue in 2021, despite a revenue increase in the same period, was primarily due to favorable customer mix and efficiencies within our laboratory operations. Raw materials costs were lower, relative to revenue, for non-VA MVP customer orders, resulting in favorable customer mix in 2021. We also observed more efficient sample processing overall in 2021, including less labor and overhead required per sample processed, which was favorable for both VA MVP and non-VA MVP orders.

The cost components related to the $4.7 million decrease in cost of revenue in 2021 were a $3.2 million decrease in raw materials costs due to favorable customer mix, a $3.1 million decrease in indirect costs due to a higher utilization of our laboratory for research and development activities, and a $0.3 million decrease in the cost of laboratory supplies and consumables, partially offset by a $1.1 million increase in labor costs as a result of increased headcount, and a $0.8 million increase in depreciation and maintenance on lab equipment.

Research and development

The $20.7 million increase in research and development in 2021 was primarily due to development of new products and lab automation efforts and consisted of a $12.1 million increase in personnel-related costs primarily related to increased headcount, a $5.1 million increase in sample processing costs incurred in our laboratory for new product development, a $2.0 million increase in IT and fixed facilities costs, a $1.0 million increase in depreciation and maintenance on research and development equipment, and a $0.5 million increase in consulting fees.

Selling, general and administrative

The $14.0 million increase in selling, general and administrative in 2021 was primarily due to a $8.6 million increase in personnel-related costs related to increased headcount, a $2.6 million increase in professional services (including corporate insurance, audit fees, and legal expenses), a $1.6 million increase in rent expense primarily related to our new Fremont facility, and a $1.2 million charge in connection with the modification of stock options held by two non-employee board members.

Interest Income, Interest Expense and Other Expense, Net

	Year Ended December 31,			Change	
	2021	2020	2019	2021 vs 2020	2020 vs 2019
	(in thousands)				
Interest income	$ 367	$ 949	$ 1,620	-61%	-41%
Interest expense	(184)	(2)	(1,133)	NM	-100%
Loss on debt extinguishment	—	—	(1,704)	—	-100%
Other expense, net	(42)	(24)	(1,440)	75%	-98%
Total	$ 141	$ 923	$ (2,657)		

Interest income and interest expense

The decrease in interest income in 2021 was driven by declines in yields on debt securities, partially offset by higher average cash and investment balances subsequent to our follow-on equity offerings in August 2020 and January 2021. Interest expense in 2021 is the recognition of imputed interest on noninterest bearing loans.

Other expense, net

Other expense, net in 2021 and 2020 consisted of foreign currency transaction gains and losses and remeasurements.

Liquidity and Capital Resources

The following tables present selected financial information and statistics as of and for the years ended December 31, 2021, 2020, and 2019 (in thousands):

	December 31,		
	2021	2020	2019
Cash and cash equivalents, and short-term investments	$ 287,064	$ 203,290	$ 128,289
Property and equipment, net	19,650	11,834	14,106
Contract liabilities	3,982	21,034	35,977
Working capital	286,918	180,083	89,616

	Year Ended December 31,		
	2021	2020	2019
Net cash used in operating activities	$ (70,828)	$ (42,653)	$ (18,069)
Net cash used in investing activities	(60,069)	(65,143)	(81,579)
Net cash provided by financing activities	169,700	121,268	134,948

From our inception through December 31, 2021, 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 financing. As of December 31, 2021, we had cash and cash equivalents in the amount of $105.6 million and short-term investments in the amount of $181.5 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, net proceeds from the offerings 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, such as the COVID-19 pandemic, 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, 2021, cash and cash equivalents held by foreign subsidiaries was $2.1 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 2021, cash used in operating activities of $70.8 million was a result of $65.2 million of net loss and a net negative change in operating assets and liabilities of $31.1 million (of which $17.1 million was related to reductions in outstanding customer prepayments as we fulfilled the related revenue contracts and $12.1 million due to an increase in accounts receivable), partially offset by non-cash adjustments to net income of $25.5 million (the most significant non-cash expenses were $14.4 million of stock-based compensation and $6.0 million of depreciation and amortization).

During 2020, cash used in operating activities of $42.7 million was a result of $41.3 million of net loss and a net negative change in operating assets and liabilities of $17.2 million (of which $14.9 million was related to reductions in outstanding customer prepayments as we fulfilled the related revenue contracts), partially offset by non-cash negative adjustments to net income of $15.8 million (the most significant non-cash expenses were $8.2 million of stock-based compensation and $5.8 million of depreciation and amortization).

During 2021, cash used in investing activities was $60.1 million due to net purchases of short-term investments of $49.0 million and $11.1 million in payments for property and equipment. Cash provided by financing activities of $169.7 million during the same period consisted of $162.3 million net proceeds from our January 2021 follow-on offering, $5.2 million proceeds from loans, and $4.4 million proceeds from stock option exercises and purchases under our Employee Stock Purchase Plan ("ESPP"), partially offset by $1.9 million repayments of loans and $0.3 million of offering costs.

During 2020, cash used in investing activities was $65.1 million due to net purchases of short-term investments of $61.9 million and $3.2 million in payments for property and equipment. Cash provided by financing activities of $121.3 million during the same period consisted of $117.5 million net proceeds from our August 2020 follow-on offering, $4.2 million proceeds from stock option exercises and purchases under our ESPP, partially offset by $0.4 million of offering costs.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist primarily of capital expenditures, variable costs of revenue, operating 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 $287.1 million as of December 31, 2021, as well as anticipated cash receipts from customers.

Capital expenditures. We expect to increase capital expenditures in future periods to support our global growth initiatives. Such expenditures are expected to consist primarily of facility renovations and improvements, laboratory equipment, and computer equipment. We currently expect capital expenditures to be between $55 and $65 million in 2022 and between $10 and $15 million in each of the next two fiscal years. In connection with our new headquarters and laboratory facility in Fremont, California, we expect to spend between $45 and $50 million (net of expected landlord reimbursements) in combined leasehold improvements, renovations, administrative, and other costs through the end of 2022. This is the reason for greater expected capital expenditures in 2022 as compared to the following two years.

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. Another primary use of cash within variable costs of revenue relates to paying our workforce. We currently expect spend to decrease in 2022 but increase in years thereafter to support revenue growth.

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 increase our spend in these areas to support our business growth in 2022. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Property leases. Our noncancelable operating lease payments were $84.6 million as of December 31, 2021. The timing of these future payments, by year, can be found in Part II, Item 8 of this Form 10-K in the Notes to Consolidated Financial Statements in Note 7, “Leases.”

Other. During the second quarter of 2021, we entered into two noninterest bearing loans to finance the purchase of $5.6 million of computer hardware, internal use software licenses, and related ongoing support. We made payments of $1.86 million in 2021. We are required to make payments of $1.86 million in each of 2022 and 2023. Further discussion of this transaction can be found in Part II, Item 1 of this Form 10-K in the Notes to Consolidated Financial Statements in Note 6, “Loans.”

Certain of our customers prepay us for a portion of the services that they expect to order from us before they place purchase orders and we deliver those services. In some cases, this prepayment can be substantial and may be paid months or a year or more in advance of these customers providing samples to us and before our delivery of the services to which some or all of the deposit relates. As of December 31, 2021, we had approximately $3.8 million in customer deposits, including $3.3 million from one customer. We are generally not required by our contracts to retain these deposits in cash or otherwise and we have generally used these deposits to make capital expenditures and fund our operations. When a customer that has prepaid us for future services cancels its contract with us, reduces the level of services that it expects to receive, or we determine that a prepayment is no longer necessary, we will repay that customer’s deposit. We do not expect such repayments to require material amounts of cash.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of these 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 have received payments from its customers in advance, but has not yet provided genome and exome sequencing and data analysis services to a customer and satisfied its performance obligations. 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 and substantially all of our revenue is derived from U.S. domestic operations.

Payment Terms

Payment terms and conditions vary by contract and customer. Our standard payment terms are typically less than 90 days from the date of invoice. 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, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

- *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. 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.

JOBS Act Accounting Election

Prior to December 31, 2021, we were a smaller reporting company and eligible to take advantage of the same reduced disclosures that an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), could avail itself to. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We had irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and therefore, are subject to the same new or revised accounting standards as other public companies that are not smaller reporting companies or emerging growth companies.

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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 105,585	$ 68,525
Short-term investments	181,479	134,765
Accounts receivable, net	18,468	6,349
Inventory and other deferred costs	5,610	5,639
Prepaid expenses and other current assets	7,089	5,441
Total current assets	318,231	220,719
Property and equipment, net	19,650	11,834
Operating lease right-of-use assets	53,822	10,271
Other long-term assets	4,825	2,018
Total assets	$ 396,528	$ 244,842
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 9,221	$ 8,301
Accrued and other current liabilities	18,110	11,301
Contract liabilities	3,982	21,034
Total current liabilities	31,313	40,636
Long-term operating lease liabilities	52,797	8,541
Other long-term liabilities	2,117	720
Total liabilities	86,227	49,897
Commitments and contingencies (Note 12)		
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; 44,904,512 and 39,105,548 shares issued and outstanding at December 31, 2021 and 2020, respectively	4	4
Additional paid-in capital	557,558	376,788
Accumulated other comprehensive income (loss)	(166)	22
Accumulated deficit	(247,095)	(181,869)
Total stockholders' equity	310,301	194,945
Total liabilities and stockholders' equity	$ 396,528	$ 244,842

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2021	2020	2019
Revenue	$ 85,494	$ 78,648	$ 65,207
Costs and expenses			
Cost of revenue	53,837	58,534	43,127
Research and development	49,312	28,568	22,418
Selling, general and administrative	47,698	33,692	22,080
Total costs and expenses	150,847	120,794	87,625
Loss from operations	(65,353)	(42,146)	(22,418)
Interest income	367	949	1,620
Interest expense	(184)	(2)	(1,133)
Loss on debt extinguishment	—	—	(1,704)
Other expense, net	(42)	(24)	(1,440)
Loss before income taxes	(65,212)	(41,223)	(25,075)
Provision for income taxes	14	57	9
Net loss	$ (65,226)	$ (41,280)	$ (25,084)
Net loss per share, basic and diluted	$ (1.49)	$ (1.20)	$ (1.39)
Weighted-average shares outstanding, basic and diluted	43,886,730	34,374,903	18,011,470

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2021	2020	2019
Net loss	$ (65,226)	$ (41,280)	$ (25,084)
Other comprehensive income (loss), net of tax			
Foreign currency translation adjustment	49	12	3
Change in unrealized gain (loss) on available-for-sale debt securities	(237)	16	6
Comprehensive loss	$ (65,414)	$ (41,252)	$ (25,075)

See accompanying notes to consolidated financial statements.

