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, 2019

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 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 28, 2019, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $513,174,177 based on the closing price of the shares of common stock on the Nasdaq Global Market. Excludes an aggregate of 12,220,162 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 March 20, 2020 was 31,474,193.

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 2020 annual meeting of stockholders (the "2020 Proxy Statement").

Personalis, Inc.

Form 10-K
For the Year Ended December 31, 2019
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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;
- 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 expectation regarding the time during which we will be an emerging growth company under the JOBS Act.

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

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

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

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

PART I

Item 1. Business.

Overview

We are a growing cancer genomics company transforming the development of next-generation therapies by providing more comprehensive molecular data about each patient's cancer and immune response. We designed our NeXT Platform to adapt to the complex and evolving understanding of cancer, providing our biopharmaceutical customers with information on all of the approximately 20,000 human genes, together with the immune system, in contrast to many cancer panels that cover roughly 50 to 500 genes. In parallel with the development of our platform technology, we have also provided population 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.

We are also developing a complementary liquid biopsy assay that analyzes all of the approximately 20,000 human genes versus the more narrowly focused liquid biopsy assays that are currently available. By combining technological innovation, operational scale, and regulatory differentiation, our NeXT Platform is designed to help our customers obtain new insights into the mechanisms of response and resistance to therapy as well as new potential therapeutic targets. Our platform enhances the ability of biopharmaceutical companies to unlock the potential of conducting translational research in the clinic rather than with pre-clinical animal models or cancer cell lines. We also announced in January 2020 a diagnostic based on our NeXT Platform that we envision being used initially by both leading clinical cancer centers as well as biopharmaceutical companies.

Our headquarters – housing our CLIA-certified, 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 biopharmaceutical companies (including large pharmaceutical 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. These opportunities represent a significant end market that is much larger than our initial clinical-trial focused market.

The information we generate is important to our customers developing three major classes of next-generation therapeutics: immunotherapies, targeted therapies, and personalized cancer therapies.

- **Immunotherapies:** Over the past decade, a number of drugs have emerged based on the discovery that the immune system plays a key role in addressing cancer. Checkpoint inhibitors, a specific type of immunotherapy, has generated substantial increases in worldwide sales over the past decade. The commercial success of these drugs has shown the potential of immunotherapy; however, the 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, we believe it will enable 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. These drugs are not designed to influence the immune system directly but the success of immunotherapies has brought acknowledgment that the immune system has a significant effect on their efficacy. 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 which of these therapies a patient may respond to. We believe that more comprehensive coverage of all of the approximately 20,000 genes positions us competitively against existing cancer panels that cover roughly 50 to 500 genes. We are positioning our company to be a leading provider of the complex information that we believe will continue to inform the development of targeted cancer therapies.

- **Personalized Cancer Therapies:** Many biopharmaceutical companies are pursuing personalized cancer therapies, which are designed and manufactured, individually, for each patient based on genomic alterations in a given patient's tumor. While there are many potential approaches to developing these therapies, including neoantigen-based vaccines and T-cell therapies, all of them can potentially benefit from the data and analytics that our platform can generate about a patient's tumor. Many of our customers have leveraged our U.S. Food and Drug Administration (the "FDA") Device Master File as a component of their investigational new drug ("IND") filings with the FDA. We anticipate that if drugs are approved

that used our platform in the clinical trials forming the basis for approval, we may be able to derive revenue in connection with the sale of these drugs. We believe we are working with the majority of companies developing neoantigen-targeted personalized cancer therapies.

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 clinical utility for our platform as a diagnostic for advanced cancer therapies. Separately, we are also acquiring samples and are building a database which will hold value for our biopharmaceutical customers and may ultimately allow us to discover new mechanisms of cancer treatment.

Financial Highlights

Our revenues have grown rapidly as our penetration of clinical trials in advanced oncology therapeutics and our relationship with the VA MVP has expanded, consistent with our reputation as a leader in the field. We generated revenues of $9.4 million, $37.8 million, and $65.2 million for the years ended December 31, 2017, 2018, and 2019, respectively. We also incurred net losses of $23.6 million, $19.9 million, and $25.1 million for the years ended December 31, 2017, 2018, and 2019, respectively.

As of December 31, 2019, we had $128.3 million of cash and cash equivalents and short-term investments, an increase of $108.5 million from December 31, 2018. Our revenues are primarily generated through sales of our services to the VA MVP and biopharmaceutical companies. Unlike diagnostic or therapeutic companies, we have not sought reimbursement through traditional healthcare payors. We raised $144.0 million in our June 2019 initial public offering, net of underwriter commissions, and prior to that had raised $89.6 million in preferred stock equity financing to date.

Our Products and Services

Our genomic sequencing and analytics solutions are focused on the following customer applications: Oncology research and immuno-oncology, oncology diagnostics, and whole genome sequencing. We have one reportable segment from the sale of sequencing and data analysis services and substantially all of our revenues to date have been derived from sales in the United States.

Oncology Research and Immuno-oncology

We work closely with biopharmaceutical companies who are advancing new therapies in three major areas: immunotherapies, targeted therapies, and personalized cancer therapies. We have a critical role in generating new data and biological insight from patients in those clinical trials.

NeXT Platform

Our NeXT Platform is a high-accuracy, clinical-grade, next-generation sequencing and analysis platform that enables two services for our customers: ImmunoID NeXT Tumor Biopsy and NeXT Liquid Biopsy (in development).

Our NeXT Platform is designed to provide comprehensive analysis of both a tumor and its immune microenvironment, from a single limited tissue sample. Our platform covers the deoxyribonucleic acid (“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. Revenues from early customer pilots of NeXT Tumor Biopsy were recognized in Q4 2019.

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, which we plan to launch in 2020, will target approximately 20,000 genes, enabling 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 (“RWD”) such as electronic health records to generate real-world evidence (“RWE”) 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

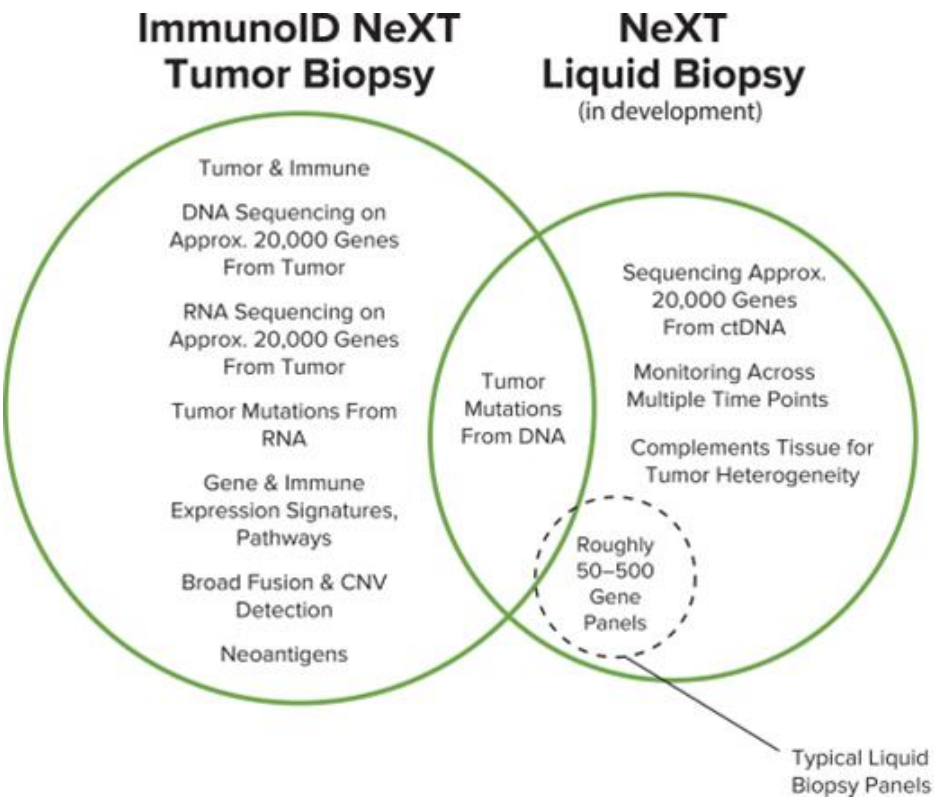
We have also shown that our NeXT Platform technology can analyze cell-free DNA (“cfDNA”) obtained from blood plasma, also known as a liquid biopsy. As with a tissue biopsy, we plan to analyze all of the approximately 20,000 human genes in each plasma sample, in contrast to currently marketed liquid biopsy panels. We expect this cfDNA to 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 plan to launch 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.

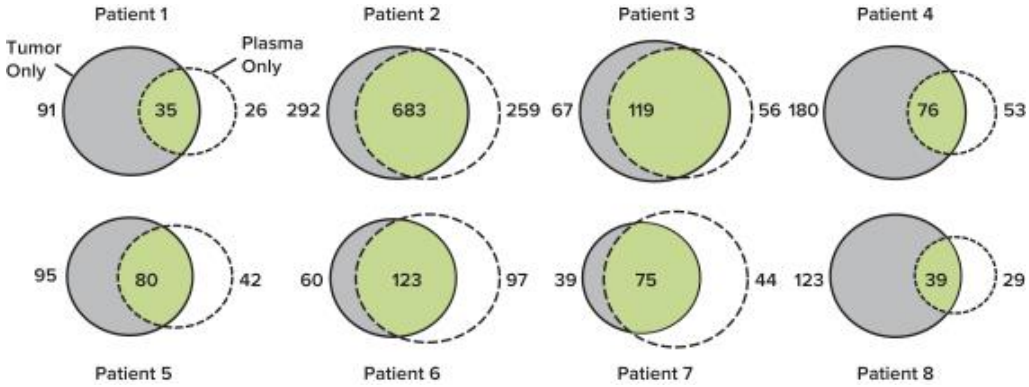
We believe tumor biopsy and liquid biopsy approaches to tumor molecular profiling can provide complementary information for each patient. Tumor biopsies provide tumor immune microenvironment and tumor gene expression information that current liquid biopsy panels do not provide. Liquid biopsies can be 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 50 to 500 driver genes, we are designing our cfDNA approach, NeXT Liquid Biopsy, which is currently in development, 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.

Figure 2: ImmunoID NeXT tumor biopsy and NeXT liquid biopsy (in development) yields complementary data.



We believe that combining tumor biopsies with cfDNA can provide a more complete picture of the spectrum of mutations found in a cancer patient. As an example of this, we compared the mutations found in eight late-stage colorectal tumor biopsy samples with those found in the plasma taken at the same time. We found a range of overlap between tumor biopsy-identified sequence variations and the sequences generated using cfDNA. These observations show that, while there was significant overlap between the tumor and liquid biopsy results, there were also mutations unique to tumor biopsy and vice versa (see examples of this in Figure 3). This observation underscores the concept that tissue and liquid biopsies may be complementary, and when combined, may provide a more complete picture of the patient's disease.

Figure 3. Overlap of sequence variations detected in matched tumor and blood plasma.



Numbers indicate variants detected in the tumor only, plasma only, or in both.

We anticipate that our 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 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.

ACE 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: ACE Extended Cancer Panel for DNA, ACE Extended Cancer Panel for RNA, ACE Cancer Research Exome, and ACE Cancer Research Transcriptome.

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 revenues since inception, excluding revenues from the Veteran's Affairs Million Veteran Program (discussed below), were derived from ACE Extended Cancer Panel and Cancer Research services.

Oncology Diagnostics

Over time, we expect to work with our biopharmaceutical customers and research collaborators to build evidence of clinical utility for our platform as a diagnostic for advanced cancer therapies. We see a growing long-term diagnostic opportunity for NeXT as a one-stop, universal tumor molecular profiling test for cancer patients covering all of the approximately 20,000 human genes compared to the roughly 50 to 500 genes covered by many currently marketed panels. We have released a diagnostic based on our NeXT Platform that we envision being used in clinical trials with biopharmaceutical and clinical partners. This product analyzes FFPE tumor samples with our NeXT Platform and returns a CLIA diagnostic report for physicians that details the therapeutic options for patient-based on the tumor mutations identified from our analysis of the sample. We also see this product as one that will help us build our internal NeXT database over time.

NeXT Dx Test

In January 2020, we announced the launch of the NeXT Dx Test to help oncologists identify potential therapies and clinical trial options for cancer patients. The Personalis 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 a few hundred genes. The Personalis 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 targeted to both leading clinical cancer centers as well as biopharmaceutical companies. No revenues from NeXT Dx were recognized in our fiscal year 2019.

ACE CancerPlus Test

In June 2015, we launched our ACE CancerPlus Test based on a 1,400-gene panel. We built upon this experience by introducing the NeXT Dx Test described above.

Whole Genome Sequencing

Since 2012, we have been contracted to provide DNA sequencing and data analysis services to the United States Veterans Affair's (the "VA") Million Veteran Program (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. Up to a million veterans are expected to enroll in the VA MVP study by 2021. With more than 825,000 enrollees to date, the VA MVP exceeds the enrollment numbers of any single VA study or research program in the past, and is in fact one of the largest population sequencing efforts in history. 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, and 2019. To date, we have been contracted to deliver approximately 115,000 genome sequence data sets to the VA MVP, and we expect revenue from the contracts awarded to date to continue into 2021. 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 and expect to continue to develop 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 revenues in recent years, 67% of our total revenues in 2019 and 49% in 2018. In 2017, VA MVP accounted for less than 10% of our revenues.

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.

- **The information we provide to personalized cancer therapy companies is used to design therapeutics**. Many biopharmaceutical companies are pursuing personalized cancer therapies, which are designed and manufactured, individually, for each patient based on genomic alterations in a given patient's tumor. While there are many potential approaches towards developing these therapies including neoantigen therapeutics, peptide-based vaccines, RNA and DNA vaccines, virally or bacterially encoded vaccines, and adoptive cell therapies, all of them benefit from the data and analytics that our platform can generate about a patient's tumor. We anticipate that drugs approved based on these therapeutic strategies may specify the use of our platform, enabling us to derive revenue in connection with the sale of commercial drugs, including the data generation and information processing required to treat each patient. We believe we are working with the majority of companies developing neoantigen-targeted personalized cancer therapies.

- **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, 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 are developing a complementary liquid biopsy test, which also offers broad 20,000-gene coverage versus more narrowly focused liquid biopsy tests that are currently available.** We have also shown that our technology can analyze DNA 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. We are not aware of any other company developing a cfDNA platform that analyzes all of the approximately 20,000 human genes. We expect this cfDNA to 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 plan to launch our first liquid biopsy assay 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 tumor. To achieve this mission, our strategy is to:

- **Drive adoption of our platform by establishing and expanding relationships with leading developers of oncology therapeutics.** We believe that we can address the leading companies in oncology therapeutics with a small team of sales representatives and highly targeted marketing efforts. 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, allowing us to develop sciences-based dialog with our customers who are conducting clinical trials in many parts of their organizations. Once we have completed pilot studies with these customers, we work to expand our footprint by partnering with them on additional clinical trials using the newest versions of our technology. We plan to continue to enter into such partnerships and pursue a publication strategy that further demonstrates the utility of our platform.

- **Invest in new product innovations and enhancements to maintain our leading position.** We will continue to make investments in new products that enhance our platform and further our competitive advantages. As the breadth of data used in drug development and cancer treatment becomes more and more complex, we believe our biopharmaceutical customers will look to our platform as a complete solution to drive efficiency in research and development. In 2020 we expect to launch a liquid biopsy test, which also offers broad 20,000-gene coverage versus the more narrowly focused liquid biopsy tests that are currently available.

- **Continue to build a body of evidence demonstrating the utility of comprehensive genomic data.** We expect the actionable information that customers gain from our platform will increase demand for our services. We intend to align ourselves with our customers, enabling them to develop better cancer therapeutics, which in turn demonstrates the utility of our platform. We expect this supportive cycle to increase our penetration into pharmaceutical and biotechnology enterprises over time.

- **Continue to grow our relationship with the VA MVP.** In addition to providing a stable source of revenue, our relationship with the VA MVP has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. The substantial experience that we have and expect to continue to develop in whole genome sequencing also optimally positions us for what we anticipate to be the longer-term strategic direction of the cancer genomics industry.

- **Leverage a growing body of evidence from our platform to develop a diagnostic.** It is estimated that over 70% of oncology therapeutics in development are classified as personalized medicines, which require specific diagnostic testing prior to administration. We see a growing long-term diagnostic opportunity for NeXT as a one-stop, universal tumor profiling test for cancer patients. We announced the launch of our NeXT Dx Test in January 2020, which is a clinical diagnostic test based on our ImmunoID NeXT Platform and is one of the first cancer diagnostic platforms to profile all of the 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 a few hundred genes. NeXT Dx is targeted initially at leading clinical cancer centers as well as biopharmaceutical companies for use in clinical trials.

- **Build out a comprehensive tumor-genomics database**. We also see a growing long-term opportunity to generate rich databases of content across a large number of cancer patients. Most current diagnostic based databases built using cancer panels cover just a small fraction of genes and miss information about the immune system whereas our platform will provide comprehensive information. This database would serve as a valuable tool to discover new cancer biology, new biomarkers, and potential therapeutic targets. It may include integration with other sources of RWD, such as electronic health records, which can generate RWE that may be used to reduce risk in early discovery by helping to identify biomarkers of response, improve trial execution through external control arms, expand indications for therapy, reduce trial size, and improve trial design.

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 are sequencing and analyzing up to 180 trillion bases of DNA per week in our facility. We believe this capacity is already larger than most cancer genomics companies and we are building the automation and other infrastructure to scale further as demand increases and in support of the planned 2020 launch of our NeXT liquid biopsy assay.

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.

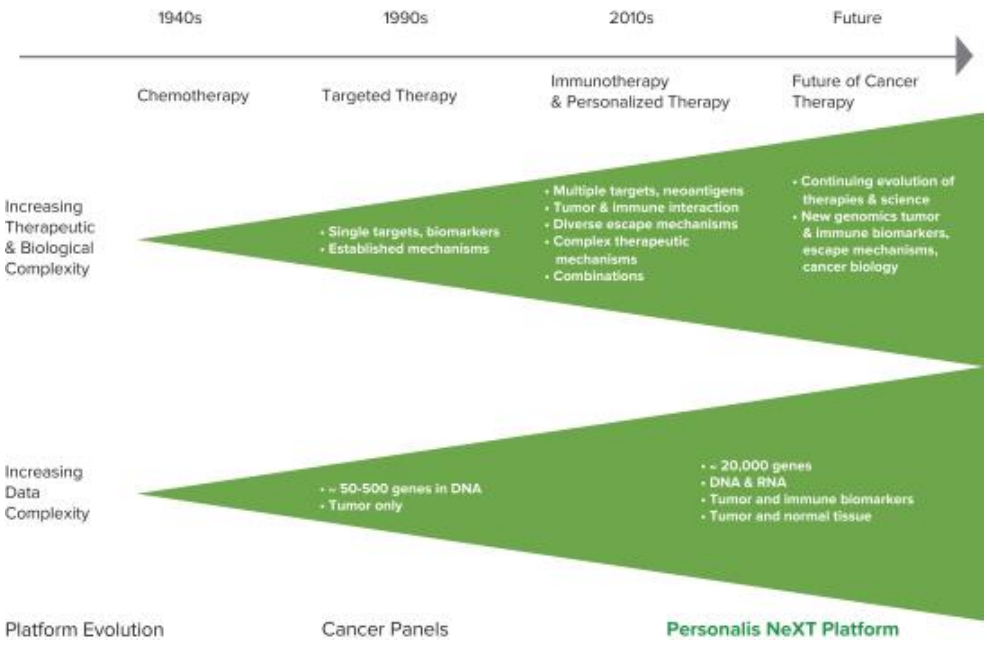
We leverage our proprietary software, laboratory automation and protocols, and other operational and technological know how to power our NeXT Platform.

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 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 platform helps 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. NeXT represents the next step of our existing ACE platform, allowing customers to move up the value chain by gaining more information from a single sample. We believe that our platform has 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 platform 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 a 2020 American Cancer Society report, "Cancer Facts & Figures," 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, and more than 1.8 million people were expected to be diagnosed with the disease in 2020. 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. In 2019, we derived substantially all of our revenues 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 revenues come from single time point testing, we believe our revenues from multiple time point testing will continue to grow. We also derive revenues 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. We announced the launch of our NeXT Dx Test in January 2020, which is a clinical diagnostic test based on our ImmunoID NeXT Platform and is one of the first cancer diagnostic platforms to profile all of the 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 a few hundred genes. NeXT Dx is targeted initially at leading clinical cancer centers as well as biopharmaceutical companies for use in clinical trials.

Our Customers

Since inception, we have provided our services to more than 50 biopharmaceutical customers, including several of the largest pharmaceutical companies in the world. We have also provided our services to universities and non-profits, diagnostics companies, and government entities. Some of our announced customers include Pfizer Inc., Merck & Co., Inc., and Indivumed GmbH.

In 2019, VA MVP and Pfizer Inc. accounted for 67% and 13% of our revenues, respectively. No other customer accounted for 10% or more of our revenues. In 2018, we had three customers account for 10% or more of our revenues: VA MVP at 49%, Merck & Co., Inc. at 12%, and Pfizer Inc. at 10%. In 2017, Merck & Co., Inc. accounted for 11% of our revenues while two other customers also contributed 10% or more of our revenues.

Our Competition

We provide a comprehensive, exome-scale analysis of both a tumor and its microenvironment, including the immune cells, from a single tissue sample.

Our primary competition comes from companies offering genomic profiling services for either the tumor or the immune microenvironment. These companies offer services that implement various technological approaches including next-generation sequencing and microarray analyses. These competitors include Guardant Health, Inc., Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Roche Molecular Systems, Inc., NanoString Technologies, Inc., Personal Genome Diagnostics, Inc., and Adaptive Biotechnologies Corporation.

Competitors within the broader genomics profiling space include laboratory companies such as Laboratory Corporation of America Holdings, Quest Diagnostics, Inc., Caris Life Sciences, Inc., Myriad Genetics, Inc., Tempus, Inc., InVitae Corp., BGI Group, Macrogen, Inc., Natera, Inc., Illumina, Thermo Fisher Scientific Inc., NeoGenomics, Inc., and MedGenome Inc., as well as other companies that provide sequencing services to biopharmaceutical companies. 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 ACE assay, and specific follow-on applications and implementations for enhancing sequencing coverage of certain genomic regions and analyzing cell-free nucleic acids. 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, 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—Risks Related to Our Intellectual Property.”

Our patent portfolio is comprised of patents and patent applications owned by the company. These patents and patent applications generally fall into four 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; and
- clinical interpretation methods, including claims directed to methods of ranking genes associated with a phenotype and inheritance pattern.

As of December 31, 2019, we own twelve issued U.S. and foreign patents in China and the United Kingdom and several pending U.S. and foreign patent applications. Issued U.S. patents in our portfolio of company-owned patents and patent applications are expected to expire between 2033 and 2037, excluding any additional term for patent term adjustments or patent term extensions.

Government Regulations

Federal and State Laboratory Licensing Requirements

Under the Clinical Laboratory Improvement Amendments of 1988 ("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 College of American Pathologists ("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 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 intend to market a 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.

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.

Other federal fraud and abuse laws to which we are subject include, but are not limited to, the federal civil and criminal false claims laws including the FCA, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government, and the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies. Under the FCA, private citizens can bring claims on behalf of the government through qui tam actions. We must also operate within the bounds of the fraud and abuse laws of the states in which we do business which may apply to items or services reimbursed by non-governmental third-party payers, including private insurers.

Efforts to ensure that our business arrangements with third parties 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 the Health Insurance Portability and Accountability Act of 1996 ("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.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

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

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 to August 2018), with three one-year renewal option periods that may be exercised upon discretion of the VA MVP (September 2018 to August 2019; September 2019 to August 2020; and September 2020 to August 2021). 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. To date, the VA MVP has exercised two of its three one-year renewal options, meaning that our current task order extends through August 2020.

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.

Agreements with Illumina

On March 21, 2017 we received a quotation for supply of genetic analysis products (the "Quote") from Illumina. The Quote provided information as to the cost of five Illumina® Product Care NovaSeq®6000 Comprehensive Plans and five NovaSeq™6000 Sequencing System instruments. The term of the Quote extended through March 31, 2017. On March 31, 2017, we submitted a purchase order to Illumina for five NovaSeq™6000 Sequencing System instruments, all of which we have received. On March 1, 2019, we received another quotation for supply of genetic analysis products (the "Second Quote") from Illumina. The Second Quote provided information as to the cost of five NovaSeq™6000 Sequencing System instruments. The term of the Second Quote extended through March 31, 2019. On March 20, 2019, we submitted a purchase order to Illumina for five NovaSeq™6000 Sequencing System instruments, four of which we have received and one of which will be received on or before the due date of March 23, 2023.

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 December 31, 2021, or later if the VA MVP Agreement is extended.

The Subcontract Agreement extends through the last day of the VA MVP Agreement, currently August 2021 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 November 22, 2017, we entered into a pricing agreement with Illumina. The pricing agreement provided pricing terms for the NovaSeq™ 5000/6000 S4 Reagent Kit (each, a "Kit"). On March 26, 2019, we entered into a new pricing agreement with Illumina, which replaced in its entirety the agreement dated November 22, 2017. The new 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.

On December 13, 2017, we received a Fast Track genetic analysis services agreement (the "Services Agreement") from Illumina that provided pricing information for the Infinium Global Screening Array V2.0 Fast Track Service, a service we used to fulfill one of our VA MVP task orders. The term of the Services Agreement extended through June 30, 2019. Illumina continues to provide us similar genotyping Fast Track services that we use to fulfill our VA MVP task orders, but such services are now pursuant to Illumina's standard terms and conditions rather than a separate services agreement.

On February 22, 2019 we received a quotation for supply of genetic analysis products (the "Master Quote") from Illumina that provides for additional pricing terms on Illumina products, which was updated on November 19, 2019. The term of the Master Quote extends through December 31, 2020.

Our Employees

As of December 31, 2019, we had 182 employees, of which 181 were full-time employees. Of these full-time employees, 71 were in research and development, 56 in laboratory operations, 29 in commercial operations and 25 in general and administrative functions. 177 of our full-time employees are located in the United States (including 158 who work at our corporate headquarters in Menlo Park, California and 19 who work remotely) and 4 are located in Europe. As of December 31, 2019, more than 75 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.

Our Facilities

Our corporate headquarters are located in Menlo Park, California, and comprise approximately 31,280 square feet of space, pursuant to an operating lease that expires in 2020. 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 laboratory is located in this facility.

We believe that this facility is sufficient to meet our current needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

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.

Our operations and financial results are subject to various risks and uncertainties including those described below. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks or others not specified below materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline.

Risks Related to Our Business and Strategy

We have 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 revenues to achieve or sustain profitability.

We have incurred net losses since our inception. For the years ended December 31, 2019, 2018, and 2017 we had net losses of $25.1 million, $19.9 million, and $23.6 million, respectively. As of December 31, 2019, we had an accumulated deficit of $140.6 million. To date, we have not generated sufficient revenues 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 revenues 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 revenues to achieve profitability and sustain our business.

We currently derive substantially all of our revenues from sales of our services. We began offering our services through our Clinical Laboratory Improvement Amendments of 1988 ("CLIA")-certified, College of American Pathologists ("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 revenues 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 revenues from sales of our services since 2013, our services may never gain significant acceptance in the marketplace and therefore may never generate substantial revenues 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;
- the success of our sales force;
- whether biopharmaceutical companies accept that our services are sufficiently sensitive and specific;
- our ability to convince biopharmaceutical companies 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 financial condition and operating results. The COVID-19 pandemic could materially affect our operations, including at our headquarters in the San Francisco Bay Area, which is currently subject to shelter-in-place orders, and the business or operations of our manufacturers, 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 outbreak and could cause significant disruption in the operations of our customers and third-party manufacturers upon whom we rely. Our sole laboratory, 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. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to over 140 countries, including the United States. On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States and Europe for a 30-day period. Further, on March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. On March 4, 2020, the State of California declared a state of emergency related to the spread of COVID-19, and the San Francisco Department of Public Health announced aggressive recommendations to reduce the spread of the disease, including recommendations to suspend nonessential travel, encourage telecommuting, and cancel or postpone large gatherings. On March 16, 2020, the health officers of six San Francisco Bay Area counties, including San Mateo County where our headquarters and sole laboratory are located, issued shelter-in-place orders that took effect at 12:01 a.m., Pacific Time, on March 17, 2020 and remain in force until April 7, 2020, (i) directing all individuals living in those counties to shelter at their places of residence (subject to limited exceptions), (ii) directing all businesses and governmental agencies to cease non-essential operations at physical locations in those counties, (iii) prohibiting all non-essential gatherings of any number of individuals, and (iv) ordering cessation of all non-essential travel. While the order allows for continued operation of so-called Essential Businesses, which includes certain critical healthcare operations and services, we have substantially closed our office space and limited access to our laboratory space, to protect our employees and to comply with the provisions described within the order, and we are prioritizing the fulfillment of customer orders to those related to time-sensitive healthcare projects, such as in-process clinical trials, and will fulfill other customer orders to the extent we have the ability to do so with limited laboratory staffing. The effect of the shelter-in-place order may negatively impact productivity and disrupt our business, and may disrupt the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Several of our customers have been delayed in sending us samples, and the order may disrupt additional customers from sending purchase orders and samples to us as they implement their own precautionary measures. Many of our customers, potential customers and potential partners have also put in place policies restricting visitors from other companies, and therefore our sales team and members of management have been unable to meet such parties in person, which may result in reduced acquisition of new customers, fewer orders from existing customers and fewer potential partnering opportunities. Such disruptions in our operations, and our customers' and suppliers' operations, may adversely affect our financial condition and operating results. In addition, on March 19, 2020, the Governor of California and the State Public Health Officer and Director of the California Department of Public Health ordered all individuals living in the State of California to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic. Authorities in other states, where our customers, suppliers and partners may be located, are following suit and issuing orders with similar goals and restrictions.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues 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 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.

Some of our present and potential competitors, including Guardant Health, Inc., Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Roche Molecular Systems, Inc., NanoString Technologies, Inc., Personal Genome Diagnostics, Inc., Adaptive Biotechnologies Corporation, and NeoGenomics, Inc., may have widespread brand recognition and substantially greater financial and technical resources and development, production capacities, and 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 significant levels of market share. In addition, competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, well-established, and well-financed companies. 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, 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 revenues 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.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products 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 2019 revenues and accounts receivable.

Like other genomics profiling companies that sell to the pharmaceutical industry, we have customer concentration. We currently derive a significant portion of our revenues from the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP"), which accounted for 67% and 49% of our revenues for the year ended December 31, 2019 and 2018, respectively. Our top five customers, including the VA MVP, accounted for 90% and 82% of our revenues for the year ended December 31, 2019 and 2018, respectively. There are inherent risks whenever a large percentage of revenues are concentrated with a limited number of customers. It is not possible for us to predict the future level of demand for our services that will be generated by these customers. In addition, revenues 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 facts, some of which may be outside of our control. Further, while we have long-term contractual arrangements with certain of our customers, these customers are not required to purchase a minimum number of analyses. If any of these customers suspend or terminate clinical trials, receive less funding, experience declining or delayed sales, or otherwise chose to reduce or eliminate their use of our services, 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 revenues 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 revenues, cash position, and results of operations. Further, if our largest customers were to cease using or stop payment for our services, it would have a material adverse effect on our accounts receivable, increasing our credit risk. The failure of these customers to pay their balances, or any customer to pay future outstanding balances, would result in an operating expense and reduce our cash flows.

We currently derive a substantial portion of our revenues from DNA sequencing and data analysis services that we provide 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 is substantially reduced, our business, financial condition, operating results, and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues 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 option renewal periods with the VA for the VA MVP, pursuant to which we received orders from the VA MVP in September 2017, 2018, and 2019.

The VA MVP's orders for DNA sequencing and data analysis services 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. We have no certainty that funding will be made available for our services. If the priorities of the VA, the VA MVP, or the U.S. government change, funding for our services may be limited or not available, and our business, financial condition, and operating results and cash flows would be materially harmed. The success of our business and our future operating results are significantly dependent on the VA MVP's 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.

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 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, 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 revenues 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 revenues.

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, 2019, we had approximately $36.0 million in customer deposits, including $32.5 million from one customer. However, as of that date, we had $128.3 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. If a customer that has prepaid us for future services cancels its contract with us or reduces the level of services that it expects to receive, we would generally be required to repay that customer's deposit with little or no notice. 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.

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, 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. Our master subcontractor agreement with Illumina is set to expire in August 2021, and our various pricing agreements with Illumina are set to expire on various dates up to December 2022. Any disruption in Illumina's operations, or our inability to negotiate an extension to our agreements with Illumina on acceptable terms, or at all, could impact our supply chain and laboratory operations and our ability to conduct our business and generate revenue. Our suppliers could cease supplying these materials, reagents, and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing equipment, materials, reagents, or sequencers, 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. 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. 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 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.

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 United States and worldwide resulting from the ongoing COVID-19 outbreak. 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 and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next 12 months, we cannot assure you that we will generate sufficient revenues from commercial sales to adequately fund our operating needs or achieve or sustain profitability.