PERSONALIS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2018	18,474,742	$ 89,404	3,085,307	$ 1	$ 9,131	$ (15)	$ (115,505)	$ (106,388)
Issuance of common stock warrants	—	—	—	—	572	—	—	572
Elimination of fractional shares upon reverse stock split (see Note 8)	(39)	—	(34)	(1)	1	—	—	—
Exercise of common stock warrants	—	—	207,712	—	8	—	—	8
Conversion of Series A, B and C redeemable convertible preferred stock to common stock	(18,474,703)	(89,404)	18,474,703	2	89,402	—	—	89,404
Conversion of redeemable convertible preferred stock warrants to common stock warrants	—	—	—	—	2,086	—	—	2,086
Proceeds from initial public offering, net of offering costs	—	—	9,109,725	1	139,827	—	—	139,828
Proceeds from exercise of stock options	—	—	287,932	—	713	—	—	713
Proceeds from ESPP purchases	—	—	77,684	—	684	—	—	684
Stock-based compensation	—	—	—	—	4,858	—	—	4,858
Foreign currency translation adjustment	—	—	—	—	—	3	—	3
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	(25,084)	(25,084)
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

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,		
	2021	2020	2019
Cash flows from operating activities:			
Net loss	$ (65,226)	$ (41,280)	$ (25,084)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock-based compensation expense	14,378	8,238	4,858
Depreciation and amortization	6,014	5,758	4,748
Noncash operating lease cost	2,950	1,409	982
Amortization of premium (discount) on short-term investments	2,031	391	(39)
Loss on debt extinguishment	—	—	1,704
Change in fair value of convertible preferred stock warrant liability	—	—	1,403
Other	169	60	622
Changes in operating assets and liabilities			
Accounts receivable	(12,118)	(3,049)	1,069
Inventory and other deferred costs	29	(1,076)	(1,174)
Prepaid expenses and other assets	(2,658)	(2,312)	(2,559)
Accounts payable	(1,457)	751	1,398
Accrued and other current liabilities	3,365	3,529	1,971
Contract liabilities	(17,052)	(14,942)	(6,920)
Operating lease liabilities	(962)	(850)	(1,048)
Other long-term liabilities	(291)	720	—
Net cash used in operating activities	(70,828)	(42,653)	(18,069)
Cash flows from investing activities:			
Purchases of available-for-sale debt securities	(267,128)	(161,775)	(78,897)
Proceeds from maturities of available-for-sale debt securities	213,083	99,878	5,700
Proceeds from sales of available-for-sale debt securities	5,059	—	—
Purchases of property and equipment	(11,083)	(3,246)	(8,382)
Net cash used in investing activities	(60,069)	(65,143)	(81,579)
Cash flows from financing activities:			
Proceeds from public offerings, net of underwriting discounts and commissions	162,258	117,500	144,025
Payments of costs related to public offerings	(342)	(435)	(4,197)
Proceeds from loans	5,167	—	20,000
Repayments of loans	(1,857)	—	(25,000)
Payments of loan costs	—	—	(490)
Debt extinguishment costs	—	—	(794)
Proceeds from exercise of equity awards	4,474	4,203	1,396
Other	—	—	8
Net cash provided by financing activities	169,700	121,268	134,948
Effect of exchange rates on cash, cash equivalents and restricted cash	47	7	2
Net change in cash, cash equivalents and restricted cash	38,850	13,479	35,302
Cash and cash equivalents, beginning of period	68,525	55,046	19,744
Cash, cash equivalents and restricted cash, end of period	$ 107,375	$ 68,525	$ 55,046

Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:			
Cash and cash equivalents	$ 105,585	$ 68,525	$ 55,046
Restricted cash, included in other long-term assets	1,790	—	—
Total cash, cash equivalents and restricted cash	$ 107,375	$ 68,525	$ 55,046

Supplemental cash flow information:			
Cash paid for interest	$ —	$ —	$ 1,257
Cash paid for income taxes, net of refunds	39	35	6
Acquisition of property and equipment included in accounts payable and accrued liabilities	3,006	282	41

See accompanying notes to consolidated financial statements.

Note 1. Company and Nature of Business

Personalis, Inc. (the “Company”) was incorporated in Delaware on February 21, 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 is a provider of advanced genetic tests for cancer. The Company also provides sequencing and data analysis services to support population sequencing initiatives, which accounts for the majority of its revenue. The Company’s genetic tests for cancer are sold primarily to pharmaceutical companies, biopharmaceutical 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. In June 2020, the Company began partnering with a clinical genomics and life sciences company headquartered in China to expand business operations into China. 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.

Reverse Stock Split

On June 4, 2019, the Company filed an amendment to the Company’s amended and restated certificate of incorporation to effect a reverse split of shares of the Company’s common stock and redeemable convertible preferred stock on a four-for-one basis (the “Reverse Stock Split”). The par value of the common stock and redeemable convertible preferred stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, options to purchase common stock, share data, per share data, redeemable convertible preferred stock and related information contained in these consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Initial Public Offering

On June 24, 2019, the Company completed an initial public offering (“IPO”) in which it issued and sold 9,109,725 shares of its common stock at a public offering price of $17.00 per share. The Company received net proceeds of $139.8 million after deducting underwriting discounts, commissions and offering expenses. Offering expenses were $4.2 million and consisted of fees and expenses incurred in connection with the sale of the Company’s common stock in the IPO, including legal, accounting, printing, and other IPO-related costs.

A warrant to purchase 188,643 shares of our common stock was exercised prior to completion of the IPO. In addition, in connection with the IPO, all shares of the Company’s then-outstanding redeemable convertible preferred stock were automatically converted into 18,474,703 shares of the Company’s common stock, and all then-outstanding warrants to purchase the Company’s convertible preferred stock were automatically converted into warrants to purchase 84,585 shares of the Company’s common stock, all of which were exercised as of December 31, 2020 (see Note 10).

Follow-On and At-the-Market Equity Offerings

On August 14, 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, commissions. The Company also incurred $0.4 million of offering costs, including legal, accounting, printing and other offering-related costs.

On January 29, 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.

On December 30, 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, 2021 and 2020. The Company had no bad debt expense in 2021 and 2020. During the year ended December 31, 2019, bad debt expense was $0.1 million and included in selling, general and administrative expenses.

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,	
	2021	2020	2019	2021	2020
VA MVP	53%	71%	67%	*	*
Natera, Inc.	10%	*	*	39%	*
Pfizer Inc.	*	*	13%	*	*
AbbVie Inc.	*	*	*	18%	*
Merck & Co., Inc.	*	*	*	15%	59%

* 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 sequencing and data analysis services to support the development of personalized cancer vaccines and other next-generation cancer immunotherapies, as well as to support population sequencing initiatives. The Company's contracts are in the form of a combination of signed agreements, statements of work, and/or purchase orders. Under Topic 606, 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 less than 90 days 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 purposes, 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 accompanying 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.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, convertible preferred stock warrants, common stock warrants, common stock subject to repurchase, and equity awards are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

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, 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, and U.S. treasuries.

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 the Company’s genomic analysis 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 genomic analysis 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 twelve 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, 2021, 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 or lease prepayments reclassified from “Other long-term assets” upon lease commencement. 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. Lease payments are recognized as an expense on a straight-line basis over the lease term. 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

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued Accounting Standards Update (“ASU”) 2019-12, Income taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and clarifies and amends the existing guidance. The new standard is effective January 1, 2021 and the Company has adopted it effective December 31, 2020. The new standard did not have a material impact on the Company’s consolidated financial statements.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued 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. In November 2019, the FASB delayed the effective date for Topic 326 as applicable to smaller reporting companies to the first quarter of 2023. While the Company will no longer qualify as a smaller reporting company starting in the first quarter of 2022, the delayed effective date still applies to the Company. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and related disclosures. The Company will apply the new guidance by means of a cumulative-effect adjustment to the opening retained earnings as of the beginning of the first reporting period in which the guidance is effective.

JOBS Act Accounting Election

Prior to December 31, 2021, the Company was an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company had irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and therefore, the Company was subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Note 3. Revenue

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

	Year Ended December 31,		
	2021	2020	2019
VA MVP	$ 45,671	$ 56,154	$ 43,545
All other customers	39,823	22,494	21,662
Total	$ 85,494	$ 78,648	$ 65,207

Revenue from countries outside of the United States, based on the billing addresses of customers, represented 8%, 5%, and 4% of the Company's revenue for the years ended December 31, 2021, 2020 and 2019, respectively.

Contract Assets and Liabilities

Contract assets as of December 31, 2021 and 2020 were immaterial.

The Company's contract liabilities consist of consideration received from customers in excess of revenue recognized and are presented as current liabilities in the consolidated balance sheets.

The balance of contract liabilities was $4.0 million and $21.0 million as of December 31, 2021 and 2020, respectively. Revenue recognized in 2021, 2020, and 2019 that were included in the contract liability balance at the beginning of each reporting period were $19.1 million, $33.8 million, and $35.4 million, respectively.

Revenue allocated to remaining performance obligations represent contracted revenue that has not yet been recognized ("contracted not recognized revenue"), which include VA MVP contract liabilities and amounts that will be invoiced and recognized as revenue in future periods. Contracted not recognized revenue was $7.6 million as of December 31, 2021, which the Company expects to recognize as revenue within the next three quarters. The Company has elected the optional exemption that allows for the exclusion of contracts with an original expected duration of one year or less.

Note 4. Balance Sheet Details

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

	December 31,	
	2021	2020
Raw materials	$ 4,081	$ 2,675
Other deferred costs	1,529	2,964
Total inventory and other deferred costs	$ 5,610	$ 5,639

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

	December 31,	
	2021	2020
Machinery and equipment	$ 15,877	$ 13,854
Computer equipment	13,286	10,467
Construction in progress	5,393	322
Computer software costs	2,213	278
Leasehold improvements	1,357	987
Furniture and fixtures	517	440
Total	38,643	26,348
Less: accumulated depreciation and amortization	(18,993)	(14,514)
Property and equipment, net	$ 19,650	$ 11,834

Depreciation and amortization expense for the years ended December 31, 2021, 2020, and 2019 was $6.0 million, $5.8 million, and $4.7 million, respectively.

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

	December 31, 2021	December 31, 2020
Accrued compensation	$ 10,673	$ 8,041
Operating lease liabilities	3,728	2,445
Loans—current portion (Note 6)	1,806	—
Accrued liabilities	883	313
Employee ESPP contributions	517	407
Customer deposits	382	—
Accrued taxes	121	95
Total accrued and other current liabilities	$ 18,110	$ 11,301

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, 2021 and 2020 (in thousands):

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	

December 31, 2020	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 4,767	$ —	$ —	$ 4,767	
Money market funds	22,614	—	—	22,614	Level 1
Commercial paper	41,145	—	(1)	41,144	Level 2
Total cash and cash equivalents	68,526	—	(1)	68,525	
Short-term investments:					
Commercial paper	25,470	—	—	25,470	Level 2
U.S. government securities	18,260	1	—	18,261	Level 2
Corporate debt securities	29,576	—	(8)	29,568	Level 2
U.S. agency securities	61,436	31	(1)	61,466	Level 2
Total short-term investments	134,742	32	(9)	134,765	
Total assets measured at fair value	$ 203,268	$ 32	$ (10)	$ 203,290	

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, 2021, 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, 2021 have maturities due in one year or less, except for debt securities with an aggregate cost basis of $40.5 million and fair value of $40.3 million that have maturities ranging from 13 months to 21 months.

The Black-Scholes option-pricing model was used to estimate the fair value of the convertible preferred stock warrants at the date of issuance and at each subsequent consolidated balance sheet date. The fair value of the convertible preferred stock warrants was also estimated at the time of conversion to common stock warrants (see Note 10). Under this option-pricing model, convertible preferred stock warrants were valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the redeemable convertible preferred stock and common stock are inferred by analyzing these options.

The fair value of each convertible preferred stock warrant was estimated using the Black-Scholes option-pricing model with the assumptions described below. Upon conversion to common stock warrants in the second quarter of 2019 (see Note 10), no further fair value measurements were made. Therefore, there is no activity with respect to periods after the second quarter of 2019. For the periods indicated, the Company has limited historical volatility information available, and the expected volatility was based on actual volatility for comparable public companies projected over the expected terms of the warrants. The Company did not apply a forfeiture rate to the warrants as there is not enough historical information available to estimate such a rate. The risk-free interest rate was based on the U.S. Treasury yield curve over the expected term of the warrants.

	Period Ended June 24, 2019
Expected term (in years)	5.01 - 5.26
Volatility	57.20% - 57.24%
Risk-free interest rate	1.75%
Dividend yield	–%

The following table sets forth a summary of the changes in the fair value of the Company’s Level 3 financial instruments (in thousands):

	Warrant Liability
Balance — December 31, 2018	$ 683
Change in fair value	1,403
Reclassification of warrant liability to additional paid-in capital on conversion	(2,086)
Balance — December 31, 2019	$ —

Note 6. Loans

Revolving Loan

In June 2017, the Company entered into a $10.0 million revolving loan and security agreement (the “Revolving Loan”) with TriplePoint Capital LLC (“TriplePoint”). The Company borrowed $5.0 million under the Revolving Loan. Borrowings under the Revolving Loan bore an interest rate of prime, plus 6.75%. The Revolving Loan also had a 5.5% end of term loan payment on the highest outstanding principal amount. The Revolving Loan required monthly interest-only payments until the maturity date. The Revolving Loan’s original maturity date was December 31, 2018, and in December 2018 the maturity date was further extended until March 22, 2019. Upon determining that the change in cash flows between the previous and revised credit facility was not greater than 10%, the Company accounted for the transaction as a debt modification.

In connection with the Revolving Loan, the Company issued to TriplePoint a warrant to purchase up to 62,096 shares of the Company’s Series C redeemable convertible preferred stock at an exercise price of $8.052 per share, which was exercised in August 2020 (see Note 10).