We will need to invest in our infrastructure in advance of increased demand for our services, and 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, expanding our internal quality assurance program, 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 facility 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 revenues do not meet our expectations we may not be able to promptly adjust or reduce our spending to levels commensurate with our revenues. 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 sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our genomic analysis conducted in our laboratory. We do not have any clinical reference laboratory facilities other than our facility in Menlo Park, 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 outbreak, we may limit our operations or temporarily close our office and/or laboratory space. 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 diagnostic and other services, disruptions in our operations, or the backlog of samples that could develop if our facility is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation 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. 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 facility 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 became inoperable, we would likely not be able to license or transfer our technology to another facility 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 a facility with such qualifications to perform our services, it may not be available to us on commercially reasonable terms.

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 result in a material disruption of our services, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our confidential information.

Despite 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 confidential information that they maintain, our such information technology systems are potentially vulnerable to breakdown or other damage or interruption from 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 employees, third-party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. 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, or hostile foreign governments or agencies. 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 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. 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.

While we have not experienced any such system failure, accident, or security breach to date and believe that our data protection efforts and our investment in information technology reduce the likelihood of such incidents in the future, 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. 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.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information (“PHI”), personally identifiable information (“PII”), credit card and other financial information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties. 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. 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 we use to manage this sensitive data.

The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take 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 employee 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 such access, breach, or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services (“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. Additionally, in connection with the ongoing COVID-19 pandemic, most of our employees are working remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations.

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. In addition, numerous breach incidents could lead to possible penalties in excess of $1.68 million. 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. 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 revenues and/or subject us to additional liabilities.

In addition, the interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union (the “EU”), and elsewhere are often uncertain, contradictory and in flux. For example, the EU-wide General Data Protection Regulation (EU) 2016/679 (“GDPR”) became applicable on May 25, 2018, replacing data protection laws issued by of each EU member state based on the Directive 95/46/EC (the “Directive”). Unlike the Directive, which needed to be transposed at a national level, the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to implement more stringent operational requirements for processors and controllers of personal data, including, for example, transparent and expanded disclosure to data subjects (in a concise, intelligible and easily accessible form) about how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to health data and pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements, and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR will be significant—the greater of €20 million or 4% of global turnover. The GDPR 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, ultimately having an adverse impact on our business, and harm our business and financial condition. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Further, the United Kingdom’s vote in favor of exiting the EU, often referred to as Brexit, and ongoing developments in the United Kingdom regarding Brexit have created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

Compliance with U.S. and international data protection 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 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 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 in compliance with applicable law could result in our own non-compliance with privacy laws. Such failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection 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 success depends on our ability to provide reliable, 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 can also be flaws in the databases, third-party tools, and algorithms we use, and 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.

Inaccurate results or misunderstandings of, or inappropriate reliance on, the information we provide to our customers could lead to, or be associated with, side effects or adverse events in patients who use our tests, including treatment-related death, and could lead to termination of our services or 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 (such as our planned liquid biopsy test) 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.

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 Scientific Officer, Clinton Musil, our Chief Business 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, 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 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, 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. 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 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 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 depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process, our clinical report systems, our billing systems, our business intelligence systems, our logistics and customer relationship systems, our customer-facing web-based software, our customer reporting, and our family history and risk assessment tools. 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.

Although we invest substantially in the backup/restore, high-availability architecture, monitoring and reporting, documentation and preventive security controls of our systems, all information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts and natural disasters. Our servers are potentially vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. 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.

Additionally, we have internally developed, and expect to continue to invest in and expand, proprietary informatics and software systems that are designed to manage the unique aspects and challenges of our genomics laboratory and on which we depend. Any disruption of failure of our internally developed informatics and software systems could have an adverse effect on our business.

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.

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. 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 acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. 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 "—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.

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

Our business depends on our ability to quickly and reliably provide test results to our customers, which in turn, requires that specimens are transported and delivered to us in a timely manner. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, terrorist acts, or threats or for other reasons could adversely affect specimen integrity and our ability to process specimens in a timely manner and service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

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.

The 2017 tax reform law and possible future changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, 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. 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 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 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 a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. 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, 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. 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.

Risks Related to Government Regulation

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 United States 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. 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.

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, we may be required to obtain premarket clearance for our tests and associated software under Section 510(k) of the FDC Act or approval of a premarket approval application ("PMA"). We would also be subject to ongoing regulatory requirements such as registration and listing requirements, medical device reporting requirements, and quality control requirements. If our tests are considered medical devices not subject to enforcement discretion, 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 over 1,700 different 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, one classification regulation that could be relevant to one or more of our tests is a recently finalized classification for genetic health risk ("GHR") assessment tests. On April 6, 2017, in response to a *de novo* request for reclassification submitted by another company, the FDA issued an order classifying genetic tests known as genetic health risk assessment systems ("GHR tests") as Class II devices subject to premarket notification and specified special controls requirements. On November 7, 2017, the FDA codified this classification at 21 C.F.R. § 866.5950. If our tests are considered medical devices that are not subject to enforcement discretion 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. Although the FDA has also issued a proposal for a simplified path to market GHR tests that would amend the classification regulation at 21 C.F.R. § 886.5950 such that manufacturers would only be subject to a one-time marketing review to ensure that they meet the applicable FDA requirements prior to selling GHR tests in the market, the FDA has yet to finalize this proposal, and we do not know if and when finalization will occur. Even if the FDA finalizes the proposed limited exemption for GHR tests, 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 (if and when finalized), 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 good clinical practices ("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 revenues 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.

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 United States. 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 revenues in doing so.

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, or if any of our products otherwise fail to comply with FDA regulatory requirements as enforced, 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 revenues, 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.

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

- the 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 the Children's Health Insurance Program ("CHIP") to report annually to CMS information related to (i) payments and other transfers of value to physicians 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;

- the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payer" statute);

- 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; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors employing, exercising control over, licensed professionals in violation of state laws prohibiting corporate practice of medicine and other professions, and prohibitions against the splitting of professional fees with licensed professionals; and

- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

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

The growth of our business and our expansion outside of the United States 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.

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. If 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 UK 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 UK 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.

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 is uncertain. If we develop in vitro diagnostic tests and decide to seek reimbursement, and if such tests are inadequately covered by insurance and 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.

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 United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

Changes in health care policy could increase our costs, decrease our revenues, 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 & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives to delay the implementation of certain requirements of the ACA. Concurrently, Congress has 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other 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 Affordable Care Act 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 2027 unless additional Congressional action is taken. 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 a new system of incentive payments beginning in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

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 revenues 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. 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 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.

Risks Related to Our Intellectual Property

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. 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, including ACE ImmunoID and ImmunoID NeXT technology. In order to avoid infringing these third-party patents, we may find it necessary to 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 United States 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 United States 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 United States 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 and more mature and developed intellectual property portfolios.

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 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 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.

There are a number of recent changes to the patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act (the "AIA") enacted within the last several years involves significant changes in patent legislation. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. As an example, assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the AIA, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, means that the party that is first to file in the United States generally is awarded the patent rights, regardless of whether such party invented the claimed invention first.

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

Further, 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 United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many 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 United States, 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 2037, 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 2040. In addition, although upon issuance in the United States 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 United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing 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 United States 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 United States 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 United States allow for various post-grant opposition proceedings, such as *inter partes* review proceedings, that have not been extensively tested, and their outcome is therefore uncertain. 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 United States, 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 United States 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. 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 expect to 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 United States can be less extensive than those in the United States. 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 United States. 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 United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. 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 United States. 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 European Union 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 United States 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 United States 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 product. 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.

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

Any future collaborations that we 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 may include that:

- 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 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 products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;
- collaborators with marketing, manufacturing, and distribution rights to one or more 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;
- 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 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 products;
- collaborators may own or co-own intellectual property covering our 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; 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.

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.

Risks Related to Our Common Stock

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;
- 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; 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 outbreak 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 revenues 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 revenues 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 and other large customers are not obliged to deliver tissue samples or other specimen to us at any particular time or at all. The rate at which we receive tissue samples or other specimen 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 specimen 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 revenues from quarter to quarter. 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.

Based solely on the most recent Schedules 13G and 13D filed with the SEC, reports filed with the SEC under Section 16 of the Exchange Act, and our outstanding shares of common stock as of December 31, 2019, our directors, executive officers and their affiliates and holders of greater than five percent of our outstanding common stock beneficially owned approximately 39.5% of our outstanding capital stock as of December 31, 2019. As a result, these stockholders, acting together, will be 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, 2019, we had 31,243,029 shares of common stock outstanding, all of which shares are eligible 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, 2019 will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, holders of up to an aggregate of 18,790,983 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.

An active trading market for our common stock may not be sustained.

Our common stock is currently listed on The Nasdaq Global Market under the symbol "PSNL." However, we cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell your shares of our common stock when desired, or the prices that you may obtain for your shares. Further, an inactive market may also impair our ability to raise capital by selling our common stock and may impair our ability to enter into strategic partnerships or acquire businesses, products, or technologies using our common stock as consideration.

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.

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

As of December 31, 2019, we had federal and state net operating loss carryforwards of approximately $114.9 million and approximately $72.2 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 income tax liabilities. Under the Tax Cuts and Jobs Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. In addition, under Section 382 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 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 would harm our future operating results by effectively increasing our future tax obligations.

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.

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 United States 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 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 or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

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 additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision is being reviewed and may be ultimately overturned by the Delaware Supreme Court.

The requirements of being a public company may strain our resources, result in litigation and 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 an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 (the "JOBS 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 will need 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 prospectus 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.

We also expect that being a public company and these new rules and regulations will make it more 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 will have reduced strategic flexibility and will be under pressure to focus on short-term results, which may materially and adversely affect our ability to achieve long-term profitability.

We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the closing of our initial public offering of our common stock (our "IPO"). Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- December 31, 2024.

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

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this accommodation and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Material weaknesses in our internal control over financial reporting may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our financial statements.

Management evaluates our internal control systems, processes, and procedures for compliance with the requirements of a smaller reporting company under Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"). This evaluation includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A "material weakness" is a

deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with preparation of our financial statements for the years ended December 31, 2017 and 2018, management identified a material weakness in our internal controls due to a lack of sufficient full-time accounting staff with requisite experience and deep technical accounting knowledge to (i) identify and resolve complex accounting issues under generally accepted accounting principles in the United States ("GAAP") and (ii) allow for appropriate segregation of duties. The identified material weakness could result in misstatements to our consolidated financial statements that would be material and would not be prevented or detected on a timely basis.

We implemented additional procedures to remediate this material weakness, however, we cannot assure you that these or other measures will prevent future material weaknesses from occurring. Remediation of the material weakness involved hiring a Chief Financial Officer in March 2019 and four additional accounting resources in the second, third, and fourth quarters of 2019, including two Certified Public Accountants with the specific technical accounting and financial reporting experience necessary for a public company. We will continue to assess the adequacy of our accounting personnel and resources, and will add additional personnel, as well as adjust our resources, as necessary, commensurate with any increase in the size and complexity of our business.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the U.S. Securities and Exchange Commission (the "SEC") or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our reputation, financial condition, and operating results could suffer.

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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters are located in Menlo Park, California, and comprise approximately 31,280 square feet of space, pursuant to an operating lease that expires in 2020. 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 laboratory is located in this facility.

We believe that this facility is sufficient to meet our current needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we are a party to litigation and subject to claims that arise in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. As of December 31, 2019, the Company was not involved in any material legal proceedings.

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

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

Holders

As of March 20, 2020, there were approximately 144 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.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from our Public Offering of Common Stock

On June 19, 2019, the registration statement on Form S-1 (Registration No. 333-231703) for our IPO of our common stock was declared effective by the SEC. On June 24, 2019, we closed our IPO and sold an aggregate of 9,109,725 shares of our common stock, inclusive of the exercise in full by the underwriters of their option to purchase up to an additional 1,188,225 shares of common stock, for an aggregate price of approximately $155 million. Upon completion of the sales of the shares of our common stock, our IPO terminated.

The underwriters of our IPO were Morgan Stanley & Co. LLC, BofA Securities, Inc., Cowen and Company, LLC, and Oppenheimer & Co. Inc. We paid the underwriters of our IPO an underwriting discount and commission totaling $10.8 million and incurred $4.2 million in offering costs. Thus, the net offering proceeds, after deducting underwriting discounts and offering expenses, were approximately $139.8 million. No payments were made to our directors or officers or their associates, holders of 10% or more of any class of our equity securities, or any affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on June 20, 2019 pursuant to Rule 424(b)(4).

Issuer Purchases of Equity Securities

During the quarter ended December 31, 2019, we did not purchase any of our equity securities that are registered under Section 12 of the Exchange Act.

Item 6. Selected Financial Data.

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," and the information contained in Item 7 of Part II, "Management's Discussion and Analysis of Financial Condition and Results of Operations." Historical results are not necessarily indicative of future results.

	Year Ended December 31,		
	2019	2018	2017
Consolidated Statements of Operations:	(in thousands, except share and per share data)		
Revenues	$ 65,207	$ 37,774	$ 9,393
Costs and expenses			
Costs of revenues	43,127	25,969	11,736
Research and development	22,418	14,304	9,919
Selling, general and administrative	22,080	11,271	9,901
Total costs and expenses	87,625	51,544	31,556
Loss from operations	(22,418)	(13,770)	(22,163)
Interest income	1,620	293	100
Interest expense	(1,133)	(1,894)	(1,303)
Loss on debt extinguishment	(1,704)	(4,658)	—
Other (expense) income, net	(1,440)	150	(227)
Loss before income taxes	(25,075)	(19,879)	(23,593)
Provision for income taxes	(9)	(7)	(5)
Net loss	$ (25,084)	$ (19,886)	$ (23,598)
Net loss per share, basic and diluted	$ (1.39)	$ (6.49)	$ (7.78)
Weighted-average shares outstanding, basic and diluted	18,011,470	3,063,157	3,031,636

	December 31, 2019	December 31, 2018	December 31, 2017
Consolidated Balance Sheet Data:	(in thousands)		
Cash and cash equivalents, and short-term investments	$ 128,289	$ 19,744	$ 22,617
Working capital	89,616	(28,291)	(22,262)
Total assets	157,291	41,670	33,563
Total debt	—	4,996	17,506
Long-term obligations	639	804	1,183
Total liabilities	50,601	58,654	50,171
Redeemable convertible preferred stock	—	89,404	75,995
Total stockholders' equity (deficit)	106,690	(106,388)	(92,603)

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 and our final prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on June 20, 2019 (the "Prospectus"). 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 and in our Prospectus.

This section of this Form 10-K generally discusses 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 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 Prospectus.

Overview

We are a growing cancer genomics company transforming the development of next-generation therapies by providing more comprehensive molecular data about each patient's cancer and immune response. We designed our NeXT Platform to adapt to the complex and evolving understanding of cancer, providing our biopharmaceutical customers with information on all of the approximately 20,000 human genes, together with the immune system, in contrast to many cancer panels that cover roughly 50 to 500 genes. In parallel with the development of our platform technology, we have also provided population 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.

We are also developing a complementary liquid biopsy assay that analyzes all of the approximately 20,000 human genes versus the more narrowly focused liquid biopsy assays that are currently available. By combining technological innovation, operational scale, and regulatory differentiation, our NeXT Platform is designed to help our customers obtain new insights into the mechanisms of response and resistance to therapy as well as new potential therapeutic targets. Our platform enhances the ability of biopharmaceutical companies to unlock the potential of conducting translational research in the clinic rather than with pre-clinical animal models or cancer cell lines. We also announced in January 2020 a diagnostic based on our NeXT Platform that we envision being used initially by both leading clinical cancer centers as well as biopharmaceutical companies.

We generated revenues of $65.2 million, $37.8 million, and $9.4 million for the years ended December 31, 2019, 2018, and 2017, respectively. In 2019, 67% of our revenues were generated from the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP") as compared to 49% in 2018. Non-VA MVP revenues increased by 13% in 2019 compared to 2018. We also incurred net losses of $25.1 million, $19.9 million and $23.6 million for the years ended December 31, 2019, 2018, and 2017, respectively.

As of December 31, 2019, we had $128.3 million in cash and cash equivalents, and short-term investments. From inception through December 31, 2019, we have funded our operations primarily through cash from operations, redeemable convertible preferred stock issuances, debt issuances, and proceeds from our initial public offering. We expect that our existing cash and cash equivalents, and short-term investments will provide sufficient funds to sustain operations through at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

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 revenues 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 revenues, 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 revenues and costs 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 do 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 commercial growth.** Investment in research and development, including the development of new products is critical to establish and maintain our leading position. In particular, we have invested in NeoantigenID, a neoantigen characterization report, ImmunogenomicsID, a broad biomarker report, and ImmunoID NeXT, our universal cancer immunogenomics platform. We are also collaborating with key opinion leaders from academic cancer centers, such as Inova Health System, Stanford Medicine, and the Parker Institute for Cancer Immunotherapy, to support the utility of our platform. We believe this work is critical to gaining customer adoption and expect our investments in these efforts to increase. We believe utility for our product may result in additional expenditures to develop and market new products, including a diagnostic or database.

- **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 revenues 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.

In addition to the factors described above, as our headquarters and laboratory operations are located in San Mateo County, California, our operations have been impacted by the ongoing COVID-19 pandemic. On March 16, 2020, the Health Officer of the County of San Mateo (the “Health Officer”) issued a shelter-in-place order (the “San Mateo Order”), which directed all businesses to cease non-essential operations at physical locations in the county. The San Mateo Order also directed all individuals living in the county to shelter at their place of residence with limited exceptions. The intent of the San Mateo Order is to slow the spread of COVID-19 to the maximum extent possible. The San Mateo Order became effective on March 17, 2020 and will continue to be in effect through April 7, 2020, or until it is extended, rescinded, superseded, or amended in writing by the Health Officer. Similar orders were issued in neighboring counties, including Santa Clara County, such that the substantial majority of our employees are subject to a shelter-in-place order. While the San Mateo Order allows for continued operation of so-called Essential Businesses, which includes certain critical healthcare operations and services, to comply with the San Mateo Order, we are prioritizing the fulfillment of customer orders to those related to time-sensitive healthcare projects, such as in-process clinical trials, and will fulfill other customer orders to the extent we have the ability to do so with limited laboratory staffing. In addition, on March 19, 2020, the Governor of California and the State Public Health Officer and Director of the California Department of Public Health ordered all individuals living in the State of California to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic (the “California Order” and, together with the San Mateo Order, the “Orders”). Other states in the United States, including Massachusetts and New York, have followed suit by issuing orders with similar goals and restrictions.

Beyond the immediate impact of the Orders to our operations, the ongoing COVID-19 pandemic, the Orders, and similar orders issued by other authorities to impose restrictions intended to mitigate the impact of the COVID-19 pandemic, may disrupt our supply chain, including our ability to acquire raw materials, disrupt customer demand, reduce our ability to receive customer samples on a normal basis, disrupt our customer and vendor relationships, divert management attention, and negatively impact employee productivity due to work-from-home policies. The scope and duration of such impact is highly uncertain. We are unable to predict or quantify the impact of any potential disruption to our supply chain, changes in consumer demand, or any other actions that may become necessary as events unfold.

Components of Operating Results

Revenues

We derive our revenues 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 revenues are primarily generated through contracts with companies in the pharmaceutical industry, healthcare organizations, and government entities. Our ability to increase our revenues will depend on our ability to further penetrate this market. To do this, we are developing a growing set of additional state-of-the-art products, advancing our operational infrastructure, building our regulatory credentials and expanding our targeted marketing efforts. Unlike diagnostic or therapeutic companies, we have not to date sought reimbursement through traditional healthcare payors. We sell through a small direct sales force.

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

Costs and Expenses

Costs of revenues

Costs of revenues consist of production material costs, personnel costs (salaries, bonuses, benefits, and stock-based compensation), costs of consumables, laboratory supplies, depreciation and service maintenance on capitalized equipment, and information technology (“IT”) and facility costs. We expect the costs of revenues to increase as our revenues grow, but the cost per unit of data delivered to decrease over time 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 development of our products. These expenses consist primarily of payroll and personnel costs (salaries, bonuses, benefits, and stock-based compensation), costs of consumables, laboratory supplies, depreciation and service maintenance on capitalized equipment, and IT and facility costs. These expenses also include costs associated with our collaborations, which we expect to increase over time.

We expense our research and development expenses in the period in which they are incurred. We expect to increase our research and development expenses as we continue to develop new products.

Selling, general, and administrative expenses

Selling expenses consist of personnel costs, customer support expenses, direct marketing expenses, educational and promotional 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, audit and legal expenses, consulting costs, and IT and facility costs. We expense all selling, general, and administrative expenses 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 also expect general and administrative expenses will increase as we scale our operations.

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalents, and short-term investments. Interest income increased significantly in 2019 as a result of us investing proceeds from the IPO. We expect a continued higher level of interest income in 2020 for this reason.

Interest Expense

Interest expense primarily consists of cash and non-cash interest costs related to our term loan, convertible promissory notes, revolving loan, and growth capital loan. We record costs incurred in connection with the issuance of debt as a direct deduction from the debt liability. We amortize these costs over the term of our debt agreements as interest expense in our consolidated statements of operations. After the payoff of our growth capital loan in August 2019, we no longer have any outstanding debt and have not incurred interest expense from that point forward.

Loss on Debt Extinguishment

We incurred loss on debt extinguishment in 2018 resulting from changes in the maturity dates of the convertible notes issued in 2017. We also incurred 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 (Expense) Income, Net

Other (expense) income, net consists of changes in the fair value of the compound derivative instrument, changes in fair value of convertible preferred stock warrant liability, and foreign currency exchange gains and losses. Future periods will not include changes in fair value of the compound derivative instrument, due to extinguishment of the related convertible notes, nor will future periods include changes in fair value of convertible preferred stock warrants, due to the conversion of such warrants to common stock warrants. See Notes 6 and 10 included elsewhere in this annual report for further discussion of these two items. We expect our foreign currency gains and losses to continue to fluctuate in the future due to changes in foreign currency exchange rates.

Results of Operations

The following table sets forth our consolidated statements of income data (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Revenues	$ 65,207	$ 37,774	$ 9,393
Costs and expenses			
Costs of revenues	43,127	25,969	11,736
Research and development	22,418	14,304	9,919
Selling, general and administrative	22,080	11,271	9,901
Total costs and expenses	87,625	51,544	31,556
Loss from operations	(22,418)	(13,770)	(22,163)
Interest income	1,620	293	100
Interest expense	(1,133)	(1,894)	(1,303)
Loss on debt extinguishment	(1,704)	(4,658)	—
Other (expense) income, net	(1,440)	150	(227)
Loss before income taxes	(25,075)	(19,879)	(23,593)
Provision for income taxes	(9)	(7)	(5)
Net loss	$ (25,084)	$ (19,886)	$ (23,598)
Net loss per share, basic and diluted	$ (1.39)	$ (6.49)	$ (7.78)
Weighted-average shares outstanding, basic and diluted	18,011,470	3,063,157	3,031,636

Revenues

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

	Year Ended December 31,			Percentage change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
VA MVP	$ 43,545	$ 18,601	$ 421	134%	4,318%
All other customers	21,662	19,173	8,972	13%	114%
Total revenues	$ 65,207	$ 37,774	$ 9,393	73%	302%

The following table shows our concentration of revenues by customer:

	Year Ended December 31,		
	2019	2018	2017
VA MVP	67%	49%	*
Pfizer Inc.	13%	10%	*
Merck & Co., Inc.	*	12%	11%
Customer A	*	*	13%
Customer B	*	*	10%

* Less than 10% of revenues

VA MVP

The increase in 2019 revenues from the VA MVP was driven by an increase in the volume of samples we tested in the period, partially offset by lower prices per sample.

All Other Customers

The increase in 2019 revenues from all other customers was primarily due to an increase in the volume of samples we tested in relation to the sequencing and data analysis services we provided to our customers.

Costs and Expenses

	Year Ended December 31,			Percentage change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
	(in thousands)				
Costs of revenues	$ 43,127	$ 25,969	$ 11,736	66%	121%
Research and development	22,418	14,304	9,919	57%	44%
Selling, general and administrative	22,080	11,271	9,901	96%	14%
Total costs and expenses	$ 87,625	$ 51,544	$ 31,556	70%	63%

Costs of revenues

The increase in 2019 was primarily due to the increase in revenues discussed above. The cost components related to the increase in costs of revenues were an $11.7 million increase in production materials, a $2.2 million increase related to personnel costs including salaries, bonuses, benefits, and stock-based compensation expenses, a $1.6 million increase in depreciation and service maintenance on capitalized equipment, a $0.5 million increase in the consumption cost of consumables and laboratory supplies, a $0.9 million increase in IT and facility costs, and a $0.3 million increase in other costs.

Research and development

The increase in 2019 was primarily due to increased development activities for new product offerings, lab and automation development costs, and IT and facility costs. Research and development expenses increased due to an increase of $4.0 million in personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expenses, a $2.8 million increase in laboratory and automation supplies consumed, a $1.2 million increase in depreciation, service maintenance on capitalized equipment, and cost of expensed equipment, and $0.2 million increase in other costs.

Selling, general and administrative

The increase in 2019 was due to a $7.3 million increase in personnel-related expenses including salaries, bonuses, benefits, and stock-based compensation expenses primarily related to increased headcount, a $3.0 million increase in professional services primarily related to public company-related costs (including corporate insurance, audit fees, and legal expenses), and a $0.5 million increase in other costs.

Interest income, interest expense, and loss on debt extinguishment

	Year Ended December 31,			Percentage change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
	(in thousands)				
Interest income	$ 1,620	$ 293	$ 100	453%	193%
Interest expense	(1,133)	(1,894)	(1,303)	(40)%	45%
Loss on debt extinguishment	(1,704)	(4,658)	—	(63)%	NM
Total interest income, interest expense and loss on debt extinguishment	$ (1,217)	$ (6,259)	$ (1,203)		

Interest income

The increase in 2019 was due to investments of proceeds from our IPO.

Interest expense

The lower interest expense in 2019 was due to the repayment of the $20 million growth capital loan in August 2019, which resulted in no further outstanding debt for the remainder of the year, as well as 2018 including significant interest expense from the Convertible Notes and Revolving Loan.

Loss on debt extinguishment

The $1.7 million loss on debt extinguishment in 2019 resulted from the extinguishment of our $20 million Growth Capital Loan facility. The $4.7 million loss on debt extinguishment in 2018 resulted from changes in the maturity dates of the Convertible Notes issues in 2017.

Other (expense) income, net

	Year Ended December 31,			Change $	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
	(in thousands)				
Changes in fair values of warrants for Series B and Series C convertible preferred stock	$ (1,403)	$ (391)	$ (64)	$ (1,012)	$ (327)
Changes in fair value of the compound derivative instrument	—	574	(162)	(574)	736
Other	(37)	(33)	(1)	(4)	(32)
Total other (expenses) income, net	$ (1,440)	$ 150	$ (227)	$ (1,590)	$ 377

Other expenses, net in 2019 were primarily comprised of a $1.4 million increase in the fair values of warrants for Series B and Series C redeemable convertible preferred stock. Other income, net in 2018 was primarily comprised of a $0.6 million decrease in fair value of the compound derivative instrument, partially offset by a $0.4 million increase in the fair values of warrants for Series B and Series C redeemable convertible preferred stock.

Liquidity and Capital Resources

The following table presents selected financial information and statistics as of and for the years ended December 31, 2019, 2018, and 2017 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Cash and cash equivalents, and short-term investments	$ 128,289	$ 19,744	$ 22,617
Property and equipment, net	14,106	11,452	6,342
Contract liabilities	35,977	42,897	24,690
Total debt	—	4,996	17,506
Working capital	89,616	(28,291)	(22,262)
Cash (used in) provided by operating activities	(18,069)	5,572	290
Cash used in investing activities	(81,579)	(7,852)	(5,158)
Cash provided by (used in) financing activities	134,948	(591)	16,404

From our inception through December 31, 2019, we have funded our operations primarily from $144.0 million in net proceeds from our initial public offering in June 2019 and $89.6 million from issuance of redeemable convertible preferred stock, as well as cash from operations and debt financing. On March 22, 2019, we received $20.0 million in gross cash proceeds from a growth capital loan. As of December 31, 2019, we had cash and cash equivalents in the amount of $55.0 million.

We have incurred net losses since our inception. We anticipate that our current cash and cash equivalents and marketable securities, 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 offering 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, 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. 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.

On March 22, 2019, we entered into a growth capital loan (the “Growth Capital Loan”) with TriplePoint to provide for a $20.0 million growth capital loan facility and as of June 30, 2019, had drawn down the full $20.0 million available under the facility. We 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, we were required to make monthly interest-only payments through April 1, 2020 and 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, we 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, we issued a warrant to purchase 65,502 shares of common stock to TriplePoint at an exercise price of $9.16 per share exercisable for seven years from March 22, 2019. We 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 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, we paid off the Growth Capital Loan in its entirety and recorded a $1.7 million loss on extinguishment of debt in the consolidated statements of operations.

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.

During 2019, cash used by operating activities of $18.1 million was a result of $25.1 million of net loss and the net negative change in operating assets and liabilities of $7.3 million, partially offset by non-cash negative adjustments to net income of $14.3 million.

Cash used by investing activities of $81.6 million during 2019 consisted of purchases of available-for-sale debt securities, net of maturities and sales, of $73.2 million, and cash used to acquire property and equipment of $8.4 million.

Cash provided by financing activities of $134.9 million during 2019 consisted primarily of $139.8 million of proceeds from initial public offering, net of underwriting discounts and commissions, $1.4 million of proceeds from issuance of common stock under employee stock plans, and net proceeds from the issuance of a Growth Capital Loan of $20.0 million, partially offset by cash used to repay a revolving loan and issue and repay the Growth Capital Loan of $26.3 million.

Investments in property and equipment

The Company's capital expenditures were $8.4 million during 2019, which was primarily related to the acquisition of property and equipment used for our sequencing and data analysis services.

Debt

We previously entered into various forms of convertible debt and revolving loans to finance our operations prior to our IPO. After our IPO, we paid off all remaining debt and now have zero outstanding debt balances as of 2019.

Further information regarding the Company's debt issuances can be found in Part II, Item 8 of this Form 10-K in the Notes to Consolidated Financial Statements in Note 6, "Borrowings."

Contractual Obligations

As a "smaller reporting company", we are not required to provide this disclosure.

Off-balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2019.

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, revenues, 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 the accounting policies discussed below have the greatest potential impact on our consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

Revenue Recognition

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

On January 1, 2017, we early adopted the new accounting standard ASC Topic 606 using the full retrospective method. Results for reporting periods beginning after January 1, 2017, are presented under ASC Topic 606. The impact of adopting ASC Topic 606 was not material on our consolidated financial statements.

Revenue Recognition

We generate our revenues 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.

Upon adoption of ASC Topic 606, 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 all 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 are 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 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. 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 applies judgment in evaluating when a customer obtains control of the promised service, which is when the sequencing and data analysis service results are delivered to customers, at an amount that reflects the consideration to which we expect to be entitled to in exchange for those services. 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 revenues upon providing sequencing and data analysis services.

All of our revenues and trade receivables are generated from contracts with customers and substantially all of our revenues are derived from U.S. domestic operations. The following section describes the accounting policies that we believe have significant judgment, or changes in judgment, as a result of adopting ASC Topic 606.

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.

Convertible Preferred Stock Warrants

We accounted for warrants to purchase shares of our redeemable convertible preferred stock as liabilities at their estimated fair value because the warrants may have obligated us to transfer assets to the holders at a future date upon a deemed liquidation event. The warrants were recorded at fair value upon issuance and were subject to remeasurement to fair value at each period end, with any fair value adjustments recognized in the consolidated statements of operations and comprehensive loss. We adjusted the warrant liability for changes in fair value until the conversion of redeemable convertible preferred stock into common stock.

Common Stock Warrants

Our common stock warrants are classified as equity as they meet all criteria for equity classification. The common stock warrants were recorded at fair value upon issuance, or conversion to common stock warrants in the case of our convertible preferred stock warrants, as additional paid-in-capital in the consolidated balance sheets. The common stock warrants are not subsequently remeasured.

Convertible Instruments

We evaluate and account for conversion options embedded in convertible instruments in accordance with ASC Topic 815, *Derivatives and Hedging Activities.* Applicable GAAP requires companies to bifurcate conversion options from their host instruments and account for them as freestanding derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not remeasured at fair value under other GAAP with changes in fair value reported in earnings as they occur, and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, using a fair value-based method, for costs related to all stock-based payments including stock options and stock awards. Our determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option-pricing model.

The fair value of the option granted is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period which usually is the vesting period, on a straight-line basis.

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, the volatility data was estimated based on a study of publicly traded industry peer companies. 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 equity-settled award.

We estimated the fair value of the time-based employee stock options using the Black-Scholes option-pricing model based on the date of grant with the following assumptions:

Common Stock Valuations

The estimated fair value of the common stock underlying our stock options was determined at each grant date by our board of directors, with input from management. All options to purchase shares of our common stock are intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant.