The estimated fair value of the warrant upon draw down of $0.1 million was based on the Black-Scholes option-pricing model. The Company recorded the fair value of the warrant at issuance as a reduction in the debt-carrying value and as a warrant liability. The debt-carrying value reduction was accreted using the effective interest method as additional interest expense over the contractual period of 1.5 years for the Revolving Loan.

The Revolving Loan had an effective interest rate of 19.22% per year. Interest expense for the year ended December 31, 2019 was $0.2 million. On March 22, 2019, this Revolving Loan was repaid in full.

Growth Capital Loan

On March 22, 2019, the Company entered into a growth capital loan (the “Growth Capital Loan”) with TriplePoint to provide for a $20.0 million growth capital loan facility and had drawn down the full $20.0 million available under the facility. The Company used $5.1 million of the Growth Capital Loan to repay, in its entirety, all amounts outstanding under the Revolving Loan. Borrowings under the Growth Capital Loan bore interest at a floating rate of prime, plus 5.00% for borrowings up to $15.0 million and the prime rate plus 6.50% for borrowings greater than $15.0 million. Under the agreement, the Company was required to make monthly interest-only payments through April 1, 2020 and was required to make 36 equal monthly payments of principal, plus accrued interest, from April 1, 2020 through March 1, 2023, when all unpaid principal and interest was to become due and payable. The agreement allowed voluntary prepayment of all, but not part, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee of 1.00% of the outstanding balance if prepaid in months one through 12 of the loan term. In addition to the final payment, the Company paid an amount equal to 2.75% of each principal amount drawn under this Growth Capital Loan facility.

In connection with the Growth Capital Loan, the Company issued a warrant to purchase 65,502 shares of common stock to TriplePoint at an exercise price of $9.16 per share, which was exercised in August 2020 (see Note 11). The Company recorded the issuance-date fair value of the warrant of $0.6 million and fees paid to TriplePoint of $0.3 million as a debt discount, which was amortized over the term of the Growth Capital Loan using the effective interest rate method.

Upon issuance, the Growth Capital Loan had an effective interest rate of 15.23% per year. Interest expense for the year ended December 31, 2019 was $1.0 million.

On August 14, 2019, the Company paid off the Growth Capital Loan in its entirety. In connection with this debt repayment, the Company recorded a $1.7 million loss on extinguishment of debt in the consolidated statements of operations.

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.

In April 2021, the Company entered into another payment agreement, with the same financing entity, to finance the purchase of $3.1 million of certain computer hardware and related hardware maintenance. The Company is required to pay three equal payments of $1.0 million in July 2021, June 2022, and June 2023. The nature of this agreement and resulting accounting treatment are the same as the payment agreement described in the preceding paragraph.

The total initial present value of the payment agreements was $5.2 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 year ended December 31, 2021 was $0.2 million. Amounts outstanding under the payment agreements are as follows (in thousands):

	December 31,	
	2021	2020
Principal	$ 3,714	$ —
Less: unamortized discount	(220)	—
Total carrying amount	3,494	—
Less: current portion (included in accrued and other current liabilities)	(1,806)	—
Long-term portion (included in other long-term liabilities)	$ 1,688	$ —

Note 7. Leases

In February 2015, the Company entered into a noncancelable operating lease for approximately 31,280 square feet of space used for its current laboratory and corporate headquarters. In April 2020, the Company extended the term of the lease through November 30, 2027. The lease includes an option to extend the term for a period of three years with rent payments equal to then current fair market rent for the space. 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 May 2021, the Company amended the lease to expand the premises subject to the lease to include an additional 14,710 square feet of space (the “Expansion Lease”). The Expansion Lease expires on December 31, 2022 and has no option to extend the term.

In August 2019, the Company entered into a noncancelable operating lease for a co-located data center space. The lease expires on August 31, 2022 and includes an option to extend the term for a period of three years immediately following the expiration of the term with rent payments to be negotiated upon such a renewal. The Company determined the extension option is not reasonably certain to be exercised. In April 2020, the lease was modified to increase the data center space available for the Company’s use for the remainder of the lease term.

In August 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 future corporate headquarters and expanded laboratory facility. The lease term is 13.5 years and commences in June 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 has agreed to contribute up to approximately $15.5 million. 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 prospectively over the remainder of the lease term. The lease expires on November 30, 2035 and includes two options to extend the term for a period of five-years per option with rent payments equal to then current fair market rent for the space. The

Company determined the extension options are not reasonably certain to be exercised. The lease also contains escalating rent payments.

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 on June 30, 2024, as well as various other short-term leases.

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

	Year Ended December 31,		
	2021	2020	2019
Lease cost			
Operating lease cost	$ 5,009	$ 2,295	$ 1,120
Short-term lease cost	364	227	64
Variable lease cost	1,152	748	794
Total lease cost	$ 6,525	$ 3,270	$ 1,978

As of December 31, 2021, the Company's operating leases had a weighted-average remaining lease term of 12.2 years and a weighted-average discount rate of 6.6%. 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, 2021 were as follows (in thousands):

	Amount
2022	$ 3,879
2023	6,196
2024	6,803
2025	7,001
2026	7,217
2027 and thereafter	53,526
Total future minimum lease payments	84,622
Less: imputed interest	(28,097)
Present value of future minimum lease payments	56,525
Less: current portion of operating lease liability	(3,728)
Long-term operating lease liabilities	$ 52,797

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, 2021, 2020 and 2019, was $3.3 million, $1.7 million and $1.2 million, respectively. Right-of-use assets obtained in exchange for new operating lease liabilities, during 2021, 2020 and 2019, were $46.5 million, $9.8 million and $2.8 million, respectively.

Note 8. Redeemable Convertible Preferred Stock

Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock, and Series C redeemable convertible preferred stock (collectively the "Redeemable Convertible Preferred Stock") previously outstanding consisted of the following as of December 31, 2018 and as of immediately prior to the automatic conversion of the Redeemable Convertible Preferred Stock into common stock:

	December 31, 2018			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
			(in thousands)	
Series A	31,250,000	7,812,497	$ 20,500	$ 20,261
Series B	19,288,150	4,799,548	22,078	22,047
Series C	24,700,000	5,862,697	47,206	47,096
Total redeemable convertible preferred stock	75,238,150	18,474,742	$ 89,784	$ 89,404

Immediately prior to the closing of the Company's IPO, all shares of the Company's then-outstanding Redeemable Convertible Preferred Stock, as shown in the table above, automatically converted on a one-for-one basis into an aggregate of 18,474,703 shares of common stock. The Reverse Stock Split was effected on a holder-by-holder basis with no fractional shares issued, which resulted in 39 fewer shares of common stock issued as compared to the amounts shown in the above table.

Note 9. 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, 2021 and December 31, 2020 were as follows:

	December 31,	
	2021	**2020**
Reserved for issuance upon exercise of options outstanding under the 2011 Plan	2,573,020	3,389,711
Reserved for issuance upon exercise or settlement of awards outstanding under the 2019 Plan	4,358,820	2,399,513
Reserved and available for issuance under the 2019 Plan	1,684,213	1,977,069
Reserved for issuance upon exercise or settlement of awards outstanding under the Inducement Plan	171,275	199,300
Reserved and available for issuance under the Inducement Plan	806,067	800,700
Reserved and available for issuance under the ESPP	583,348	320,582
Total number of shares reserved	10,176,743	9,086,875

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, 2021, 2020, and 2019 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, 2018	4,110,130	$ 3.16	6.94	$ 24,716
Options granted	988,913	11.81		
Options exercised	(287,932)	2.47		
Options cancelled	(79,676)	6.61		
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 cancelled	(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 cancelled	(110,107)	13.88		
Balance—December 31, 2021	5,002,419	$ 10.66	6.89	$ 28,308
Options vested and exercisable as of December 31, 2021	3,062,512	$ 6.67	5.78	$ 24,149

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 $14.27 on December 31, 2021 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 $13.14, $7.17, and $8.00 per share for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, the unrecognized stock-based compensation of unvested options was $18.1 million, which is expected to be recognized over a weighted-average period of 2.3 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 was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	5.50 - 6.27	5.50 - 6.40	5.00 - 6.87
Volatility	67.97 - 69.90%	61.74 - 68.18%	56.20 - 63.08%
Risk-free interest rate	0.62 - 1.39%	0.36 - 1.66%	1.53 - 2.52%
Dividend yield	–%	–%	–%

Performance-Based Stock Option Activity

Pursuant to the 2019 Plan, in March 2020, the Company's board of directors granted the Company's 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 year ended December 31, 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
Options granted	—					
Options exercised	—					
Options cancelled	—					
Balance—December 31, 2021	421,000	$	5.10	8.21	$	3,861
Options vested and exercisable as of December 31, 2021	421,000	$	5.10	8.21	$	3,861

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $14.27 on December 31, 2021 and the exercise price of the underlying stock options. As of December 31, 2021, 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, 2021, 2020 and 2019 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, 2018	—	$	—		
RSUs granted	120,000		8.86		
RSUs vested	—		—		
RSUs cancelled	—		—		
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 cancelled	(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 cancelled	(61,059)		18.45		
Balance—December 31, 2021	1,679,696	$	16.35	$	23,969

The Company granted 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, or in some cases quarterly over a three-year period. The Company accounted for the fair value of the 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 $14.27 on December 31, 2021. As of December 31, 2021, the unrecognized stock-based compensation cost of unvested RSUs was $25.1 million, which is expected to be recognized over a weighted-average period of 2.9 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, 2021, 2020 and 2019, 128,289, 164,164 and 77,684 shares of common stock were purchased under the ESPP, respectively. The following assumptions were used to calculate the stock-based compensation for each stock purchase right granted under the ESPP:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.49	0.49 - 0.50	0.37 - 0.50
Volatility	55.92 - 74.88%	65.15 - 102.10%	59.06 - 59.91%
Risk-free interest rate	0.04 - 0.06%	0.11 - 0.12%	1.55 - 2.14%
Dividend yield	–%	–%	–%
Fair value	$6.30 - $8.21	$4.29 - $8.12	$3.48 - $5.01

Stock-based Compensation Expense

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

	Year Ended December 31,		
	2021	2020	2019
Cost of revenue	$ 1,414	$ 854	$ 480
Research and development	4,064	1,773	903
Selling, general and administrative	8,900	5,611	3,475
Total stock-based compensation expense	$ 14,378	$ 8,238	$ 4,858

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

	Year Ended December 31,		
	2021	2020	2019
Stock options	$ 8,585	$ 4,729	$ 4,217
Performance-based stock options	—	1,392	280
RSUs	4,765	1,401	26
ESPP	1,028	716	335
Total stock-based compensation expense	$ 14,378	$ 8,238	$ 4,858

Note 10. Redeemable Convertible Preferred Stock Warrants

In September 2014, the Company entered into a loan and security agreement with Silicon Valley Bank to borrow up to $3.0 million under an equipment loan to be secured by the equipment financed (the "Term Loan"). The Term Loan was repaid in full in September 2018. In connection with the Term Loan, the Company issued a warrant to purchase 22,489 shares of its Series B redeemable convertible preferred stock at an exercise price of $4.60 per share. In June 2017, as additional consideration for the Revolving Loan (see Note 6), the Company issued a warrant to purchase up to 62,096 shares of its Series C redeemable convertible preferred stock at an exercise price of $8.052.

At initial recognition, the convertible preferred stock warrants were recorded at their estimated fair values ($0.1 million each initially) and were subject to remeasurement at each consolidated balance sheet date, with changes in fair value recognized as a component of net income. See Note 5 for the estimated fair values and changes in fair values relating to periods presented.

Immediately prior to the closing of the Company's IPO, the redeemable convertible preferred stock warrants automatically converted to common stock warrants. As a result of the automatic conversion of the redeemable convertible preferred stock warrants to common stock warrants, the Company revalued the redeemable convertible preferred stock warrants as of the completion of the IPO and reclassified the outstanding preferred stock warrant liability balance to additional paid-in capital with no further remeasurements as the common stock warrants were deemed permanent equity. The fair value transferred to additional paid-in capital was $2.1 million.

Subsequent to the conversion to a common stock warrant and before the end of the Company's second quarter ended June 30, 2019, the warrant for 22,489 shares was exercised. The Company issued 19,069 shares of common stock as the warrant allowed a net share settlement. Separately, the warrant for 62,096 shares issued in June 2017 was exercised in August 2020. The Company issued 40,357 shares of common stock as the warrant allowed for a net share settlement.