In the absence of a public trading market for our common stock prior to our IPO, on each grant date, we developed an estimate of the fair value of our common stock based on the information known to us on the date of grant, upon a review of any recent events and their potential impact on the estimated fair value per share of the common stock, and in part on input from an independent third-party valuation firm. As provided in Section 409A of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), we generally relied on our valuations for up to 12 months unless we experienced a material event that would have affected the estimated fair value per common share.

Our valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the "Practice Aid"). The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise using the "backsolve" method, which estimates the fair value of our company by reference to the value and preferences of our last round of financing, as well as our capitalization.

The assumptions used to determine the estimated fair value of our common stock were based on numerous objective and subjective factors, combined with management's judgment, including external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry:

- our stage of development;

- the rights, preferences, and privileges of our redeemable convertible preferred stock relative to those of our common stock;

- the prices at which we sold shares of our redeemable convertible preferred stock;

- our financial condition and operating results, including our levels of available capital resources;

- the progress of our research and development efforts, our stage of development, and business strategy;

- equity market conditions affecting comparable public companies; and

- general U.S. market conditions and the lack of marketability of our common stock.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- *Income approach*. The income approach attempts to value an asset or security by estimating the present value of the future economic benefits it is expected to produce. These benefits can include earnings, cost savings, tax deductions, and disposition proceeds from the asset. An indication of value may be developed in this approach by discounting expected cash flows to their present value at a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation over the asset's holding period, and the risks associated with realizing the cash flows in the amounts and at the times projected. The discount rate selected is typically based on rates of return available from alternative investments of similar type and quality as of the valuation date. The most commonly employed income approach to valuation is the discounted cash flow analysis.

- *Market Approach*. The market approach attempts to value an asset or security by examining observable market values for similar assets or securities. Sales and offering prices for comparable assets are adjusted to reflect differences between the asset being valued and the comparable assets, such as, location, time and terms of sale, utility, and physical characteristics. When applied to the valuation of equity, the analysis may include consideration of the financial condition and operating performance of the company being valued relative to those of publicly traded companies or to those of companies acquired in a single transaction, which operate in the same or similar lines of business.

- *Cost Approach*. The cost approach to valuation is based upon the concept of replacement cost as an indicator of value and the notion that an investor would pay no more for an asset than what it would cost to replace the asset with one of equal utility. The cost approach estimates value based upon the estimated cost of replacing or reproducing the asset, less adjustments for physical deterioration and functional obsolescence, if relevant. When applied to an enterprise, a type of cost approach referred to as the Net Asset Method is sometimes employed. This method measures the value of equity as the sum of the values of its assets reduced by the sum of the values of its liabilities. The resulting equity is reflective of a 100% ownership interest in the business. This approach is frequently used in valuing holding companies.

Based on our early stage of development and other relevant factors, we considered all three approaches and chose to apply both income and market approaches in our analyses. We determined these approaches were the most appropriate methods for allocating our enterprise value to determine the estimated fair value of our common stock for valuations performed for periods up to our IPO. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Following our IPO, our board of directors determines the fair value of our common stock based on the closing quoted market price of our common stock on the date of grant.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement.

We have elected to account for the tax on Global Intangible Low-Taxed Income, enacted as part of the Tax Cuts and Jobs Act as a component of tax expense in the period in which the tax is incurred.

JOBS Act Accounting Election

We are 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. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and therefore, we will be subject to the same new or revised accounting standards as other public companies that are not 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, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 55,046	$ 19,744
Short-term investments	73,243	—
Accounts receivable, net	3,300	4,457
Inventory and other deferred costs	4,606	3,432
Prepaid expenses and other current assets	3,383	1,926
Total current assets	139,578	29,559
Property and equipment, net	14,106	11,452
Operating lease right-of-use assets	1,845	—
Other long-term assets	1,762	659
Total assets	$ 157,291	$ 41,670
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 7,337	$ 6,565
Accrued and other current liabilities	6,648	3,392
Contract liabilities	35,977	42,897
Short-term debt	—	4,996
Total current liabilities	49,962	57,850
Redeemable convertible preferred stock warrant liability	—	683
Other long-term liabilities	639	121
Total liabilities	50,601	58,654
Commitments and Contingencies (Note 12)		
Redeemable convertible preferred stock	—	89,404
Stockholders' equity (deficit)		
Common stock, $0.0001 par value — 200,000,000 shares authorized and 31,243,029 shares issued and outstanding as of December 31, 2019; 102,700,000 shares authorized and 3,085,307 shares issued and outstanding as of December 31, 2018	3	1
Additional paid-in capital	247,282	9,131
Accumulated other comprehensive loss	(6)	(15)
Accumulated deficit	(140,589)	(115,505)
Total stockholders' equity (deficit)	106,690	(106,388)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 157,291	$ 41,670

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,		
	2019	2018	2017
Revenues	$ 65,207	$ 37,774	$ 9,393
Costs and expenses			
Costs of revenues	43,127	25,969	11,736
Research and development	22,418	14,304	9,919
Selling, general and administrative	22,080	11,271	9,901
Total costs and expenses	87,625	51,544	31,556
Loss from operations	(22,418)	(13,770)	(22,163)
Interest income	1,620	293	100
Interest expense	(1,133)	(1,894)	(1,303)
Loss on debt extinguishment	(1,704)	(4,658)	—
Other (expense) income, net	(1,440)	150	(227)
Loss before income taxes	(25,075)	(19,879)	(23,593)
Provision for income taxes	(9)	(7)	(5)
Net loss	$ (25,084)	$ (19,886)	$ (23,598)
Net loss per share, basic and diluted	$ (1.39)	$ (6.49)	$ (7.78)
Weighted-average shares outstanding, basic and diluted	18,011,470	3,063,157	3,031,636

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (25,084)	$ (19,886)	$ (23,598)
Other comprehensive income (loss), net of tax			
Foreign currency translation adjustment	3	(5)	7
Change in unrealized gain on available-for-sale debt securities	6	—	—
Comprehensive loss	$ (25,075)	$ (19,891)	$ (23,591)

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 Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2016	16,806,745	$ 75,995	3,020,842	$ 1	$ 2,196	$ (17)	$ (72,021)	$ (69,841)
Proceeds from exercise of stock options	—	—	30,625	—	76	—	—	76
Stock-based compensation	—	—	—	—	753	—	—	753
Foreign currency translation adjustment	—	—	—	—	—	7	—	7
Net loss	—	—	—	—	—	—	(23,598)	(23,598)
Balance—December 31, 2017	16,806,745	75,995	3,051,467	1	3,025	(10)	(95,619)	(92,603)
Equity component credited to additional paid-in capital upon Convertible Notes modification on May 31, 2018 and August 20, 2018 (see Note 6)	—	—	—	—	4,690	—	—	4,690
Convertible Notes conversion on September 20, 2018 (see Note 6); including issuance of Series C redeemable convertible preferred stock	1,667,997	13,409	—	—	—	—	—	—
Proceeds from exercise of stock options	—	—	33,840	—	99	—	—	99
Stock-based compensation	—	—	—	—	1,317	—	—	1,317
Foreign currency translation adjustment	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(19,886)	(19,886)
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 Notes 2 and 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 expenses	—	—	9,109,725	1	139,827	—	—	139,828
Proceeds from exercise of stock options	—	—	287,932	—	713	—	—	713
Proceeds from ESPP purchase	—	—	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

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (25,084)	$ (19,886)	$ (23,598)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	4,748	3,066	1,216
Noncash operating lease cost	982	—	—
Stock-based compensation expense	4,858	1,317	753
Loss on debt extinguishment	1,704	4,658	—
Change in fair value of convertible preferred stock warrant liability	1,403	391	64
Change in fair value of compound derivative instrument	—	(574)	162
Accretion of noncash interest and debt reduction	156	1,188	928
Other	427	(5)	6
Changes in operating assets and liabilities			
Accounts receivable	1,069	(2,519)	(1,203)
Inventories and other deferred costs	(1,174)	(2,068)	(539)
Prepaid expenses and other assets	(2,559)	(1,265)	177
Accounts payable	1,398	2,164	2,635
Accrued and other current liabilities	1,999	997	684
Contract liabilities	(6,920)	18,207	19,072
Other long-term liabilities	(1,076)	(99)	(67)
Net cash (used in) provided by operating activities	(18,069)	5,572	290
Cash flows from investing activities:			
Purchase of available-for-sale debt securities	(78,897)	—	—
Proceeds from maturities of available-for-sale debt securities	5,700	—	—
Purchase of property and equipment	(8,382)	(7,852)	(5,158)
Net cash used in investing activities	(81,579)	(7,852)	(5,158)
Cash flows from financing activities:			
Proceeds from initial public offering, net of underwriting discounts and commissions	144,025	—	—
Payment of costs related to initial public offering	(4,197)	—	—
Proceeds from borrowings	20,000	—	17,225
Payments of borrowing costs	(490)	—	(63)
Repayments under borrowing arrangements	(25,000)	(645)	(823)
Debt extinguishment costs	(794)	—	—
Proceeds from issuance of common stock under ESPP	684	—	—
Proceeds from exercise of stock options	712	76	65
Other	8	(22)	—
Net cash provided by (used in) financing activities	134,948	(591)	16,404
Effect of exchange rates on cash flows and cash equivalents	2	(2)	4
Net increase (decrease) in cash and cash equivalents	35,302	(2,873)	11,540
Cash and cash equivalents, beginning of period	19,744	22,617	11,077
Cash and cash equivalents, end of period	$ 55,046	$ 19,744	$ 22,617
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 1,257	$ 698	$ 321
Income taxes paid	$ 6	$ 7	$ 5
Supplemental disclosures of noncash investing and financing activities:			
Acquisition of property and equipment included in accounts payable and accrued liabilities	$ 41	$ 323	$ 521
Convertible Notes conversion on September 20, 2018 (see Note 6)	$ -	$ 13,431	$ -

See accompanying notes to consolidated financial statements.

Note 1. Company and Nature of Business

Description 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. The Company is a growing cancer genomics company transforming the development of next-generation therapies by providing more comprehensive molecular data about each patient's cancer and immune response. The Company operates and manages its business as one reportable operating segment, which is the sale of sequencing and data analysis services.

Significant Risks and Uncertainties

The Company has incurred net operating losses each year since inception. As of December 31, 2019, the Company had an accumulated deficit of $140.6 million.

In June 2019, the Company completed an initial public offering ("IPO") of its common stock and raised proceeds of $139.8 million, after deducting underwriting discounts, commissions and offering expenses. Management believes that these proceeds combined with existing sources of liquidity will be sufficient to fund operations for at least one year from the issuance of these consolidated financial statements. However, there can be no assurance that additional financing will not be required or that the Company will be successful in raising additional capital on terms that are acceptable to the Company.

If the Company requires but is unable to obtain additional funding, the Company could be required to modify, delay, or abandon some of its planned future expansion or expenditures or reduce some of its ongoing operating costs, which could harm its business, operating results, financial condition, and ability to achieve its intended business objectives.

Approval of Amended and Restated Certificate of Incorporation

An amended and restated certificate of incorporation, which authorized 200,000,000 shares of common stock and 10,000,000 shares of preferred stock, became effective in June 2019 in connection with the closing of the Company's IPO. As of December 31, 2019 no shares of preferred stock are outstanding.

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 subsidiary, Personalis (UK) 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 revenues and expenses during the reporting period. The estimates include, but are not limited to, useful lives assigned to long-lived assets, the valuation of common and convertible redeemable preferred stock and related warrants and options, the valuation of the compound derivative instrument, 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 20, 2019, the Company completed an 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, all of which were paid by December 31, 2019.

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, of which 62,096 are still outstanding as of December 31, 2019 (see Note 10).

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 has not experienced any losses on its deposits of cash and cash equivalents.

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 and zero as of December 31, 2019 and 2018, respectively. During the year ended December 31, 2019, bad debt expense was $0.1 million and included in selling, general and administrative expenses. The Company had no bad debt expense in 2018 and 2017.

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

	Revenue			Accounts Receivable	
	Year Ended December 31,			As of December 31,	
	2019	2018	2017	2019	2018
VA MVP	67%	49%	*	19%	*
Pfizer Inc.	13%	10%	*	23%	33%
Merck & Co., Inc.	*	12%	11%	*	10%
Customer A	*	*	13%	*	17%
Customer B	*	*	10%	*	10%
Indivumed GmbH	*	*	*	30%	*

* Less than 10% of revenues 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 revenues from sequencing and data analysis services to support the development of personalized cancer vaccines and other next-generation cancer immunotherapies. 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.

Costs of Revenues

The Company's costs of revenues primarily consist of production materials, personnel costs (e.g., salaries, bonuses, benefit, and stock-based compensation), cost of expensed equipment, consumables and laboratory supplies, information technology ("IT") and facility costs, and depreciation and service maintenance contracts on capitalized equipment.

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 employee-related costs (including stock-based compensation), laboratory and automation supplies and equipment, and related depreciation and amortization expenses.

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 the options using the Black-Scholes option-pricing model. The Company determines 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 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 is deemed to be a compensatory plan and therefore is included in stock-based compensation expense.

Foreign Currency Translation

The functional currency of the Company's foreign subsidiary is the British pounds sterling. In preparing its consolidated financial statements, the Company is required to translate the financial statements of this subsidiary from British pounds sterling to U.S. dollars. Accordingly, monetary assets and liabilities of the Company's subsidiary are remeasured using exchange rates in effect at the end of the period. Costs in the local currency are remeasured using average exchange rates for the period, except for costs related to those consolidated balance sheet items that are remeasured using historical exchange rates. Since the Company's functional currency is deemed to be the local currency, any gain or loss associated with the translation of its consolidated financial statements is included as a component of stockholders' equity (deficit), in accumulated other comprehensive income (loss).

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.

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 stock options 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 loss in stockholders' equity (deficit). 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 (expense) income, net. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity (deficit) is reclassified out of stockholders' equity (deficit) 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 values 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

Inventories, consisting of supplies used in the Company's sequencing and data 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 sequencing and data analysis contracts that have not been completed or recognized as revenues. 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 operations 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.

Internally used software, whether purchased or developed, is capitalized at cost and amortized on a straight-line basis over its estimated useful life. Costs associated with internally developed software are expensed until the point at which the project has reached the development stage. Subsequent additions, modifications, or upgrades to internal-use software are capitalized only to the extent that they provide additional functionality. Software maintenance and training costs are expensed in the period in which they are incurred. The capitalization of software requires judgment in determining when a project has reached the development stage and the period over which the Company expects to benefit from the use of that software.

Compound Derivative Instrument

The convertible notes issued in June 2017 (see Note 6) contained embedded features that provided the lenders with multiple settlement alternatives. Certain of these settlement features provided the lenders a right to a fixed number of the Company's shares upon conversion of the notes (the "conversion option"). Other settlement features provided the lenders the right or the obligation to receive cash or a variable number of shares upon the completion of a capital-raising transaction, change of control, or default of the Company (the "redemption features").

Certain conversion and redemption features embedded in the convertible notes met the requirements for separate accounting and were accounted for as a single, compound derivative instrument. The compound derivative instrument was recorded at fair value at inception and was subject to remeasurement to fair value at each consolidated balance sheet date, with the change in fair value reflected as other (expense) income in the consolidated statements of operations. The compound derivative instrument was recorded as a compound derivative liability at fair value, which was $0.5 million as of the issuance date and zero and $0.7 million as of December 31, 2018 and 2017, respectively (see Note 5). Upon modification of the convertible notes on August 20, 2018 (see Note 6), the compound derivative instrument was eliminated.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU No. 2014-09"). Subsequently, the FASB also issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606), which adjusted the effective date of ASU No. 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which amends the principal-versus-agent implementation guidance and illustrations in ASU No. 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies identifying performance obligation and licensing implementation guidance and illustrations in ASU No. 2014-09; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU No. 2014-09 (collectively, the "Revenue ASUs").

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenues arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2017. The guidance permits two methods of adoption: retrospectively to

each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company performed a detailed review of its revenue agreements and assessed the differences in accounting for such contracts under this guidance compared with previous revenue accounting standards. On January 1, 2017, the Company early adopted ASU No. 2014-09 using the full retrospective method. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. Results for all periods presented are under ASC Topic 606.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU No. 2016-02"). In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases, which provides clarification to ASU 2016-02. These ASUs (collectively, the "new lease standard") require an entity to recognize a lease liability and a right-of-use ("ROU") asset on the balance sheet for leases with lease terms of more than 12 months. Lessor accounting is largely unchanged, while lessees will no longer be provided with a source of off-balance sheet financing. This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842) —Targeted Improvements, which allows entities to elect a modified retrospective transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoption rather than in the earliest period presented.