Note 11. Common Stock Warrants

In connection with the sale of Series A redeemable convertible preferred stock in August 2011, the Company issued a warrant to purchase 188,643 shares of common stock to an investor who purchased Series A redeemable convertible preferred stock in August 2011 at an exercise price of $0.04 per share. The Company recorded the issuance-date fair value of the warrant of $0.1 million in equity as the warrant met all criteria for equity classification. The common stock warrant was exercised in June 2019 prior to the Company's IPO and is no longer outstanding.

In connection with the Growth Capital Loan agreement (see Note 6), the Company issued a warrant to purchase 65,502 shares of common stock to the lender at an exercise price of $9.16 per share. The Company recorded the issuance-date fair value of the warrant of $0.6 million in equity as the warrant met all criteria for equity classification. The warrant was exercised in September 2020 and is no longer outstanding. The Company issued 39,415 shares of common stock as the warrant allowed for a net share settlement.

Note 12. Commitments and Contingencies

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. Accruals for litigation and 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. As of December 31, 2021, the Company was not involved in any material 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 13. Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing the 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 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,		
	2021	2020	2019
Net loss	$ (65,226)	$ (41,280)	$ (25,084)
Weighted-average common shares outstanding—basic and diluted	43,886,730	34,374,903	18,011,470
Net loss per common share—basic and diluted	$ (1.49)	$ (1.20)	$ (1.39)

The Company incurred net losses in the periods presented, and as a result, potential common shares from stock options, common stock warrants, 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 potentially dilutive shares excluded from the computation of diluted net loss per common share because their effect was anti-dilutive:

	Year Ended December 31,		
	2021	2020	2019
Common stock warrants	—	—	127,598
Options to purchase common stock	5,423,419	5,369,306	4,731,435
Unvested restricted stock units	1,679,696	619,218	120,000
ESPP	87,367	58,802	75,405
Total	7,190,482	6,047,326	5,054,438

Note 14. Income Taxes

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

	Year Ended December 31,		
	2021	2020	2019
Domestic	$ (65,415)	$ (41,404)	$ (25,111)
Foreign	203	181	36
Loss before income taxes	$ (65,212)	$ (41,223)	$ (25,075)

Provision for Income Taxes

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

	Year Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ —	$ —	$ —
State	—	26	1
Foreign	43	31	8
Total current	43	57	9
Deferred:			
Foreign	(29)	—	—
Total deferred	(29)	—	—
Provision for income taxes	$ 14	$ 57	$ 9

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 2021, 2020, and 2019 as follows:

	Year Ended December 31,		
	2021	2020	2019
Expected tax (benefit) at federal statutory rate	-21%	-21%	-21%
Effect of:			
State taxes	-9%	-10%	-8%
Change in valuation allowance	36%	38%	28%
Stock-based compensation	-3%	-4%	2%
Research and development credit	-3%	-3%	-3%
Other	–%	–%	2%
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 has been paid as of December 31, 2021. 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,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 61,219	$ 43,221
Research and development credits	12,127	8,455
Deferred revenue	164	695
Accruals	2,846	2,260
Stock-based compensation	4,435	2,157
Operating lease liabilities	16,406	3,198
Other intangibles	321	366
Other	115	96
Total gross deferred tax assets	97,633	60,448
Less: valuation allowance	(81,628)	(56,846)
Total deferred tax assets	16,005	3,602
Deferred tax liabilities:		
Property and equipment	(356)	(612)
Operating lease right-of-use assets	(15,620)	(2,990)
Total deferred tax liabilities	(15,976)	(3,602)
Net deferred tax assets	$ 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 $24.8 million and $16.8 million during the years ended December 31, 2021 and 2020, respectively.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2021, the Company had a net operating loss carryforward for federal income tax purposes of approximately $222.5 million, portions of which will begin to expire in 2031. The Company had a total state net operating loss carryforward of approximately $166.3 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, 2021, the Company has federal credits of approximately $6.1 million, which will begin to expire in 2031 and state research credits of approximately $6.0 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,	
	2021	2020
Beginning balance	$ 2,148	$ 1,581
Gross increase—tax position in current period	918	567
Ending balance	$ 3,066	$ 2,148

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, 2021, 2020, and 2019, no interest or penalties were required to be recognized relating to unrecognized tax benefits.

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, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholder's equity (deficit) and cash flows, for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2022, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matters

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

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
February 24, 2022

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Personalis, Inc. and subsidiaries (the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021 of the Company and our report dated February 24, 2022, expressed an unqualified opinion on those financial statements.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
February 24, 2022

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our CEO and CFO have concluded that as of December 31, 2021, 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 Securities and Exchange Commission'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, 2021 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, 2021, 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. The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report that is included in Part II, Item 8, of this Annual Report on Form 10-K.

Changes in Internal Control

None.

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.

Compensatory Arrangements of Certain Officers

On February 16, 2022 and February 21, 2022, the compensation committee of the board of directors of the Company approved the amendment and restatement of the terms of executive severance agreements for Messrs. West and Tachibana and Dr. Chen, each dated February 23, 2022 (collectively, the "A&R Executive Severance Agreements").

Provisions that were amended in the A&R Executive Severance Agreement with Mr. West (the "West Severance Agreement"), include, among other things:

- In the event that there is a "separation from service" (as defined in the West Severance Agreement), the period to receive payment of COBRA health insurance premiums will be shortened to the earlier of (i) 12 months or (ii) the date upon which Mr. West obtains coverage under a subsequent employer's medical plan.
- In the event of a separation from service within 12 months after the effective date of "change in control" (as defined in the West Separation Agreement), the vesting of each of Mr. West's then-outstanding unvested equity compensation awards shall accelerate as to all of then-unvested shares subject to each such award, or, in the case of any other separation from service, the vesting of each of Mr. West's then-outstanding unvested equity compensation awards shall accelerate as to the number of the then-unvested shares subject to each such award that would have become vested within the first 24 months following such separation from service, subject to certain conditions.

Provisions that were amended in the A&R Executive Severance Agreements with each of Mr. Tachibana and Dr. Chen (together, the "Officer Severance Agreements"), include, among other things:

- In the event that there is a "separation from service" (as defined in the Officer Severance Agreements), the period to receive payment of COBRA health insurance premiums will be shortened to the earlier of (i) 12 months for Mr. Tachibana and 9 months for Dr. Chen or (ii) the date upon which the executive obtains coverage under a subsequent employer's medical plan.

- In the event that there is a separation from service that is not within 12 months after a "change in control" (as defined in the Officer Severance Agreements), the executive will be entitled to 6 months of his then current base salary, subject to certain conditions.

Appointment of Director

On February 17, 2022, upon recommendation of the nominating and corporate governance committee of the board of directors, the board of directors increased the size of the board of directors from 7 to 8 members, and appointed Olivia K. Bloom, to the board of directors as a Class I director, which appointment will become effective on March 1, 2022. Ms. Bloom's term will expire, along with the terms of the other Class I directors, at the Company's annual meeting of stockholders in 2023. The board of directors also appointed Ms. Bloom to serve as a member of the audit committee of the board of directors, with such appointment effective upon her appointment to the board of directors.

There are no arrangements or understandings between Ms. Bloom and any other persons pursuant to which she was selected as a director. The board of directors has determined that Ms. Bloom qualifies as an independent director under the independence requirements set forth under Rule 5605(a)(2) of the Nasdaq Rules and listing standards. Additionally, there are no transactions involving the company and Ms. Bloom that we would be required to report pursuant to Item 404(a) of Regulation S-K.

In connection with her appointment to the board of directors and the audit committee, and pursuant to the Company's amended and restated non-employee director compensation policy (the "Amended Personalis, Inc. Non-Employee Director Compensation Policy"), Ms. Bloom will receive annual cash retainers for her service on the board of directors and any committee of the board of directors, an initial equity grant and annual equity grants, each in the amounts set forth in the Company's Amended Non-Employee Director Compensation Policy.

The company will also enter into its standard form of indemnification agreement with Ms. Bloom.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021 in connection with the solicitation of proxies for the Company’s 2022 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.

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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021, 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, 2021” and “Security Ownership of Certain Beneficial Owners and Management” in the Company’s 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021, 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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021, and is incorporated herein by reference.

Item 14. Principal Accounting 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 2022 Proxy Statement to be filed with the SEC within 120 days after December 31, 2021, 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 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.

(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	3.2	6/24/2019
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 John West and the Registrant, dated June 2, 2019.	S-1/A	333-231703	10.5	6/7/2019
10.6#	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
10.7#	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
10.8	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
10.9¥	Contract No. VA240-17-D-0103, by and between the U.S. Department of Veterans Affairs and the Registrant, dated September 28, 2017.	S-1	333-231703	10.10	5/23/2019
10.10¥	Master Services Subcontract Agreement, by and between Illumina, Inc. and the Registrant, dated November 1, 2017.	S-1	333-231703	10.13	5/23/2019
10.11¥	Pricing Agreement, by and between Illumina, Inc. and the Registrant, dated March 26, 2019.	S-1	333-231703	10.19	5/23/2019
10.12	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
10.13#	Amendment to Employment Terms Letter, by and between John West and the Registrant, dated May 6, 2020.	10-Q	001-38943	10.1	5/7/2020
10.14#	Personalis, Inc. 2020 Inducement Plan and forms of agreements thereunder.	S-8	333-238080	99.1	5/7/2020
10.15	Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated August 25, 2021.	10-Q	001-38943	10.1	11/4/2021
10.16	Amendment No. 1 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated December 8, 2021.				
10.17¥	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
10.18#	Amended Personalis, Inc. Non-Employee Director Compensation Policy, dated February 17, 2022.				
10.19#	Amended and Restated Executive Severance Agreement, by and between John West and the Registrant, dated February 23, 2022.				
10.20#	Amended and Restated Executive Severance Agreement, by and between Dr. Richard Chen and the Registrant, dated February 23, 2022.				
10.21#	Amended and Restated Executive Severance Agreement, by and between Aaron Tachibana and the Registrant, dated February 23, 2022.				
21.1	Subsidiaries of the Registrant as of December 31, 2021.				
23.1	Consent of Deloitte & Touche LLP, 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 Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal 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 Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1	Consent to be Named as a Director Nominee of Oliva Bloom.
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 and Exhibit 32.2 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 24, 2022

Personalis, Inc.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John West and Aaron Tachibana, jointly and severally, 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/ John West **John West**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 24, 2022
/s/ Aaron Tachibana **Aaron Tachibana**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 24, 2022
/s/ A. Blaine Bowman **A. Blaine Bowman**	Director	February 24, 2022
/s/ Alan Colowick **Alan Colowick, M.D.**	Director	February 24, 2022
/s/ Karin Eastham **Karin Eastham**	Director	February 24, 2022
/s/ Kenneth Ludlum **Kenneth Ludlum**	Director	February 24, 2022
/s/ Jonathan MacQuitty **Jonathan MacQuitty, Ph.D.**	Director	February 24, 2022
/s/ Woodrow A. Myers, Jr. **Woodrow A. Myers, Jr., M.D.**	Director	February 24, 2022

Exhibit 10.16

AMENDMENT NO. 1 TO LEASE

This **AMENDMENT NO. 1 TO LEASE** ("Amendment") is dated as of this 8th day of December,2021, by and between **ARDENWOOD VENTURES I, LLC**, a Delaware limited liability company ("**Landlord**"), and **PERSONALIS, INC.**, a Delaware corporation ("**Tenant**").

RECITALS

A. Landlord and Tenant entered into that certain Lease Agreement dated as of August 24, 2021 (the "Lease") for premises located at 6600 Dumbarton Circle in Fremont, California, comprised ofapproximately 100,808 rentable square feet of floor area as more particularly described in the Lease;

B. Landlord and Tenant now desire to amend the Lease on the terms and conditions set forth herein.

AGREEMENT

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which arehereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Definitions.** All capitalized terms used in this Amendment but not otherwise defined shall havethe meanings assigned to them in the Lease.

2. **Elevator.** The first sentence of Paragraph 2 of the Work Letter is hereby amended in its entiretyto read as follows:

> "Tenant shall cause the Tenant Parties to construct, furnish or install all improvements, equipment or fixtures, that Tenant deems reasonably necessary for Tenant's intended use of the Leased Premises, including laboratory, research and development, and manufacturing facilities, which may include, without limitation, a new freight elevator (collectively, the "**Tenant Improvements**")."