On January 1, 2019, the Company adopted ASU No. 2016-02, and its associated amendments using the modified retrospective transition method by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. There was no cumulative-effect adjustment recorded to retained earnings upon adoption. Under the standard, a lessee is required to recognize a lease liability and ROU asset for all leases. The new guidance also modified the classification criteria and requires additional disclosures to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. Consistent with current guidance, a lessee's recognition, measurement, and presentation of expenses and cash flows arising from a lease continues to depend primarily on its classification. The Company elected the package of practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification, its assessment as to whether a contract was or contains a lease, and its initial direct costs for any leases that existed prior to January 1, 2019. The Company also elected the practical expedient not to separate lease and non-lease components. In addition, the Company elected the short-term lease exception as a practical expedient.

At the date of adoption, the Company derecognized a deferred rent liability in the amount of $0.3 million, and recognized a ROU asset and respective lease liability in the amount of $1.7 million and $2.0 million, respectively. As of December 31, 2019, lease liabilities in the amount of $1.4 million and $0.6 million are included in "Accrued and other current liabilities" and "Other long-term liabilities," respectively.

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 of 2019, the FASB delayed the effective date for Smaller Reporting Companies to the first quarter of 2023. 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

The Company is 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 has irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and therefore, the Company will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Note 3. Revenues

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

	Year Ended December 31,		
	2019	2018	2017
VA MVP	$ 43,545	$ 18,601	$ 421
All other customers	21,662	19,173	8,972
Total	$ 65,207	$ 37,774	$ 9,393

Revenues from countries outside of the United States, based on the billing addresses of customers, represented 4%, 3%, and 2% of the Company's revenues for the years ended December 31, 2019, 2018 ,and 2017, respectively.

Contract Assets and Liabilities

The Company had no contract assets as of December 31, 2019 and 2018.

The Company's contract liabilities consist of customer deposits in excess of revenues recognized and are presented as current liabilities in the consolidated balance sheets.

The balance of contract liabilities was $36.0 million and $42.9 million as of December 31, 2019 and 2018, respectively. Revenues recognized in 2019, 2018, and 2017 that were included in the contract liability balance at the beginning of each reporting period were $35.4 million, $16.0 million, and $1.1 million, respectively.

Revenues allocated to remaining performance obligations represent contracted revenues that have not yet been recognized ("contracted not recognized revenues"), which include VA MVP contract liabilities and amounts that will be invoiced and recognized as revenues in future periods. Contracted not recognized revenues were $68.8 million as of December 31, 2019, which we expect to recognize as revenues over the next 15 months.

Note 4. Balance Sheet Details

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

	December 31,	
	2019	2018
Raw materials	$ 1,424	$ 2,134
Other deferred costs	3,182	1,298
Total inventory and other deferred costs	$ 4,606	$ 3,432

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

	December 31,	
	2019	2018
Machinery and equipment	$ 12,511	$ 7,951
Computer equipment	8,855	6,822
Furniture and fixtures	368	150
Leasehold improvement	987	1,016
Capitalized software costs	—	182
Computer software costs	198	202
Construction in progress	234	333
Total	$ 23,153	$ 16,656
Less: Accumulated depreciation and amortization	(9,047)	(5,204)
Property and equipment, net	$ 14,106	$ 11,452

Depreciation and amortization expense for the years ended December 31, 2019, 2018, and 2017 was $4.7 million, $3.1 million, and $1.2 million, respectively.

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

	December 31,	
	2019	2018
Accrued compensation	$ 4,147	$ 2,843
Operating lease right-of-use liabilities	1,361	—
Accrued liabilities	689	59
Accrued taxes	210	181
Accrued interest	—	207
Deferred rent	—	99
Other current liabilities	241	3
Total accrued and other current liabilities	$ 6,648	$ 3,392

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, 2019 and 2018 (in thousands):

	As of December 31, 2019				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents					
Cash	$ 1,271	$ —	$ —	$ 1,271	
Money market funds	12,495	—	—	12,495	Level 1
Commercial paper	41,281	—	(1)	41,280	Level 2
Total cash and cash equivalents	55,047	—	(1)	55,046	
Short-term investments					
Commercial paper	17,898	—	(6)	17,892	Level 2
U.S. government securities	4,011	—	—	4,011	Level 2
Corporate debt securities	13,953	1	(6)	13,948	Level 2
U.S. agency securities	32,776	20	(2)	32,794	Level 2
Asset-backed securities	4,598	—	—	4,598	Level 2
Total short-term investments	73,236	21	(14)	73,243	
Total assets measured at fair value	$ 128,283	$ 21	$ (15)	$ 128,289	

	As of December 31, 2018				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents					
Cash	$ 1,602	$ —	$ —	$ 1,602	
Money market funds	18,142	—	—	18,142	Level 1
Total cash and cash equivalents	19,744	—	—	19,744	
Total assets measured at fair value	$ 19,744	$ —	$ —	$ 19,744	
Liabilities					
Long-term liabilities					
Convertible preferred stock warrants liability				$ 683	Level 3
Total liabilities measured at fair value				$ 683	

There have been no realized gains or losses on sales of marketable securities for the periods presented. The Company began investing in marketable debt securities during the third quarter of 2019 and, therefore, 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, 2019, 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, 2019 have maturities due in one year or less, except for debt securities with an aggregate cost basis and fair value of $3.0 million that have maturities of 13 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	Year Ended December 31, 2018	Year Ended December 31, 2017
Expected term (in years)	5.01 - 5.26	5.17 - 7.00	6.75 - 7.50
Volatility	57.20% - 57.24%	55.56% - 56.42%	56.07% - 69.87%
Risk-free interest rate	1.75%	2.58% - 3.01%	1.97% - 2.33%
Dividend yield	–%	–%	–%

The fair value of the compound derivative instrument was estimated at the date of inception in June 2017 and at each subsequent consolidated balance sheet date using a hybrid method that combines probability-weighted and with-or-without methods using unobservable inputs, which are classified as Level 3 within the fair value hierarchy. The primary inputs for this approach included the probability of achieving various settlement scenarios that provide the lenders the right or the obligation to receive cash or a variable number of shares upon the completion of a capital transaction. The probability assumptions related to estimating various settlement scenarios as of December 31, 2018 and 2017, and the inception date ranged between 0.2% and 70%, and a discount rate of 35.1% was applied to estimated future cash flows. After the initial measurement, changes in the fair value of this compound derivative were recorded in other income (expense), net.

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	Derivative Asset	Derivative Liability
Balance—December 31, 2016	$ 59	$ —	$ —
Issuance of convertible preferred stock warrants	169	—	—
Initial fair value of derivative liability	—	—	509
Change in fair value	64	—	162
Balance—December 31, 2017	$ 292	$ —	$ 671
Initial fair value of derivative asset	—	623	—
Change in fair value	391	(97)	(671)
Elimination as a result of debt extinguishment	—	(526)	—
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. Borrowings

Amounts outstanding under the Company's financing arrangements consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Credit agreement		
Revolving Loan	$ —	$ 5,000
Total principal payments due	$ —	$ 5,000
Less: Reduction in carrying value	—	(4)
Total amounts outstanding	$ —	$ 4,996
Less: Current portion	—	(4,996)
Long-Term portion	$ —	$ —

Term Loan

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"). On October 3, 2014, the Company borrowed $2.4 million under the Term Loan. The Term Loan required 12 interest-only payments, followed by 36 equal monthly installments of principal, plus interest, which began on October 3, 2015.

In connection with the Term Loan, the Company issued to the bank a warrant exercisable for ten years from the date of grant to purchase 22,489 shares of the Company's Series B redeemable convertible preferred stock at an exercise price of $4.60 per share (see Note 10).

The estimated fair value of the warrants 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 four years for the Term Loan.

On September 30, 2018, the Term Loan was repaid in full.

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"). Borrowings under the Revolving Loan bear an interest rate of prime, plus 6.75%. The Revolving Loan also has a 5.5% end of term loan payment on the highest outstanding principal amount. The Revolving Loan requires 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 current credit facility was not greater than 10%, the Company accounted for the transaction as a debt modification.

As of December 31, 2018, the Company's outstanding principal under the Revolving Loan was $5.0 million and $5.0 million was available to borrow.

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 exercisable for seven years from June 28, 2017 (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. The Revolving Loan interest expense for the year ended December 31, 2018 was $0.9 million. Interest expense for the year ended December 31, 2019 was not material.

The Company accrued $0.2 million as of December 31, 2018 related to accretion of final payment due at maturity per the agreement using the effective interest rate method.

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 as of June 30, 2019, 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 exercisable for seven years from March 22, 2019. 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 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.

Convertible Notes

On June 29, 2017, the Company entered into a convertible promissory note agreement with certain existing redeemable convertible preferred stockholders and third parties (collectively, the "Investors") for the issuance of convertible promissory notes with a face value of $12.2 million (the "Convertible Notes"). Under the terms of the Convertible Notes agreement, the Convertible Notes bore interest of 8.00% per annum, with a maturity date of June 28, 2018. In the event that the Company issued and sold shares of its equity securities (the "Equity Securities") to Investors on or before the maturity date in an equity financing with total proceeds to the Company of not less than $10 million (including the conversion of the Convertible Notes or other convertible securities issued for capital raising purposes) (a "Qualified Financing"), then the outstanding principal amount of the Convertible Notes and any unpaid accrued interest would have automatically converted in whole without any further action by the holder into such Equity Securities sold in the Qualified Financing at a conversion price equal to the price paid per share for Equity Securities by the Investors in the Qualified Financing multiplied by 0.8. If the Company consummated a change of control while the Convertible Notes remained outstanding, the Company would have repaid the holders in cash an amount equal to 150% of the outstanding principal amount of the Convertible Notes, plus any unpaid accrued interest on the original principal. The Convertible Notes had customary events of default.

Certain conversion and redemption features of the Convertible Notes met the requirements for separate accounting and were accounted for as a single, compound derivative instrument. The compound derivative instrument was recorded at fair value at inception and was subject to remeasurement to fair value at each consolidated balance sheet date, with any changes in fair value recognized in the consolidated statements of operations as other (expense) income, net. The estimated fair value of the compound derivative instrument was $0.5 million at issuance and was recorded as a reduction in the carrying value of the Convertible Notes and as a single, compound derivative liability. The Convertible Notes carrying value reduction was accreted using the effective interest method as interest expense over the Convertible Notes contractual period of one year. The Convertible Notes had an effective interest rate of 12.69% per year.

On May 31, 2018, the original maturity date for the Convertible Notes was extended to June 28, 2019 (previously June 28, 2018). The maturity date extension was deemed substantial and was accounted for as a debt extinguishment. In connection with the debt extinguishment on May 31, 2018, the fair value of the Convertible Notes was allocated between the carrying amount of the Convertible Notes and accrued interest of $13.1 million, a compound derivative asset of $0.6 million, and an equity component of $3.9 million, which was credited to additional paid-in capital within the consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit). A $3.3 million loss on debt extinguishment was also recorded in the consolidated statements of operations. The new carrying value of the Convertible Notes was accreted using the effective interest method as interest expense over the new contractual period of 1.1 years.

On August 20, 2018, the maturity date for the Convertible Notes was extended to September 20, 2018 (previously June 28, 2019). The term change was deemed substantial and was accounted for as a debt extinguishment. In connection with the debt extinguishment on August 20, 2018, the fair value of the Convertible Notes was allocated between the new carrying amount of the Convertible Notes and accrued interest of $13.4 million, and an equity component of $0.8 million, which resulted in a credit to additional paid-in capital. Upon modification, the compound derivative asset was eliminated. A $0.8 million loss on debt extinguishment was also recorded in the consolidated statements of operations. The new carrying value of Convertible Notes was accreted using the effective interest method as interest expense over the new contractual period of one month.

On September 20, 2018, upon the maturity of the Convertible Notes, the carrying amount, including accrued interest of $13.4 million, was converted into 1,667,997 shares of the Company's Series C redeemable convertible preferred stock at a conversion price equal to $8.052 per share. No gain or loss was recorded on the conversion.

The Convertible Notes interest expense for the year ended December 31, 2018 was $0.9 million.

Note 7. Leases

Operating Lease Obligations

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 office space. The lease expires on November 30, 2020 and includes an option to extend the term for a period of three years immediately following the expiration of the term with rent payments equal to then current fair market rental for the space.

For the 2018 periods presented, the Company recognized rent expense on a straight-line basis over the noncancelable lease term. The Company's rent expense was $1.1 million for the year ended December 31, 2018.

In August 2019, the Company entered into a noncancelable operating lease for a co-located data center space. The lease expires on September 1, 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 adopted the new lease standard as of January 1, 2019. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. At the date of adoption, the Company determined the amounts of lease liability related to the laboratory and office space lease using a discount rate of 8.0%, which represented the Company's incremental borrowing rate. The Company determines its incremental borrowing rate for lease liability using its current borrowing rate, adjusted for various factors including level of collateralization and term. With respect to the lease for co-located data center space, the Company determined the amounts of lease liability using a discount rate of 6.6%, and the Company recognized a $1.1 million operating lease right-of-use asset and lease liability on the lease commencement date in September 2019. The Company determined that the optional renewal periods for both leases were not reasonably certain to be exercised as of the lease commencement dates. As a result, the optional renewal periods were not recognized as part of the right-of-use asset or lease liability.

Operating lease cost for the year ended December 31, 2019 was $1.1 million. Cash paid for operating lease liabilities, included in cash flow from operating activities in the Consolidated Statement of Cash Flows was $1.2 million for the year ended December 31, 2019. As of December 31, 2019, the weighted average remaining lease term for the operating leases was 1.8 years and the weighted average incremental borrowing rate was 7.3%.

Future minimum noncancelable operating lease payments at December 31, 2018, determined in accordance with the Company's historical lease accounting standard (ASC 840), were as follows (in thousands):

	Amount
2019	$ 1,091
2020	1,030
Total future minimum lease payments	$ 2,121

Future minimum lease payments under noncancelable operating leases as of December 31, 2019 were as follows (in thousands):

	Amount
2020	$ 1,408
2021	403
2022	319
Total future minimum lease payments	$ 2,130
Less: Imputed interest	(130)
Present value of future minimum lease payments	$ 2,000
Less: Current portion of operating lease liabilities	(1,361)
Operating lease liabilities - noncurrent	$ 639

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") 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					
(in thousands, except share and per share data)	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Issuance Costs	Net Carrying Value	Original Issuance Price Per Share
Series A	31,250,000	7,812,497	$ 20,500	$ 82	$ 20,261	$ 2.624
Series B	19,288,150	4,799,548	22,078	31	22,047	4.600
Series C	24,700,000	5,862,697	47,206	110	47,096	8.052
Total redeemable convertible preferred stock	75,238,150	18,474,742	$ 89,784	$ 223	$ 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 and 2019 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. The exercise price of an ISO granted to a 10% stockholder was not less than 110% of the estimated fair value of the shares on the date of grant, as determined by the board of directors (the "Board"). Options granted to new hires generally vested 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 vested monthly over a four-year period.

For stock option grants issued prior to December 31, 2015, the Company allowed employees to exercise options granted under the 2011 Plan prior to vesting (early exercise of stock options). The unvested shares are subject to the Company's repurchase rights at the original purchase price. Initially, the proceeds were recorded as an accrued liability from the early exercise of stock options and reclassified to common stock as the Company's repurchase rights lapsed. There were zero and 262 unvested shares subject to the Company's repurchase rights as of December 31, 2019 and 2018, respectively.

The Company's Board adopted and the Company's stockholders approved the Company's 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 our common stock on the date of grant. Options under the 2019 Plan may be granted for periods of up to 10 years.

At December 31, 2018 there were 4,647,839 shares of common stock available for issuance under the 2011 Plan. At December 31, 2019 there were 4,474,057 shares of common stock available for issuance under the 2011 Plan and 2,769,721 available for issuance under the 2019 Plan.

Stock Option Activity

A summary of the Company's stock option activity under the 2011 Plan and 2019 Plan for the year ended December 31, 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, 2016	2,112,394	$ 1.76	6.41	$ 2,451
Options granted	898,510	2.44		
Options exercised	(30,625)	2.12		15
Options cancelled	(95,752)	3.20		
Balance—December 31, 2017	2,884,527	$ 1.92	6.61	$ 5,860
Options granted	1,386,464	5.68		
Options exercised	(34,426)	2.80		96
Options cancelled	(126,435)	2.96		
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 vested and exercisable as of December 31, 2019	2,841,458	$ 2.97	5.13	$ 22,858

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $10.90 on December 31, 2019 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 $8.00, $5.68, and $2.44 per share for the twelve months ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, the unrecognized stock-based compensation of unvested options was $9.6 million, which is expected to be recognized over a weighted-average period of 2.8 years.

Restricted Stock Units Activity

A summary of the Company's RSUs activity under the 2019 Plan for the year ended December 31, 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

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 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 $10.90 on December 31, 2019.

Amortization of stock-based compensation expense related to RSUs in 2019 was not material. As of December 31, 2019, the unrecognized stock-based compensation of unvested RSUs was $1.0 million, which is expected to be recognized over a weighted-average period of 2.9 years.

Valuation of Stock Options

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The fair value of stock options is recognized on a straight-line basis over the requisite service periods of the awards.

The fair value of stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	5.00 - 6.87	1.50 - 6.35	5.97 - 6.95
Volatility	56.20 - 63.08%	52.19 - 56.47%	56.05 - 65.78%
Risk-free interest rate	1.53 - 2.52%	2.62 - 2.88%	1.88 - 2.10%
Dividend yield	–%	–%	–%

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 maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting tranches, the times from grant until the midpoints for each of the tranches may be averaged to provide an overall expected term.

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 Yield. 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.

2019 Employee Stock Purchase Plan

In May 2019, the Board adopted the 2019 Employee Stock Purchase Plan (the "ESPP"), which was approved by the Company's stockholders in June 2019. A total of 250,000 shares of common stock are initially reserved for issuance under the ESPP. The number of shares may be increased in accordance with the terms of the ESPP.

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. Except for the initial offering period, the ESPP provides for separate six-month offering periods beginning on May 1 and November 1 of each year. The initial offering period ran from June 20, 2019 through October 31, 2019.

During the year ended December 31, 2019, 77,684 shares of common stock were purchased under the ESPP. The total compensation expense related to the ESPP for the year ended December 31, 2019 was $0.3 million. The following range of assumptions were used to calculate stock-based compensation for each stock purchase right granted under the ESPP: weighted-average expected life of 0.37 – 0.5 years; expected volatility of 59.1 – 59.9%; risk-free interest rate of 1.6 - 2.1%; and a zero dividend yield.

Stock-based Compensation Expense

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

	Year Ended December 31,		
	2019	2018	2017
Costs of revenues	$ 480	$ 177	$ 74
Research and development	903	429	225
Selling, general, and administrative	3,475	711	454
Total stock-based compensation expense	$ 4,858	$ 1,317	$ 753

During the year ended December 31, 2019, 67,418 shares with performance conditions vested. The awards were subject to two vesting criteria: (i) a time-based service criterion, and (ii) a performance criterion of an initial public offering, which were met in connection with our June 20, 2019 IPO. The Company recognized $0.3 million of stock-based compensation expense for all such awards. During the years ended December 31, 2018 and 2017, no shares with performance conditions vested and no stock-based compensation expense was recognized related to shares with performance conditions.

Note 10. Redeemable Convertible Preferred Stock Warrants

In September 2014, in connection with the Term Loan (see Note 6), 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. The estimated fair value of the Series B convertible preferred stock warrant on the date of issuance of $0.1 million was recorded as a debt reduction. As of the issuance date, the fair value of the Series B convertible preferred stock warrant was calculated using the Black-Scholes option-pricing model and was based on a contractual term of ten years, a risk-free interest rate of 2.52%, expected volatility of 66.53%, and 0% expected dividend yield.

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, subject to certain adjustments, such as any stock splits, stock dividends, recapitalizations, reclassifications, combinations, or similar transactions. The remaining term of the Series C convertible preferred stock warrant is seven years from June 28, 2017.

The estimated fair value of the Series C convertible preferred stock warrant on the date of issuance of $0.1 million was recorded as a debt reduction. As of the issuance date, the fair value of the Series C convertible preferred stock warrant was calculated using the Black-Scholes option-pricing model and was based on a contractual term of seven years, a risk-free interest rate of 1.97%, expected volatility of 64.33%, and 0% expected dividend yield.

At initial recognition, the convertible preferred stock warrants were recorded at their estimated fair values and were subject to remeasurement at each consolidated balance sheet date, with changes in fair value recognized as a component of net income. As of December 31, 2018, the fair values of the convertible preferred stock warrants were calculated to be $0.7 million.

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 are now 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 common stock warrant for 22,489 shares was exercised. As a result, the Company issued 19,069 shares of common stock as the contract allows a net share settlement. Separately, the common stock warrant issued in June 2017 for 62,096 shares was still outstanding as of December 31, 2019.

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 as of December 31, 2019.

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 exercisable for seven years from March 22, 2019. 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 is still outstanding as of December 31, 2019.

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, 2019, 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. Net Loss per Share Attributable to Common Stockholders

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Because the Company reported a net loss for the years ended December 31, 2019, 2018, and 2017, the number of shares used to calculate diluted net loss per common share is the same as the number of shares used to calculate basic net loss per common share for those periods presented because the potentially dilutive shares would have been antidilutive if included in the calculation.

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 data):

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net loss attributable to common stockholders	$ (25,084)	$ (19,886)	$ (23,598)
Denominator:			
Weighted-average shares outstanding	18,011,955	3,063,516	3,035,791
Less: Weighted-average shares subject to repurchase	(485)	(359)	(4,155)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders — basic and diluted	18,011,470	3,063,157	3,031,636
Net loss per share attributable to common stockholders—basic and diluted	$ (1.39)	$ (6.49)	$ (7.78)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Year Ended December 31,		
	2019	2018	2017
Redeemable convertible preferred stock	—	18,474,742	16,806,746
Conversion of Convertible Notes[1]	—	—	1,580,151
Common stock warrants	127,598	188,643	188,643
Series B preferred stock warrant	—	22,489	22,489
Series C preferred stock warrant	—	62,096	62,096
Options to purchase common stock	4,731,435	4,110,130	2,884,527
Unvested early exercised common stock options	—	262	2,213
Unvested Restricted Stock Units	120,000	—	—
Employee Stock Purchase Plan	75,405	—	—
Total	5,054,438	22,858,362	21,546,865

(1) Calculated as $12.2 million principal and $0.5 million accrued but unpaid interest as of December 31, 2017.

Note 14. Income Taxes

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

	Year Ended December 31,		
	2019	2018	2017
Domestic	$ (25,111)	$ (19,897)	$ (23,613)
Foreign	36	18	20
Loss before income taxes	$ (25,075)	$ (19,879)	$ (23,593)

Provision for Income Taxes

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

	Year Ended December 31,		
	2019	2018	2017
Current:			
Federal	$ —	$ —	$ —
State	1	2	1
Foreign	8	5	4
Total current	9	7	5
Provision for income taxes	$ 9	$ 7	$ 5

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 2019 and 2018; and 35% to pretax loss in 2017 as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Federal statutory rate	(21)%	(21)%	(35)%
Effect of:			
State taxes	(8)%	(3)%	(7)%
Change in valuation allowance	28%	21%	(9)%
Rate impact due to tax reform	–%	–%	51%
Research and development credit	(3)%	(3)%	(2)%
Debt extinguishment	–%	4%	–%
Other	4%	2%	2%
Effective tax rate	–%	–%	–%

Tax Law Changes

The U.S. Tax Cuts and Jobs Act (the "Tax Act") was enacted on December 22, 2017. The Tax Act reduced the U.S. federal corporate tax rate from 35% in 2017 to 21% in 2018, required companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, and created new taxes on certain foreign sourced earnings. For the year ended December 31, 2017, the Company remeasured its deferred tax assets and liabilities based on the change in the federal rate to 21%. At December 31, 2018, the Company had completed its accounting for the Tax Act, which, other than the decrease in its gross deferred tax assets, did not have a material impact on the Company's 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):

	As of December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 30,375	$ 22,441
Research and development credits	6,190	4,634
Deferred revenue	2,154	4,839
Accruals	784	460
Stock-based compensation	787	297
Inventory	—	42
Operating lease liabilities	574	—
Other intangibles	426	458
Other	114	3
Total gross deferred tax assets	41,404	33,174
Less: Valuation allowance	(40,000)	(32,423)
Net deferred tax assets	$ 1,404	$ 751
Deferred tax liabilities:		
Property and equipment	(875)	(751)
Operating lease right-of-use assets	(529)	—
Net deferred tax liabilities	$ (1,404)	$ (751)

Realization of our deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Because of our 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 $7.6 million and $4.5 million for the years ended December 31, 2019 and 2018, respectively.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2019, the Company had net operating loss carryforwards for federal income tax purposes of approximately $114.9 million, portions of which will begin to expire in 2031. The Company had a total state net operating loss carryforward of approximately $72.2 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.

The Company has federal credits of approximately $3.0 million, which will begin to expire in 2031 and state research credits of approximately $3.2 million, which have no expiration date. These tax credits are subject to the same limitations discussed above.

Unrecognized Tax Benefits

The Company has incurred net operating losses since inception and does not have any significant unrecognized tax benefits. The Company's policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the consolidated statements of operations. If the Company is eventually able to recognize its uncertain positions, the effective tax rate would be reduced. The Company currently has a full valuation allowance against its net deferred tax asset, 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 of the Company's tax years remain open to examination.

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

	As of December 31,	
	2019	2018
Beginning balance	$ 1,192	$ 917
Gross increase—tax provision in current period	389	275
Ending balance	$ 1,581	$ 1,192

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, 2019, 2018, and 2017, no significant interest or penalties were required to be recognized relating to unrecognized tax benefits.

Note 15. Selected Quarterly Financial Information (Unaudited)

The following tables show a summary of the Company's quarterly financial information for each of the four quarters of 2019 and 2018 (in thousands, except per share amounts):

	For the Three Months Ended (Unaudited)			
	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Revenues	$ 18,154	$ 17,153	$ 15,825	$ 14,075
Gross profit	$ 6,565	$ 5,629	$ 5,902	$ 3,984
Net loss	$ (6,645)	$ (6,885)	$ (5,869)	$ (5,685)
Basic and diluted earnings per share	$ (0.21)	$ (0.22)	$ (0.89)	$ (1.84)

	For the Three Months Ended (Unaudited)			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Revenues	$ 13,157	$ 11,654	$ 8,799	$ 4,164
Gross profit	$ 4,829	$ 4,481	$ 2,396	$ 99
Net loss	$ (3,555)	$ (3,641)	$ (7,315)	$ (5,375)
Basic and diluted earnings per share	$ (1.16)	$ (1.19)	$ (2.39)	$ (1.76)

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 subsidiary (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ DELOITTE & TOUCHE LLP

San Jose, California
March 25, 2020

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our 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, 2019, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures.

Changes in internal control

During the fourth quarter of 2019, we remediated the material weaknesses in our internal control over financial reporting identified in connection with preparation of our financial statements for the years ended December 31, 2017 and 2018. The material weakness in internal controls was due to a lack of sufficient full-time accounting staff with requisite experience and deep technical accounting knowledge to (i) identify and resolve complex accounting issues under U.S. GAAP and (ii) allow for appropriate segregation of duties. Remediation of the material weakness involved hiring a Chief Financial Officer in March 2019 and four additional accounting resources in the second, third, and fourth quarters of 2019, including two Certified Public Accountants with the specific technical accounting and financial reporting experience necessary for a public company. Management believes these additional resources provide an appropriate remediation of the material weakness.

Management report on internal control over financial reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

In addition, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting for so long as we qualify as an “emerging growth company,” as defined under the JOBS Act.

Item 9B. Other Information.

None.

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 2020 Proxy Statement to be filed with the SEC within 120 days after December 31, 2019 in connection with the solicitation of proxies for the Company’s 2020 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 2020 Proxy Statement to be filed with the SEC within 120 days after December 31, 2019, 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, 2019” and “Security Ownership of Certain Beneficial Owners and Management” in the Company’s 2020 Proxy Statement to be filed with the SEC within 120 days after December 31, 2019, 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 2020 Proxy Statement to be filed with the SEC within 120 days after December 31, 2019, 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 2020 Proxy Statement to be filed with the SEC within 120 days after December 31, 2019, 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.				
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
4.4	Warrant to purchase capital stock of the Registrant, issued to TriplePoint Capital LLC, dated September June 28, 2017.	S-1	333-231703	4.4	5/23/2019
4.5	Warrant to purchase capital stock of the Registrant, issued to TriplePoint Capital LLC, dated September March 22, 2019.	S-1	333-231703	4.5	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 Clinton Musil and the Registrant, dated June 2, 2019.	S-1/A	333-231703	10.6	6/7/2019
10.7#	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
10.8#	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
10.9	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
10.10¥	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
10.11¥	Quotation for Supply of Genetic Analysis Products No. 4079884, by and between Illumina, Inc. and the Registrant, dated March 21, 2017.	S-1	333-231703	10.11	5/23/2019
10.12¥	Purchase Order No. P11405, by and between Illumina, Inc. and the Registrant, dated March 31, 2017.	S-1	333-231703	10.12	5/23/2019
10.13¥	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
10.14¥	Pricing Agreement, by and between Illumina, Inc. and the Registrant, dated November 22, 2017.	S-1	333-231703	10.14	5/23/2019
10.15¥	Fasttrack Genetic Analysis Services Agreement No. MQ-20171213CG100, by and between Illumina, Inc. and the Registrant, dated December 13, 2017.	S-1	333-231703	10.15	5/23/2019
10.16¥	Quotation for Supply of Genetic Analysis Products No. SQ-20190214CG102, by and between Illumina, Inc. and the Registrant, dated February 22, 2019.	S-1	333-231703	10.16	5/23/2019
10.17¥	Quotation for Supply of Genetic Analysis Products No. 4192031, by and between Illumina, Inc. and the Registrant, dated March 1, 2019.	S-1	333-231703	10.17	5/23/2019
10.18¥	Purchase Order No. P11405, by and between Illumina, Inc. and the Registrant, dated March 20, 2019.	S-1	333-231703	10.18	5/23/2019
10.19¥	Pricing Agreement, by and between Illumina, Inc. and the Registrant, dated March 26, 2019.	S-1	333-231703	10.19	5/23/2019

10.20	Plain English Revolving Loan and Security Agreement, by and between TriplePoint Capital LLC and the Registrant, dated June 28, 2017.	S-1	333-231703	10.20	5/23/2019
10.21	First Amendment to Plain English Revolving Loan and Security Agreement, by and between TriplePoint Capital LLC and the Registrant, dated March 22, 2019.	S-1	333-231703	10.21	5/23/2019
10.22	Form of convertible promissory note of the Registrant.	S-1	333-231703	10.22	5/23/2019
10.23	Amendment No. 1 to the convertible promissory note of the Registrant.	S-1	333-231703	10.23	5/23/2019
10.24	Amendment No. 2 to the convertible promissory note of the Registrant.	S-1	333-231703	10.24	5/23/2019
10.25¥	Quotation for Supply of Genetic Analysis Products, by and between Illumina, Inc. and the Registrant, dated November 19, 2019.				
21.1	Subsidiaries of the Registrant as of December 31, 2019.				
23.1	Consent of Independent Registered Public Accounting Firm.				
24.1	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K).				
31.1	Certification of Principal Executive 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.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

# 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.

¥ Portions of this exhibit (indicated by asterisks) have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.

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: March 25, 2020

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)*	March 25, 2020
/s/ Aaron Tachibana **Aaron Tachibana**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 25, 2020
/s/ Patrick Balthrop **Patrick Balthrop**	Director	March 25, 2020
/s/ A. Blaine Bowman **A. Blaine Bowman**	Director	March 25, 2020
/s/ Alan Colowick **Alan Colowick, M.D.**	Director	March 25, 2020
/s/ Karin Eastham **Karin Eastham**	Director	March 25, 2020
/s/ Kenneth Ludlum **Kenneth Ludlum**	Director	March 25, 2020
/s/ Jonathan MacQuitty **Jonathan MacQuitty, Ph.D.**	Director	March 25, 2020
/s/ Paul Ricci **Paul Ricci**	Director	March 25, 2020

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Personalis, Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock. The following summary of the terms of our common stock is based upon our amended and restated certificate of incorporation and our amended and restated bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our amended and restated certificate of incorporation, our amended and restated bylaws, and the amended and restated investor rights agreement (the "IRA"). We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws, the IRA, and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for more information.

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 210,000,000 shares, all with a par value of $0.0001 per share, of which: 200,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution, or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then-outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are duly authorized, validly issued, fully paid, and nonassessable. All authorized but unissued shares of our common stock are available for issuance by our board of directors without any further stockholder action, except as required by the listing standards of Nasdaq. The rights, preferences, and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 10,000,000 shares of redeemable convertible preferred stock in one or more series and authorize their issuance. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our redeemable convertible preferred stock could adversely affect the voting power of holders of our common stock, and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring, or preventing a change of control or other corporate action.