3. **Initial TI Budget.** Paragraph 3(b)(iii) of the Work Letter is hereby amended in its entirety to readas follows:

> "Prior to the TI Allowance Deadline, on or before the 30th day following submission of theapplication for payment, so long as Tenant is not in monetary default, or material non- monetary default beyond the expiration of any notice and cure periods expressly set forth in the Lease or this Work Letter, under the terms of this Work Letter or the Lease, Landlordshall pay a share of such payment pari passu with Tenant, determined by multiplying the amount of such payment by a fraction, the numerator of which is the amount of the Tenant Improvement Allowance, and the denominator of which is $33,409,720, based on the "**Initial TI Budget**," defined herein as the September 27, 2021 budget delivered to Landlord by Tenant, which includes reasonable detail on the estimated construction cost of all Tenant Improvement work and materials for the entire Leased Premises, and the estimated cost of all professional services, fees and permits in connection therewith. Tenantshall pay the balance of such payment, provided that at such time as Landlord has paid theentire Tenant Improvement Allowance on account of such Tenant Improvement work, all billings shall be paid entirely by Tenant. If upon completion of the Tenant Improvement work and payment in full to the Tenant Improvement Contractor, the architect andengineer, and payment in full of all fees and permits, the portion of the cost of the Tenant

Improvement work, architects' and engineers' fees, permits and fees theretofore paid by Landlord is less than the Tenant Improvement Allowance, Landlord shall reimburse Tenant for costs expended by Tenant for Tenant Improvement work up to the amount by which the Tenant Improvement Allowance exceeds the portion of such cost theretofore paid by Landlord, it being the intent of the parties that Tenant shall in such case be entitled to the benefit of the entire Tenant Improvement Allowance. Landlord shall have no obligation to advance the Tenant Improvement Allowance to the extent it exceeds the total cost of theTenant Improvement work. In no event shall Landlord have any responsibility for the costof the Tenant Improvement work in excess of the Improvement Allowance. Landlord shall have no obligation to make any payments to Tenant Improvement Contractor's material suppliers or subcontractors or to determine whether amounts due them from Tenant Improvement Contractor in connection with the Tenant Improvement work have, in fact, been paid."

4. **Ratification.** The Lease, as amended by this Amendment, is hereby ratified by Landlord and Tenant and Landlord and Tenant hereby agree that the Lease, as so amended, shall continue in full force and effect.

5. **Miscellaneous.**

5.1 **Voluntary Agreement.** The parties have read this Amendment and the mutual releases contained in it, and on the advice of counsel they have freely and voluntarily entered into this Amendment.

5.2 **Attorney's Fees.** If either party commences an action against the other party arising out of or in connection with this Amendment, the prevailing party shall be entitled to recover from the non- prevailing party, reasonable attorney's fees and costs of suit.

5.3 **Successors.** This Amendment shall be binding on and inure to the benefit of the parties and their successors.

5.4 **Counterparts.** This Amendment may be signed in two or more counterparts. When at least one such counterpart has been signed by each party, this Amendment shall be deemed to have been fully executed, each counterpart shall be deemed to be an original, and all counterparts shall be deemed tobe one and the same agreement.

5.5 **Capitalized Terms.** Capitalized terms used in this Amendment and not otherwise definedherein shall have the same meaning ascribed to such terms in the Lease.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date firstwritten above.

LANDLORD:		**TENANT:**	
ARDENWOOD VENTURES I, LLC,		**PERSONALIS, INC.**,	
a Delaware limited liability company		a Delaware corporation	
By:	/s/ Mark S. Whiting	By:	/s/ Aaron Tachibana
Printed Name:	Mark S. Whiting	Printed Name:	Aaron Tachibana
Title:	Manager and sole member	Title:	CFO

Exhibit 10.18

PERSONALIS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Amended by the Board of Directors: February 17, 2022

Each member of the Board of Directors (the "***Board***") of Personalis, Inc. (the "***Company***") who is a non-employee director of the Company (each such member, a "***Non-Employee Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service.

The Director Compensation Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Commencing at the beginning of the first calendar quarter each year, each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears no later than 30 days following the end of each quarter in which the service occurred, prorated for any partial quarter of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Lead Independent Director (as applicable): $60,000 (in lieu of above)
   c. Chair of the Board (as applicable): $80,000 (in lieu of above)

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $10,000
   b. Member of the Compensation Committee: $7,500
   c. Member of the Nominating and Corporate Governance Committee: $5,000

3. Annual Committee Chair Service Retainer (in lieu of Committee Member Service Retainer):
   a. Chair of the Audit Committee: $20,000
   b. Chair of the Compensation Committee: $15,000
   c. Chair of the Nominating and Corporate Governance Committee: $10,000

Equity Compensation

Equity awards will be granted under the Company's 2019 Equity Incentive Plan, as amended from time to time, or any successor equity incentive plan (the "***Plan***"). All stock options granted under the Director Compensation Policy will be Nonstatutory Stock Options (as defined in the Plan), with a term of ten years from the date of grant (subject to earlier termination upon a termination of the Non-Employee Director's Continuous Service (as defined in the Plan)) and an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of a share of the Company's common stock on the date of grant.

(a) Automatic Equity Grants.

(i) Initial Grant for New Directors. Without any further action of the Board, each person who is elected or appointed for the first time to be a Non-Employee Director will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted: (x) a Nonstatutory Stock Option to purchase a number of shares of the Company's common stock (the "***Initial Option Grant***") with a value of $125,000 determined using Black-Scholes' valuation methodology based on the average closing price of the Company's common stock over the 90 calendar days prior to the grant date and with such number of shares rounded down to the nearest whole share and (y) a restricted stock unit ("***RSU***") award covering a number of shares of the Company's common stock (the "***Initial RSU Grant***" and, together with the Initial Option Grant, the "***Initial Grants***") with a value of $125,000 determined by dividing such dollar value by the average closing price of the Company's common stock over the 90 calendar days prior to the grant date and rounding down to the nearest whole share. Each Initial Grant will vest in a series of three successive equal annual installments over the three-year period measured from the date of grant, subject to the Non-Employee Director's Continuous Service through each applicable vesting date.

(ii) Annual Grant. Without any further action of the Board, at the close of business on the date of each annual meeting of the Company's stockholders (each, an "***Annual Meeting***"), each person who is then a Non-Employee Director will automatically be granted: (x) a Nonstatutory Stock Option to purchase a number of shares of the Company's common stock (the "***Annual Option Grant***") with a value of $82,500 determined using Black-Scholes' valuation methodology based on the average closing price of the Company's common stock over the 90 calendar days prior to the grant date and with such number of shares rounded down to the nearest whole share and (y) an RSU award covering a number of shares of Company's common stock (the "***Annual RSU Grant***" and, together with the Annual Option Grant, the "***Annual Grants***") with a value of $82,500 determined by dividing such dollar value by the average closing price of the Company's common stock over the 90 calendar days prior to the grant date and rounding down to the nearest whole share. Each Annual Grant will vest upon the earlier of the one (1) year anniversary of the grant date or the day prior to the Company's next Annual Meeting occurring after the grant date, subject to the Non-Employee Director's Continuous Service through the vesting date.

(b) Change in Control. Notwithstanding the foregoing vesting schedules, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a Change in Control (as defined in the Plan), the shares subject to his or her then-outstanding equity awards that were granted pursuant to the Director Compensation Policy will become fully vested immediately prior to the closing of such Change in Control.

(c) Remaining Terms. The remaining terms and conditions of each stock option or RSU award, including transferability, will be as set forth in the Company's standard Option or RSU award agreement, each in the form adopted from time to time by the Board, except that the post-termination exercise period for each stock option granted pursuant to the Director Compensation Policy shall equal the lesser of (i) 36 months from the date of termination of the Non-Employee Director's Continuous Service for any reason other than removal with cause by a vote of the stockholders in accordance with the Company's bylaws and (ii) the remaining period of the applicable stock option's ten-year term.

Expenses

The Company will reimburse Non-Employee Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Non-Employee Director timely submits to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Non-Employee Director Compensation Limit

Notwithstanding anything herein to the contrary, the cash compensation and equity compensation that each Non-Employee Director is entitled to receive under this Director Compensation Policy shall be subject to the limits set forth in Section 3(d) of the Plan.

PERSONALIS, INC.

FIRST AMENDED AND RESTATED EXECUTIVE SEVERANCE AGREEMENT

(JOHN WEST)

This First Amended and Restated Executive Severance Agreement (the "***Agreement***"), effective as of February 23, 2022 amends, supersedes and restates in its entirety that certain Executive Severance Agreement by and between John West ("***Executive"***) and Personalis, Inc. (the "***Company***") dated June 2, 2019. This Agreement is intended to provide Executive with certain benefits described herein upon the occurrence of specific events.

RECITALS

A. The Company's Board of Directors (the "***Board***") believes it is in the best interests of the Company and its shareholders to retain Executive and provide incentives to Executive to continue in the service of the Company.

B. The Board further believes that it is imperative to provide Executive with certain benefits upon termination of Executive's employment, which benefits are intended to provide Executive with financial security and sufficient income and encouragement to Executive to remain with the Company.

C. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Executive, to agree to the terms provided in this Agreement.

Now therefore, in consideration of the mutual promises, covenants and agreements contained herein, the parties hereto agree as follows:

1. At-Will Employment. Executive's employment is at-will, which means that the Company may terminate Executive's employment at any time, with or without Cause or advance notice. Similarly, Executive may resign Executive's employment at any time, with or without advance notice, and with or without Good Reason. Executive shall not receive any compensation of any kind, including, without limitation, equity award vesting acceleration and severance benefits, following Executive's last day of employment with the Company, except as expressly provided herein.

2. Benefits Upon Termination of Employment without Cause or with Good Reason. If Executive's employment is terminated without Cause (as defined below) (and other than as a result of Executive's death or disability), or Executive resigns for Good Reason (as defined below), provided such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h), such termination a "***Separation from Service***"), and provided further that Executive signs and allows to become effective a general release of all claims in favor of the Company in a form provided by the Company (the "***Release***"), within sixty (60) days after Executive's Separation from Service (the date that the Release becomes effective and may no longer be revoked by Executive is referred to as the ***"Release Date"***), then the Company shall provide Executive with the following severance benefits (the "***Separation Benefits***"):

(a) The Company shall pay Executive cash severance in an amount equal to twelve (12) months of Executive's then-current base salary, ignoring any decrease in base salary that forms the basis for Good Reason, less all applicable withholdings and deductions, paid on the Company's first regular payroll date following the Release Date.

(b) Should Executive timely elect to continue Executive's medical, dental and/or vision insurance benefits pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("***COBRA***") or any analogous provisions of applicable state law, the Company shall pay Executive's COBRA premiums for Executive and Executive's eligible dependents ("***COBRA Premiums***") for a period of twelve (12) months following Executive's Separation from Service (the "***Benefits Payment Period***") or, if earlier, the date upon which Executive obtains coverage under a medical plan by a subsequent employer. The Company's obligation to pay any COBRA Premiums will be subject to the then-current requirements of COBRA and any other laws affecting the payment of COBRA premiums by the Company. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA Premiums without potentially incurring financial costs or penalties under applicable law, the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether Executive elects health care continuation coverage (the "***Health Care Benefit Payment***"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of COBRA coverage), and shall be paid until the earlier of: (i) the date the Benefits Payment Period expires or (ii) the date upon which Executive obtains coverage under a medical plan by a subsequent employer.

(c) In addition to the Change in Control Accelerated Vesting (if applicable), as defined in that certain Employment Terms letter agreement between Executive and the Company dated June 2, 2019, as amended by that certain First Amendment to Employment Terms Agreement on May 6, 2020 (collectively, Executive's "***Employment Terms***"), in the case of a Separation from Service within twelve (12) months after the effective date of a Change in Control (as defined below), the Company shall accelerate the vesting of each of Executive's then-outstanding unvested equity compensation awards, or, in the case of any other Separation from Service, the Company shall accelerate the vesting of each of Executive's then-outstanding unvested equity compensation awards as to the number of then-unvested shares subject to each such award that would have become vested, in the ordinary course, within the first twenty-four (24) months following Executive's Separation from Service, in either case effective immediately prior to such Separation from Service.

3. Limitations and Conditions on Separation Benefits

(a) Release Prior to Payment of Benefits. Prior to the payment or provision of any of the Separation Benefits, Executive shall execute, and allow to become effective, the Release not later than sixty (60) days following Executive's Separation from Service. Such Release shall specifically relate to all of Executive's rights and claims in existence at the time of such execution and shall confirm Executive's continuing obligations to the Company (including but not limited to obligations under any confidentiality and/or non-solicitation agreement with the Company). No Separation Benefits will be paid prior to the Release Date.

(b) Income and Employment Taxes. Executive agrees that Executive shall be responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Company reasonably determines apply to any payment made hereunder, that Executive's receipt of any benefit hereunder is conditioned on Executive's satisfaction of any applicable withholding or similar obligations that apply to such benefit, and that any cash payment owed hereunder will be reduced to satisfy any such withholding or similar obligations that may apply.

(c) Compliance with Section 409A. It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that Separation Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from, or comply with, the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***") and Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9) (together, with any state law of similar effect, "***Section 409A***"). However, if the Company (or, if applicable, the successor entity thereto) determines that the Separation Benefits provided under this Agreement constitute "deferred compensation" under Section 409A and Executive is, on the date of his or her Separation from Service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "***Specified Employee***"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Separation Benefits described herein, as applicable, shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) business day after Executive's Separation from Service, (ii) the date of Executive's death, or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation (such earlier date, the "***Delayed Initial Payment Date***"). Upon the Delayed Initial Payment Date, the Company (or the successor entity thereto, as applicable) shall pay to Executive a lump sum amount equal to the applicable benefit that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefit had not been so delayed pursuant to this Section 3(c), and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. If the Separation Benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive has a Separation from Service, the Release will not be deemed effective any earlier than the Release Date. To the extent that any provision of this Agreement is ambiguous as to its exemption or compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. With respect to reimbursements or in-kind benefits provided to Executive hereunder (or otherwise) that are not exempt from Section 409A, the following rules shall apply: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during any one of Executive's taxable years shall not affect the expenses eligible for reimbursement, or in-kind benefit to be provided in any other taxable year, (ii) in the case of any reimbursements of eligible expenses, reimbursement shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense was incurred, and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

(d) **Related Matters.** Executive further acknowledges and agrees that as a condition to receipt of any Separation Benefits (i) Executive must comply with Executive's obligations under Executive's Employee Confidential Information and Invention Assignment Agreement; and (ii) resign from all Company and or affiliate positions, including membership on any Board (unless otherwise requested by the Company).

(e) **Successors**. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Executive's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

(f) **Notice**. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Executive shall be addressed to Executive at the home address which Executive most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Board Chair.

4. **Definitions**.

(a) **Cause**. For purposes of this Agreement, ***"Cause***", as determined by the Board acting in good faith and based on information then known to it, shall mean the occurrence of one or more of the following: (i) Executive's gross negligence or knowing and willful action which is or is likely to be materially injurious to the Company; (ii) any intentional act by Executive in connection with his responsibilities as an employee constituting fraud or a felony crime; (iii) Executive's consistent failure to report for work or perform his duties as directed by the Company's Board of Directors; (iv) persistent or repeated material breach of this Agreement or any agreement between Executive and the Company; (v) Executive becoming disqualified from holding office through his own act or omission; (vi) an unauthorized use or disclosure by the Executive of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company; or (vii) a material failure by the Executive to comply with the Company's written policies or rules which is or is likely to be materially injurious to the

Company; provided, however, that in any such event, there has been delivered to Executive a written demand for performance from the Board which describes the basis for the Board's belief that Executive has committed one of the acts set forth in clauses (i)-(vii) above and provides Executive with thirty (30) days to take corrective action (which may include any suspension period).

(b) **Change in Control**. For purposes of this Agreement, ***"Change in Control"*** means the consummation of a transaction or series of transactions that results in any of the following:

(i) a merger, consolidation or similar corporate transaction involving (directly or indirectly) the Company and, immediately following which the stockholders of the Company immediately prior thereto do not own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar corporate transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar corporate transaction; or

(ii) a sale or other disposition of all or substantially all of the consolidated assets of the Company that occurs over a period of not more than twelve (12) months.

However, a Change in Control will not include (1) any consolidation or merger effected exclusively to change the domicile of the Company, or (2) any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof. In addition, no transaction will be a Change in Control unless it is also "change in ownership of a corporation" or "change in ownership of a substantial portion of a corporation's assets" as defined under in Treasury Regulations Sections 1.409A-3(i)(5)(v) and (vii) without regard to any alternative definitions thereunder.

(c) **Good Reason.** For purposes of this Agreement, "***Good Reason***" for Executive's resignation of his or her employment will exist following the occurrence of any of the following without Executive's written consent: (i) a material reduction in Executive's base salary, which the parties agree is a reduction of at least ten percent (10%) of Executive's base salary (provided, however, that such reduction will not be considered Good Reason if made in connection with an across-the-board salary reduction affecting all members of management); (ii) a requirement that Executive report to a corporate officer rather than directly to the Board, or a material reduction in Executive's duties, responsibilities and/or authority, *provided*, *however*, that the acquisition of the Company in a Change in Control and subsequent conversion of the Company to a division or unit of the acquiring company will not by itself result in any such "material reduction"; (iii) a relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than fifty (50) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation; or (iv) a material breach by the Company of this Agreement. In order to resign for Good Reason, Executive must provide written notice to the Board within thirty (30) days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least thirty (30) days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than thirty (30) days after the expiration of the cure period or the date of notification to Executive that the Company will not so cure. Executive understands and agrees that the requirement for Executive's performance of services within twenty (20) miles of Palo Alto, California does not give rise to Good Reason.

5. Parachute Payments.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control from the Company or otherwise ("***Transaction Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to Executive, which of the following two alternative forms of payment would result in Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "***Full Payment***"), or (2) payment of only a part of the Transaction Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to Executive as determined in this paragraph (the "***Reduction Method***"). If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata (the "***Pro Rata Reduction Method***").

(b) Notwithstanding any provision of subsection (a) above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Transaction Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (i) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (ii) as a second priority, Transaction Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Transaction Payments that are not contingent on future events; and (iii) as a third priority, Transaction Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Transaction Payments that are not deferred compensation within the meaning of Section 409A.

(c) The professional firm engaged by the Company for general tax purposes or the Company's corporate law firm as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 5. If the professional firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such professional firm required to be made hereunder.

(d) The professional firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or Executive. If the professional firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the professional firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

6. Other Employment Terms and Conditions. The employment relationship between the parties shall be governed by the general employment policies and procedures of the Company, including those relating to the protection of confidential information and assignment of inventions; provided, however, that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or procedures, this Agreement shall control.

7. Dispute Resolution.

(a) Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16 ("***FAA***"), to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/), in San Jose, California. **Executive acknowledges that by agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.**

(b) All claims, disputes, or causes of action under this arbitration agreement, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration.

(c) This arbitration agreement shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, sexual assault disputes and sexual harassment disputes as defined in the FAA, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "***Excluded Claims***"). In the event Executive intends to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Executive will have the right to be represented by legal counsel at any arbitration proceeding.

(d) Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that Executive would be required to pay if the dispute were decided in a court of law. Nothing in this arbitration agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

8. Miscellaneous Provisions.

(a) No Duty to Mitigate. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Whole Agreement. No agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes any agreement (or portion thereof) concerning similar subject matter dated prior to the date of this Agreement, and by execution of this Agreement both parties agree that any such predecessor agreement (or portion thereof) shall be deemed null and void. For the avoidance of doubt, the parties agree that this Agreement does not supersede: (i) the provisions of Executive's Employment Terms that do not address termination or severance benefits, including without limitation the provision pertaining to Change in Control Accelerated Vesting, or (ii) Executive's Employee Confidential Information and Invention Assignment Agreement with the Company.

(d) **Choice of Law**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions, and the parties hereto submit to the exclusive jurisdiction of the state and federal courts of the State of California.

(e) **Severability**. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefor to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

(f) **Legal Fees and Expenses**. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with the execution of this Agreement.

(g) **No Assignment of Benefits**. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 8(g) shall be void.

(h) **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[REMAINDER OF THIS PAGE LEFT BLANK – SIGNATURE PAGE TO FOLLOW]

In Witness Whereof, the parties have executed this Agreement as of the date written below.

/s/ John West
John West

Address:

Date: February 23, 2022

PERSONALIS, INC.

/s/ Carol Tillis

By: Carol Tillis

Title: Vice President, Finance and Administration

Date: February 23, 2022

PERSONALIS, INC.

FIRST AMENDED AND RESTATED EXECUTIVE SEVERANCE AGREEMENT

(SENIOR VICE PRESIDENT, VICE PRESIDENT, OR EQUIVALENT INDIVIDUAL CONTRIBUTOR)

This First Amended and Restated Executive Severance Agreement (the "***Agreement***"), effective as of February 23, 2022, amends, supersedes and restates in its entirety that certain Executive Severance Agreement by and between Dr. Richard Chen ("***Executive***") and Personalis, Inc. (the "***Company***") dated June 2, 2019. This Agreement is intended to provide Executive with certain benefits described herein upon the occurrence of specific events.

RECITALS

A. The Company's Board of Directors (the "***Board***") believes it is in the best interests of the Company and its shareholders to retain Executive and provide incentives to Executive to continue in the service of the Company.

B. The Board further believes that it is imperative to provide Executive with certain benefits upon termination of Executive's employment, which benefits are intended to provide Executive with financial security and sufficient income and encouragement to Executive to remain with the Company.

C. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Executive, to agree to the terms provided in this Agreement.

Now therefore, in consideration of the mutual promises, covenants and agreements contained herein, the parties hereto agree as follows:

1. At-Will Employment. Executive's employment is at-will, which means that the Company may terminate Executive's employment at any time, with or without Cause or advance notice. Similarly, Executive may resign Executive's employment at any time, with or without advance notice, and with or without Good Reason. Executive shall not receive any compensation of any kind, including, without limitation, equity award vesting acceleration and severance benefits, following Executive's last day of employment with the Company, except as expressly provided herein.

2. Benefits Upon Termination of Employment.

(a) Termination in Connection with or Following a Change in Control. If Executive's employment is terminated without Cause (as defined below) (and other than as a result of Executive's death or disability), or Executive resigns for Good Reason (as defined below), in either case within twelve (12) months after the effective date of a Change in Control (as defined below), and provided such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h), such termination a "***Separation from Service***"), and provided further that Executive signs and allows to become effective a general release of all claims in favor of the Company in a form provided by the Company (the "***Release***"), within sixty (60) days after Executive's Separation from Service (the date that the Release becomes effective and may no longer be revoked by Executive is referred to as the ***"Release Date"***), then the Company shall provide Executive with the following severance benefits (the "***Change in Control Separation Benefits***"):

(i) The Company shall pay Executive cash severance in an amount equal to nine (9) months of Executive's then-current base salary, ignoring any decrease in base salary that forms the basis for Good Reason, less all applicable withholdings and deductions, paid on the Company's first regular payroll date following the Release Date.

(ii) Should Executive timely elect to continue Executive's medical, dental and/or vision insurance benefits pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("***COBRA***") or any analogous provisions of applicable state law, the Company shall pay Executive's COBRA premiums for Executive and Executive's eligible dependents ("***COBRA Premiums***") for a period of nine (9) months following Executive's Separation from Service (the "***Change in Control Benefits Payment Period***") or, if earlier, the date upon which Executive obtains coverage under a medical plan by a subsequent employer. The Company's obligation to pay any COBRA Premiums will be subject to the then-current requirements of COBRA and any other laws affecting the payment of COBRA premiums by the Company. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA Premiums without potentially incurring financial costs or penalties under applicable law, the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether Executive elects health care continuation coverage (the "***Health Care Benefit Payment***"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of COBRA coverage), and shall be paid until the earlier of: (i) the date the Change in Control Benefits Payment Period expires or (ii) the date upon which Executive obtains coverage under a medical plan by a subsequent employer.

(iii) The Company shall accelerate the vesting of each of Executive's then-outstanding unvested equity compensation awards, effective immediately prior to such Separation from Service.

(b) **Termination Not in Connection with or Following a Change in Control**. If Executive's employment is terminated without Cause (and other than as a result of Executive's death or disability), or Executive resigns for Good Reason, in either case at any time that is not within twelve (12) months after a Change in Control, and provided such termination constitutes a Separation from Service, and provided Executive signs and allows to become effective the Release within sixty (60) days after Executive's Separation from Service, then the Company shall provide Executive with the following severance benefits (collectively with the Change in Control Separation Benefits, the "***Separation Benefits***"):

(i) The Company shall pay Executive cash severance in an amount equal to six (6) months of Executive's then current base salary, less all applicable withholdings and deductions, paid in a lump sum on the Company's first regular payroll date after the Release Date.

(ii) Should Executive timely elect to continue Executive's medical, dental and/or vision insurance benefits pursuant to COBRA, the Company shall pay the COBRA Premiums for a period of six (6) months following the effective date of Executive's Separation from Service (the "***Benefits Payment Period***") or, if earlier, the date upon which Executive obtains coverage under a medical plan by a subsequent employer. The Company's obligation to pay any COBRA Premiums will be subject to the then-current requirements of COBRA and any other laws affecting the payment of COBRA premiums by the Company. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot provide the COBRA Premiums without potentially incurring financial costs or penalties under applicable law, the Company shall in lieu thereof pay Executive the Health Care Benefit Payment in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer, which shall be paid until the earlier of: (i) the date the Benefits Payment Period expires or (ii) the date upon which Executive obtains coverage under a medical plan by a subsequent employer.

3. Limitations and Conditions on Separation Benefits

(a) **Release Prior to Payment of Benefits**. Prior to the payment or provision of any of the Separation Benefits, Executive shall execute, and allow to become effective, the Release not later than sixty (60) days following Executive's Separation from Service. Such Release shall specifically relate to all of Executive's rights and claims in existence at the time of such execution and shall confirm Executive's continuing obligations to the Company (including but not limited to obligations under any confidentiality and/or non-solicitation agreement with the Company). No Separation Benefits will be paid prior to the Release Date.

(b) **Income and Employment Taxes**. Executive agrees that Executive shall be responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Company reasonably determines apply to any payment made hereunder, that Executive's receipt of any benefit hereunder is conditioned on Executive's satisfaction of any applicable withholding or similar obligations that apply to such benefit, and that any cash payment owed hereunder will be reduced to satisfy any such withholding or similar obligations that may apply.

(c) **Compliance with Section 409A**. It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that Separation Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from, or comply with, the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***") and Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9) (together, with any state law of similar effect, "***Section 409A***"). However, if the Company (or, if applicable, the successor entity thereto) determines that the Separation Benefits provided under this Agreement constitute "deferred compensation" under Section 409A and Executive is, on the date of his or her Separation from Service, a "specified employee" of the

Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "***Specified Employee***"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Separation Benefits described herein, as applicable, shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) business day after Executive's Separation from Service, (ii) the date of Executive's death, or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation (such earlier date, the "***Delayed Initial Payment Date***"). Upon the Delayed Initial Payment Date, the Company (or the successor entity thereto, as applicable) shall pay to Executive a lump sum amount equal to the applicable benefit that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefit had not been so delayed pursuant to this Section 3(c), and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. If the Separation Benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive has a Separation from Service, the Release will not be deemed effective any earlier than the Release Date. To the extent that any provision of this Agreement is ambiguous as to its exemption or compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. With respect to reimbursements or in-kind benefits provided to Executive hereunder (or otherwise) that are not exempt from Section 409A, the following rules shall apply: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during any one of Executive's taxable years shall not affect the expenses eligible for reimbursement, or in-kind benefit to be provided in any other taxable year, (ii) in the case of any reimbursements of eligible expenses, reimbursement shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense was incurred, and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

(d) **Related Matters.** Executive further acknowledges and agrees that as a condition to receipt of any Separation Benefits (i) Executive must comply with Executive's obligations under Executive's Employee Confidential Information and Invention Assignment Agreement; and (ii) resign from all Company and or affiliate positions, including membership on any Board (unless otherwise requested by the Company).

(e) **Successors**. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Executive's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

4.

(f) **Notice**. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Executive shall be addressed to Executive at the home address which Executive most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Chief Executive Officer.

4. **Definitions**.

(a) **Cause**. For purposes of this Agreement, ***"Cause***", as determined by the Board acting in good faith and based on information then known to it, shall mean the occurrence of one or more of the following: (i) Executive's gross negligence or knowing and willful action which is or is likely to be materially injurious to the Company; (ii) any intentional act by Executive in connection with his responsibilities as an employee constituting fraud or a felony crime; (iii) Executive's consistent failure to report for work or perform his duties as directed by the Company's Board of Directors; (iv) persistent or repeated material breach of this Agreement or any agreement between Executive and the Company; (v) Executive becoming disqualified from holding office through his own act or omission; (vi) an unauthorized use or disclosure by the Executive of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company; or (vii) a material failure by the Executive to comply with the Company's written policies or rules which is or is likely to be materially injurious to the Company.

(b) **Change in Control**. For purposes of this Agreement, ***"Change in Control"*** means the consummation of a transaction or series of transactions that results in any of the following:

(i) a merger, consolidation or similar corporate transaction involving (directly or indirectly) the Company and, immediately following which the stockholders of the Company immediately prior thereto do not own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar corporate transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar corporate transaction; or

(ii) a sale or other disposition of all or substantially all of the consolidated assets of the Company that occurs over a period of not more than twelve (12) months.

However, a Change in Control will not include (1) any consolidation or merger effected exclusively to change the domicile of the Company, or (2) any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof. In addition, no transaction will be a Change in Control unless it is also "change in ownership of a corporation" or "change in ownership of a substantial portion of a corporation's assets" as defined under in Treasury Regulations Sections 1.409A-3(i)(5)(v) and (vii) without regard to any alternative definitions thereunder.

5.

(c) Good Reason. For purposes of this Agreement, "***Good Reason***" for Executive's resignation of his or her employment will exist following the occurrence of any of the following without Executive's written consent: (i) a material reduction in Executive's base salary, which the parties agree is a reduction of at least ten percent (10%) of Executive's base salary (provided, however, that such reduction will not be considered Good Reason if made in connection with an across-the-board salary reduction affecting all members of management); (ii) a material reduction in Executive's duties, responsibilities and/or authority, *provided, however*, that a change in job position (including a change in title) after or in connection with a Change in Control shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from Executive's prior duties; (iii) a relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than fifty (50) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation; or (iv) a material breach by the Company of this Agreement. In order to resign for Good Reason, Executive must provide written notice to the Board within thirty (30) days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least thirty (30) days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than thirty (30) days after the expiration of the cure period or the date of notification to Executive that the Company will not so cure. Executive understands and agrees that the requirement for Executive's performance of services within twenty (20) miles of Palo Alto, California does not give rise to Good Reason.

5. Parachute Payments.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control from the Company or otherwise ("***Transaction Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to Executive, which of the following two alternative forms of payment would result in Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "***Full Payment***"), or (2) payment of only a part of the Transaction Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to Executive as determined in this paragraph (the "***Reduction Method***"). If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata (the "***Pro Rata Reduction Method***").

(b) Notwithstanding any provision of subsection (a) above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Transaction Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (i) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (ii) as a second priority, Transaction Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Transaction Payments that are not contingent on future events; and (iii) as a third priority, Transaction Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Transaction Payments that are not deferred compensation within the meaning of Section 409A.

(c) The professional firm engaged by the Company for general tax purposes or the Company’s corporate law firm as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 5. If the professional firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such professional firm required to be made hereunder.

(d) The professional firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive’s right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or Executive. If the professional firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the professional firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

6. Other Employment Terms and Conditions. The employment relationship between the parties shall be governed by the general employment policies and procedures of the Company, including those relating to the protection of confidential information and assignment of inventions; provided, however, that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or procedures, this Agreement shall control.

7. Dispute Resolution.

(a) Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive’s employment with the Company, or the termination of Executive’s employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16 (“***FAA***”), to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/), in San Jose, California. **Executive acknowledges that by agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.**

(b) All claims, disputes, or causes of action under this arbitration agreement, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration.

(c) This arbitration agreement shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, sexual assault disputes and sexual harassment disputes as defined in the FAA, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "***Excluded Claims***"). In the event Executive intends to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Executive will have the right to be represented by legal counsel at any arbitration proceeding.

(d) Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that Executive would be required to pay if the dispute were decided in a court of law. Nothing in this arbitration agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

8. Miscellaneous Provisions.

8.

(a) **No Duty to Mitigate**. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(b) **Waiver**. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Whole Agreement**. No agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes any agreement (or portion thereof) concerning similar subject matter dated prior to the date of this Agreement, and by execution of this Agreement both parties agree that any such predecessor agreement (or portion thereof) shall be deemed null and void. For the avoidance of doubt, the parties agree that this Agreement does not supersede the provisions of Executive's Offer Letter that do not address termination or severance benefits or Executive's Employee Confidential Information and Invention Assignment Agreement with the Company.

(d) **Choice of Law**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions, and the parties hereto submit to the exclusive jurisdiction of the state and federal courts of the State of California.

(e) **Severability**. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefor to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

(f) **Legal Fees and Expenses**. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with the execution of this Agreement.

(g) **No Assignment of Benefits**. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 8(g) shall be void.

(h) **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[REMAINDER OF THIS PAGE LEFT BLANK – SIGNATURE PAGE TO FOLLOW]

In Witness Whereof, the parties have executed this Agreement as of the date written below.

/s/ Richard Chen
Dr. Richard Chen

Address:

Date: February 23, 2022

PERSONALIS, INC.

/s/ Carol Tillis

By: Carol Tillis

Title: Vice President, Finance and Administration

Date: February 23, 2022

PERSONALIS, INC.

FIRST AMENDED AND RESTATED EXECUTIVE SEVERANCE AGREEMENT

(SENIOR VICE PRESIDENT, VICE PRESIDENT, OR EQUIVALENT INDIVIDUAL CONTRIBUTOR)

This First Amended and Restated Executive Severance Agreement (the "***Agreement***"), effective as of February 23, 2022, amends, supersedes and restates in its entirety that certain Executive Severance Agreement by and between Aaron Tachibana ("***Executive***") and Personalis, Inc. (the "***Company***") dated June 2, 2019. This Agreement is intended to provide Executive with certain benefits described herein upon the occurrence of specific events.

RECITALS

A. The Company's Board of Directors (the "***Board***") believes it is in the best interests of the Company and its shareholders to retain Executive and provide incentives to Executive to continue in the service of the Company.

B. The Board further believes that it is imperative to provide Executive with certain benefits upon termination of Executive's employment, which benefits are intended to provide Executive with financial security and sufficient income and encouragement to Executive to remain with the Company.

C. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Executive, to agree to the terms provided in this Agreement.

Now therefore, in consideration of the mutual promises, covenants and agreements contained herein, the parties hereto agree as follows:

1. At-Will Employment. Executive's employment is at-will, which means that the Company may terminate Executive's employment at any time, with or without Cause or advance notice. Similarly, Executive may resign Executive's employment at any time, with or without advance notice, and with or without Good Reason. Executive shall not receive any compensation of any kind, including, without limitation, equity award vesting acceleration and severance benefits, following Executive's last day of employment with the Company, except as expressly provided herein.

2. Benefits Upon Termination of Employment.

(a) Termination in Connection with or Following a Change in Control. If Executive's employment is terminated without Cause (as defined below) (and other than as a result of Executive's death or disability), or Executive resigns for Good Reason (as defined below), in either case within twelve (12) months after the effective date of a Change in Control (as defined below), and provided such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h), such termination a "***Separation from Service***"), and provided further that Executive signs and allows to become effective a general release of all claims in favor of the Company in a form provided by the Company (the "***Release***"), within sixty (60) days after Executive's Separation from Service (the date that the Release becomes effective and may no longer be revoked by Executive is referred to as the ***"Release Date"***), then the Company shall provide Executive with the following severance benefits (the "***Change in Control Separation Benefits***"):

(i) The Company shall pay Executive cash severance in an amount equal to twelve (12) months of Executive's then-current base salary, ignoring any decrease in base salary that forms the basis for Good Reason, less all applicable withholdings and deductions, paid on the Company's first regular payroll date following the Release Date.

(ii) Should Executive timely elect to continue Executive's medical, dental and/or vision insurance benefits pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("***COBRA***") or any analogous provisions of applicable state law, the Company shall pay Executive's COBRA premiums for Executive and Executive's eligible dependents ("***COBRA Premiums***") for a period of twelve (12) months following Executive's Separation from Service (the "***Change in Control Benefits Payment Period***") or, if earlier, the date upon which Executive obtains coverage under a medical plan by a subsequent employer. The Company's obligation to pay any COBRA Premiums will be subject to the then-current requirements of COBRA and any other laws affecting the payment of COBRA premiums by the Company. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA Premiums without potentially incurring financial costs or penalties under applicable law, the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether Executive elects health care continuation coverage (the "***Health Care Benefit Payment***"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of COBRA coverage), and shall be paid until the earlier of: (i) the date the Change in Control Benefits Payment Period expires or (ii) the date upon which Executive obtains coverage under a medical plan by a subsequent employer.

(iii) The Company shall accelerate the vesting of each of Executive's then-outstanding unvested equity compensation awards, effective immediately prior to such Separation from Service.

(b) **Termination Not in Connection with or Following a Change in Control**. If Executive's employment is terminated without Cause (and other than as a result of Executive's death or disability), or Executive resigns for Good Reason, in either case at any time that is not within twelve (12) months after a Change in Control, and provided such termination constitutes a Separation from Service, and provided Executive signs and allows to become effective the Release within sixty (60) days after Executive's Separation from Service, then the Company shall provide Executive with the following severance benefits (collectively with the Change in Control Separation Benefits, the "***Separation Benefits***"):

(i) The Company shall pay Executive cash severance in an amount equal to six (6) months of Executive's then current base salary, less all applicable withholdings and deductions, paid in a lump sum on the Company's first regular payroll date after the Release Date.

(ii) Should Executive timely elect to continue Executive's medical, dental and/or vision insurance benefits pursuant to COBRA, the Company shall pay the COBRA Premiums for a period of six (6) months following the effective date of Executive's Separation from Service (the "***Benefits Payment Period***") or, if earlier, the date upon which Executive obtains coverage under a medical plan by a subsequent employer. The Company's obligation to pay any COBRA Premiums will be subject to the then-current requirements of COBRA and any other laws affecting the payment of COBRA premiums by the Company. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot provide the COBRA Premiums without potentially incurring financial costs or penalties under applicable law, the Company shall in lieu thereof pay Executive the Health Care Benefit Payment in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer, which shall be paid until the earlier of: (i) the date the Benefits Payment Period expires or (ii) the date upon which Executive obtains coverage under a medical plan by a subsequent employer.

3. Limitations and Conditions on Separation Benefits

(a) Release Prior to Payment of Benefits. Prior to the payment or provision of any of the Separation Benefits, Executive shall execute, and allow to become effective, the Release not later than sixty (60) days following Executive's Separation from Service. Such Release shall specifically relate to all of Executive's rights and claims in existence at the time of such execution and shall confirm Executive's continuing obligations to the Company (including but not limited to obligations under any confidentiality and/or non-solicitation agreement with the Company). No Separation Benefits will be paid prior to the Release Date.

(b) Income and Employment Taxes. Executive agrees that Executive shall be responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Company reasonably determines apply to any payment made hereunder, that Executive's receipt of any benefit hereunder is conditioned on Executive's satisfaction of any applicable withholding or similar obligations that apply to such benefit, and that any cash payment owed hereunder will be reduced to satisfy any such withholding or similar obligations that may apply.

(c) Compliance with Section 409A. It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that Separation Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from, or comply with, the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***") and Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9) (together, with any state law of similar effect, "***Section 409A***"). However, if the Company (or, if applicable, the successor entity thereto) determines that the Separation Benefits provided under this Agreement constitute "deferred compensation" under Section 409A and Executive is, on the date of his or her Separation from Service, a "specified employee" of the

Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "***Specified Employee***"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Separation Benefits described herein, as applicable, shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) business day after Executive's Separation from Service, (ii) the date of Executive's death, or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation (such earlier date, the "***Delayed Initial Payment Date***"). Upon the Delayed Initial Payment Date, the Company (or the successor entity thereto, as applicable) shall pay to Executive a lump sum amount equal to the applicable benefit that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefit had not been so delayed pursuant to this Section 3(c), and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. If the Separation Benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive has a Separation from Service, the Release will not be deemed effective any earlier than the Release Date. To the extent that any provision of this Agreement is ambiguous as to its exemption or compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. With respect to reimbursements or in-kind benefits provided to Executive hereunder (or otherwise) that are not exempt from Section 409A, the following rules shall apply: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during any one of Executive's taxable years shall not affect the expenses eligible for reimbursement, or in-kind benefit to be provided in any other taxable year, (ii) in the case of any reimbursements of eligible expenses, reimbursement shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense was incurred, and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

(d) **Related Matters.** Executive further acknowledges and agrees that as a condition to receipt of any Separation Benefits (i) Executive must comply with Executive's obligations under Executive's Employee Confidential Information and Invention Assignment Agreement; and (ii) resign from all Company and or affiliate positions, including membership on any Board (unless otherwise requested by the Company).

(e) **Successors**. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Executive's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

(f) **Notice**. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Executive shall be addressed to Executive at the home address which Executive most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Chief Executive Officer.

4. **Definitions**.

(a) **Cause**. For purposes of this Agreement, ***"Cause"***, as determined by the Board acting in good faith and based on information then known to it, shall mean the occurrence of one or more of the following: (i) Executive's gross negligence or knowing and willful action which is or is likely to be materially injurious to the Company; (ii) any intentional act by Executive in connection with his responsibilities as an employee constituting fraud or a felony crime; (iii) Executive's consistent failure to report for work or perform his duties as directed by the Company's Board of Directors; (iv) persistent or repeated material breach of this Agreement or any agreement between Executive and the Company; (v) Executive becoming disqualified from holding office through his own act or omission; (vi) an unauthorized use or disclosure by the Executive of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company; or (vii) a material failure by the Executive to comply with the Company's written policies or rules which is or is likely to be materially injurious to the Company.

(b) **Change in Control**. For purposes of this Agreement, ***"Change in Control"*** means the consummation of a transaction or series of transactions that results in any of the following:

(i) a merger, consolidation or similar corporate transaction involving (directly or indirectly) the Company and, immediately following which the stockholders of the Company immediately prior thereto do not own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar corporate transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar corporate transaction; or

(ii) a sale or other disposition of all or substantially all of the consolidated assets of the Company that occurs over a period of not more than twelve (12) months.

However, a Change in Control will not include (1) any consolidation or merger effected exclusively to change the domicile of the Company, or (2) any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof. In addition, no transaction will be a Change in Control unless it is also "change in ownership of a corporation" or "change in ownership of a substantial portion of a corporation's assets" as defined under in Treasury Regulations Sections 1.409A-3(i)(5)(v) and (vii) without regard to any alternative definitions thereunder.

(c) **Good Reason.** For purposes of this Agreement, "***Good Reason***" for Executive's resignation of his or her employment will exist following the occurrence of any of the following without Executive's written consent: (i) a material reduction in Executive's base salary, which the parties agree is a reduction of at least ten percent (10%) of Executive's base salary (provided, however, that such reduction will not be considered Good Reason if made in connection with an across-the-board salary reduction affecting all members of management); (ii) a material reduction in Executive's duties, responsibilities and/or authority, *provided, however*, that a change in job position (including a change in title) after or in connection with a Change in Control shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from Executive's prior duties; (iii) a relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than fifty (50) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation; or (iv) a material breach by the Company of this Agreement. In order to resign for Good Reason, Executive must provide written notice to the Board within thirty (30) days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least thirty (30) days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than thirty (30) days after the expiration of the cure period or the date of notification to Executive that the Company will not so cure. Executive understands and agrees that the requirement for Executive's performance of services within twenty (20) miles of Palo Alto, California does not give rise to Good Reason.

5. **Parachute Payments**.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control from the Company or otherwise ("***Transaction Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to Executive, which of the following two alternative forms of payment would result in Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "***Full Payment***"), or (2) payment of only a part of the Transaction Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to Executive as determined in this paragraph (the "***Reduction Method***"). If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata (the "***Pro Rata Reduction Method***").

(b) Notwithstanding any provision of subsection (a) above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Transaction Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (i) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (ii) as a second priority, Transaction Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Transaction Payments that are not contingent on future events; and (iii) as a third priority, Transaction Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Transaction Payments that are not deferred compensation within the meaning of Section 409A.

(c) The professional firm engaged by the Company for general tax purposes or the Company's corporate law firm as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 5. If the professional firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such professional firm required to be made hereunder.

(d) The professional firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or Executive. If the professional firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the professional firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

6. Other Employment Terms and Conditions. The employment relationship between the parties shall be governed by the general employment policies and procedures of the Company, including those relating to the protection of confidential information and assignment of inventions; provided, however, that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or procedures, this Agreement shall control.

7. Dispute Resolution.

(a) Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16 ("***FAA***"), to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/), in San Jose, California. **Executive acknowledges that by agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.**

(b) All claims, disputes, or causes of action under this arbitration agreement, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration.

(c) This arbitration agreement shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, sexual assault disputes and sexual harassment disputes as defined in the FAA, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "***Excluded Claims***"). In the event Executive intends to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Executive will have the right to be represented by legal counsel at any arbitration proceeding.

(d) Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that Executive would be required to pay if the dispute were decided in a court of law. Nothing in this arbitration agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

8. Miscellaneous Provisions.

(a) **No Duty to Mitigate**. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(b) **Waiver**. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Whole Agreement**. No agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes any agreement (or portion thereof) concerning similar subject matter dated prior to the date of this Agreement, and by execution of this Agreement both parties agree that any such predecessor agreement (or portion thereof) shall be deemed null and void. For the avoidance of doubt, the parties agree that this Agreement does not supersede the provisions of Executive's Offer Letter that do not address termination or severance benefits or Executive's Employee Confidential Information and Invention Assignment Agreement with the Company.

(d) **Choice of Law**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions, and the parties hereto submit to the exclusive jurisdiction of the state and federal courts of the State of California.

(e) **Severability**. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefor to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

(f) **Legal Fees and Expenses**. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with the execution of this Agreement.

(g) **No Assignment of Benefits**. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 8(g) shall be void.

9.

(h) **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[REMAINDER OF THIS PAGE LEFT BLANK – SIGNATURE PAGE TO FOLLOW]

In Witness Whereof, the parties have executed this Agreement as of the date written below.

/s/ Aaron Tachibana
Aaron Tachibana

Address:

Date: February 23, 2022

PERSONALIS, INC.

/s/ Carol Tillis

By: Carol Tillis

Title: Vice President, Finance and Administration

Date: February 23, 2022

Exhibit 21.1

SUBSIDIARIES OF PERSONALIS, INC.

Name of Subsidiary	Jurisdiction of Incorporation
Personalis (UK) Ltd.	United Kingdom
Shanghai Personalis Biotechnology Co., Ltd.	China

Exhibit 23.1

CONSENT OF DELOITTE & TOUCHE LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-239649 and 333-251824 on Form S-3 and Registration Statement Nos. 333-232233, 333-237386, 333-238080, and 333-253528 on Form S-8 of our reports dated February 24, 2022, relating to the consolidated financial statements of Personalis, Inc. and subsidiaries (the “Company”), and the effectiveness of the Company’s internal control over financial reporting, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
February 24, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John West, certify that:

1. I have reviewed this Annual Report on Form 10-K of Personalis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2022

By: /s/ John West
John West
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL 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

I, Aaron Tachibana, certify that:

1. I have reviewed this Annual Report on Form 10-K of Personalis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2022

By: /s/ Aaron Tachibana
Aaron Tachibana
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Personalis, Inc. (the “Company”) on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2022

By: /s/ John West
John West
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Personalis, Inc. (the “Company”) on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2022

By: /s/ Aaron Tachibana
Aaron Tachibana
Chief Financial Officer
(Principal Financial Officer)

Exhibit 99.1

CONSENT OF DIRECTOR NOMINEE

I hereby consent to being named as a person who will be appointed to the Board of Directors of Personalis, Inc., a Delaware corporation (the "Company"), and to all other references to me, in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 to be filed with the U.S. Securities and Exchange Commission on February 24, 2022 on Form 10-K (the "Annual Report"). I also consent to the filing of this consent as an exhibit to the Annual Report.

Dated: February 24, 2022

/s/ Olivia Bloom

OLIVIA BLOOM