Warrants

As of December 31, 2019, our outstanding warrants consist of a warrant to purchase 62,096 shares of common stock at an exercise price of $8.052 per share exercisable for seven years from June 28, 2017 and a warrant to purchase 65,502 shares of common stock at an exercise price of $9.16 per share exercisable for seven years from March 22, 2019.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of

us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees, or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim 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 or any other claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to these choice of forum provisions. It is possible that a court of law could rule that the choice of forum provisions to be contained in our amended and restated certificate of incorporation are inapplicable or unenforceable if they are challenged in a proceeding or otherwise.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two-thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Exchange Listing

Our common stock is currently listed on The Nasdaq Global Market under the symbol “PSNL.”

[***] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

QUOTATION FOR SUPPLY OF GENETIC ANALYSIS PRODUCTS

Prepared by:

Illumina, Inc.
5200 Illumina Way
San Diego, CA, 92122-4616, US

Hereinafter referred to as “Illumina”

Prepared For:

Personalis

Hereinafter referred to as “ Personalis ”

Quotation Number:	[***]
Quotation Date:	November 19, 2019
Expiration Date:	December 31, 2020
Prepared by:	[***]
Phone Number:	[***]
Email:	[***]

I. CUSTOMER INFORMATION

Company or Institution Name:	Personalis
Address:	1330 Obrien Dr, Menlo Park, CA, 94025-1436.

II. PRODUCT & PRICING INFORMATION

Customer receives the following discount on the product families listed below (excludes promotionally priced consumables, software, hardware or new instrument purchases). For the discount to apply, Customer must agree to the following:

- This Master Quote, which can be used for multiple purchases, will only be valid until 5:00pm on the expiration date listed on page 1.
- All Customer Purchase Orders received by Illumina that include this discounted pricing must be in the quoted currency and reference this quotation.
- All discounts will be applied to Illumina's then current list price. Illumina shall at its sole discretion, adjust discount percentages for future products or for any list price adjustments to the products offered on this Quotation.
- The pricing and terms of this offer are kept confidential except as needed to execute the purchase.
- Discount for consumables applies only to the product families specified in the table herein.
- Customer understands that product pricing stated herein is not inclusive of any applicable shipping, freight and/or taxes. Any estimated shipping and freight charges listed on this quotation may differ from actual charges. Any shipping/freight costs will be pre-paid and charged back to Customer. Customer accepts responsibility for any actual incurred shipping/freight costs.

Product Family	Discount%
MiSeq Sequencing Consumables	[***]
Sample Preparation Consumables	[***]
SBS and Cluster Generation Sequencing Co	[***]
Miscellaneous Sequencing Consumables	[***]

Discount Exception		
Catalog #	**Product Description**	**Discount**
20012865	NovaSeq 5000/6000 S1 Rgt Kit (100 cyc)	[***]
20012864	NovaSeq 5000/6000 S1 Rgt Kit (200 cyc)	[***]
20012863	NovaSeq 5000/6000 S1 Rgt Kit (300 cyc)	[***]
20012862	NovaSeq 5000/6000 S2 Rgt Kit (100 cyc)	[***]
20012861	NovaSeq 5000/6000 S2 Rgt Kit (200 cyc)	[***]
20012860	NovaSeq 5000/6000 S2 Rgt Kit (300 cyc)	[***]
20012866	NovaSeq 6000 S4 Rgt Kit (300 cyc)	[***]
20027464	NovaSeq 6000 SP Reagent Kit (100 cycles)	[***]
20027465	NovaSeq 6000 SP Reagent Kit (300 cycles)	[***]
20029137	NovaSeq 6000 SP Reagent Kit (500 cycles)	[***]
20021665	NovaSeq Xp 4-Lane Kit	[***]

Catalog #	Product Description	List Price (USD)	Customer Price (USD)
MiSeq Sequencing Consumables			
MS-102-2003	MiSeq® Reagent Kit v2 (500 cycle)	[***]	[***]
MS-102-2002	MiSeq® Reagent Kit v2 (300 cycle)	[***]	[***]
MS-102-2001	MiSeq® Reagent Kit v2 (50 cycle)	[***]	[***]
MS-102-2023	MSQ® RGT KT v2 (500 CYC)-20 PK	[***]	[***]
MS-102-3001	MiSeq® Reagent Kit v3 (150 cycle)	[***]	[***]
MS-102-3003	MiSeq® Reagent Kit v3 (600 cycle)	[***]	[***]
MS-102-2022	MiSeq® RGT Kit v2 (300 cycle)-20 PK	[***]	[***]
MS-102-2021	MiSeq® RGT Kit v2 (50 cycle) - 20 PK	[***]	[***]
MS-103-1001	MiSeq® Reagent Nano Kit v2 (300 Cycles)	[***]	[***]
MS-103-1002	MiSeq® Reagent Micro Kit v2 (300 Cycles)	[***]	[***]
MS-103-1003	MiSeq® Reagent Nano Kit v2 (500 Cycles)	[***]	[***]
20021681	MiSeq FGx Reagent Micro Kit	[***]	[***]
DX-102-1001	MiSEQDx CF Clinical SEQ Assay (6 Run)"	[***]	[***]
DX-102-1004	MiSeqDx CF 139 Variant Assay (2 Run)"	[***]	[***]
NovaSeq 5000/6000 Sequencing Cons			
20012865	NovaSeq 5000/6000 S1 Rgt Kit (100 cyc)	[***]	[***]
20012864	NovaSeq 5000/6000 S1 Rgt Kit (200 cyc)	[***]	[***]
20012863	NovaSeq 5000/6000 S1 Rgt Kit (300 cyc)	[***]	[***]
20012862	NovaSeq 5000/6000 S2 Rgt Kit (100 cyc)	[***]	[***]
20012861	NovaSeq 5000/6000 S2 Rgt Kit (200 cyc)	[***]	[***]
20012860	NovaSeq 5000/6000 S2 Rgt Kit (300 cyc)	[***]	[***]
20012866*	NovaSeq 6000 S4 Rgt Kit (300 cyc)	[***]	[***]
20027464	NovaSeq 6000 SP Reagent Kit (100 cycles)	[***]	[***]
20027465	NovaSeq 6000 SP Reagent Kit (300 cycles)	[***]	[***]
20029137	NovaSeq 6000 SP Reagent Kit (500 cycles)	[***]	[***]
20021665	NovaSeq Xp 4-Lane Kit	[***]	[***]
Sample Preparation Consumables			
20014279	SureCell Whl Trans 3 Pr Kt (2 crtg kt)	[***]	[***]
20014280	SureCell Whl Trans 3 Pr Kt (6 crtg kt)	[***]	[***]
20015090	CRUK SMP v2 Consortia	[***]	[***]
20015091	CEU Consortia	[***]	[***]
20015949	TruSeq DNA Idx Kit Pl (96 idx,96 spl)	[***]	[***]
20015960	TruSeq DNA Idx Kit Set A (12 idx,24 spl)	[***]	[***]
20015961	TruSeq DNA Idx Kit Set B (12 idx,24 spl)	[***]	[***]

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Catalog #	Product Description	List Price (USD)	Customer Price (USD)
20015962	TruSeq DNA PCR-Free LT LPK (24 spl)	[***]	[***]
20015963	TruSeq DNA PCR-Free HT LPK (96 spl)	[***]	[***]
20015964	TruSeq Nano DNA LT LPK (24 spl)	[***]	[***]
20024144	ILMN Free Adptr Blkng Rgnt (12 rxns)	[***]	[***]
20006259	TruSeq Custom Amplicon Dx – FFPE QC	[***]	[***]
20006989	High Thrghpt TruSeq R Enrch DNA LPK	[***]	[***]
20006994	TruSight HLA v1 Box 4 (Post-PCR)	[***]	[***]
20010179	TruSight HLA-B Primers v2 Kit	[***]	[***]
20010184	TruSight Oncology Library Prep	[***]	[***]
20010185	TruSight Oncology DNA Library Prep	[***]	[***]
20010186	TruSight Oncology RNA Library Prep	[***]	[***]
20010187	TruSight Oncology Enrichment	[***]	[***]
20010188	TruSight Tumor 170 Content Set	[***]	[***]
20010190	TruSight HLA-DRB Primers v2 Kit	[***]	[***]
20027216	Nextera Compatible Unique Dual Idx - D	[***]	[***]
20027215	Nextera Compatible Unique Dual Idx - C	[***]	[***]
20027214	Nextera Compatible Unique Dual Idx - B	[***]	[***]
20027213	Nextera Compatible Unique Dual Idx - A	[***]	[***]
20025895	VeriSeq NIPT SMP Prep Kit (24 SMP)	[***]	[***]
20025524	Nextera DNA Flex LPK Enrich (96 Spl)	[***]	[***]
20025523	Nextera DNA Flex LPK Enrich (16 Spl)	[***]	[***]
20025520	Nextera DNA Flex LPK - Small (96 Spl)	[***]	[***]
20025519	Nextera DNA Flex LPK - Small (16 Spl)	[***]	[***]
20024586	TruSight Oncology UMI Reagents	[***]	[***]
20024145	ILMN Free Adptr Blkng Rgnt (48 rxns)	[***]	[***]
20011891	Canadian Consortia Inherited Cancer	[***]	[***]
20015965	TruSeq Nano DNA HT LPK (96 spl)	[***]	[***]
20020590	IDT-TruSeq DNA UD Idx (24 Idx, 96 Spl)	[***]	[***]
20020591	IDT-TruSeq RNA UD Idx (24 Idx, 96 Spl)	[***]	[***]
20020594	TruSeq Stranded mRNA LP (48 Spl)	[***]	[***]
20020595	TruSeq Stranded mRNA LP (96 Spl)	[***]	[***]
20020596	TruSeq Strnd Total RNA LP HMR (48 Spl)	[***]	[***]
20020597	TruSeq Strnd Total RNA LP HMR (96 Spl)	[***]	[***]
20020598	TruSeq Strnd Total RNA LP Gold (48 Spl)	[***]	[***]
20020599	TruSeq Strnd Total RNA LP Gold (96 Spl)	[***]	[***]

Catalog #	Product Description	List Price (USD)	Customer Price (USD)
20020610	TruSeq Strnd Total RNA LP Plant (48 Spl)	[***]	[***]
20020611	TruSeq Strnd Total RNA LP Plant (96 Spl)	[***]	[***]
20020612	TruSeq Strnd Total RNA LP Globin(48 Spl)	[***]	[***]
20020613	TruSeq Strnd Total RNA LP Globin(96 Spl)	[***]	[***]
20020614	TruSeq Exome Kit (24 Spl)	[***]	[***]
20020615	TruSeq Exome Kit (96 Spl)	[***]	[***]
20020616	Nextera Exome Kit (24 Spl)	[***]	[***]
20020617	Nextera Exome Kit (96 Spl)	[***]	[***]
20021354	TruSeq Neuro Panel 24/48/4	[***]	[***]
20021356	TruSeq Neuro Panel 96/288/24	[***]	[***]
20022370	IDT for Illumina TruSeq DNA UD Indices	[***]	[***]
20022371	IDT for Illumina TruSeq RNA UD Indices	[***]	[***]
20023394	TruSight cfDNA UMI HiSeq 2500 Kt(48 Spl)	[***]	[***]
20023395	TruSight cfDNA UMI HiSeq 4000 Kt(48 Spl)	[***]	[***]
20015966	TruSight® Lymphoma 40 (8 SMP)	[***]	[***]
20015967	TruSight® Lymphoma 40 (48 SMP)	[***]	[***]
20015968	TruSight® ALL 52 (16 SMP)	[***]	[***]
20015969	TruSight® ALL 52 (96 SMP)	[***]	[***]
20015970	TruSight® Myeloma 43 (16 SMP)	[***]	[***]
20015971	TruSight® Myeloma 43 (96 SMP)	[***]	[***]
20018622	TruSight Tumor 170 LPK - Watson	[***]	[***]
20018704	Nextera DNA Flex LPK (24 SPl)	[***]	[***]
20018705	Nextera DNA Flex LPK (96 SPl)	[***]	[***]
20018706	Flex Lysis reagent Kit	[***]	[***]
20018707	Nextera DNA CD Idx (24 Idx, 24 SPl)	[***]	[***]
20018708	Nextera DNA CD Idx (96 Idx, 96 SPl)	[***]	[***]
20019792	TruSeq RNA CD Idx (96 Idx, 96 Spl)	[***]	[***]
20020181	TruSeq DNA LP for Enrch (24 Spl)	[***]	[***]
20020182	TruSeq DNA LP for Enrch (96 Spl)	[***]	[***]
20020183	Exome Panel (45Mb)	[***]	[***]
20020187	Nextera DNA LP for Enrch (24 Spl)	[***]	[***]
20020188	Nextera DNA LP for Enrch (96 Spl)	[***]	[***]
20020189	TruSeq RNA LP for Enrch (48 Spl)	[***]	[***]
20020490	TruSeq RNA Enrch (12 enrch)	[***]	[***]
20020492	TruSeq RNA Sgl Idx SetA (12 Idx,48 Spl)	[***]	[***]

Catalog #	Product Description	List Price (USD)	Customer Price (USD)
20020493	TruSeq RNA Sgl Idx SetB (12 Idx,48 Spl)	[***]	[***]
FC-131-1001	NXTR® XT IDX Kit (24 IDXS, 96 SMP)	[***]	[***]
RT-402-1001	TruSq® Trgtd RNA IDX KtA, 96 IDX 384 SMP	[***]	[***]
FC-132-1001	Nextera® Mate Pair Sample PrepKit	[***]	[***]
RT-401-1001	TruSeq® Trgtd RNA IDX Kt, 48 IDX 192 SMP	[***]	[***]
IP-202-1024	TruSeq® ChIP SMP Prep Kit 48 SMP-Set B	[***]	[***]
IP-202-1012	TruSeq® ChIP SMP Prep Kit 48 SMP-Set A	[***]	[***]
AB0007	FusionPlex® CTL, for Illumina®	[***]	[***]
FC-121-0202	TruSight™ Cancer Sequencing Panel	[***]	[***]
FC-121-0205	TruSight Inherited Disease SEQ Panel"	[***]	[***]
FC-130-1010	TruSight™ Myeloid Sequencing Panel	[***]	[***]
RT-402-1002	TruSq® Trgtd RNA IDX KtB, 96 IDX 384 SMP	[***]	[***]
RT-402-1003	TruSq® Trgtd RNA IDX KtC, 96 IDX 384 SMP	[***]	[***]
RT-402-1004	TruSq® Trgtd RNA IDX KtD, 96 IDX 384 SMP	[***]	[***]
FC-140-1101	TruSite RPD CPTR KT (1INX 8 SMP)	[***]	[***]
FC-140-1102	TruSite RPD CPTR KT (2INX 8 SMP)	[***]	[***]
FC-140-1103	TruSite RPD CPTR KT (4INX 16 SMP)	[***]	[***]
FC-140-1104	TruSite RPD CPTR KT (24 INX 48 SMP)	[***]	[***]
FC-140-1105	TruSite RPD CPTR KT (24 INX 96 SMP)	[***]	[***]
FC-140-1106	TruSite RPD CPTR KT (96 INX 288 SMP)	[***]	[***]
AB0005	FusionPlex® Solid Tumor, for Illumina®	[***]	[***]
FC-131-1096	NXTR® XT DNA SMP Prep Kit (96 SMP)	[***]	[***]
SA0045	MBC Adapters A41-A48 for Illumina®	[***]	[***]
SA0044	MBC Adapters A33-A40 for Illumina®	[***]	[***]
SA0043	MBC Adapters A25-A32 for Illumina®	[***]	[***]
SA0042	MBC Adapters A17-A24 for Illumina®	[***]	[***]
SA0041	MBC Adapters A9-A16 for Illumina®	[***]	[***]
SA0040	Archer® MBC Adapters A1-A8 for Illumina®	[***]	[***]
RS-200-0012	TruSeq® Small RNA SMP PrepKit v2set A	[***]	[***]
RS-200-0024	TruSeq® Small RNA SMP PrepKit v2 set B	[***]	[***]
RS-200-0036	TruSeq® Small RNA SMP PrepKit v2 set C	[***]	[***]
RS-200-0048	TruSeq® Small RNA SMP PrepKit v2 set D	[***]	[***]
AB0019	FusionPlex® Lymphoma, for Illumina®	[***]	[***]
AB0017	FusionPlex® Pan-Heme, for Illumina®	[***]	[***]
AB0015	FusionPlex® Myeloid, for Illumina®	[***]	[***]

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Catalog #	Product Description	List Price (USD)	Customer Price (USD)
AB0013	FusionPlex® ALL, for Illumina®	[***]	[***]
15027865	NX#-TDE1,TGMNT DNA ENZ,24RXN,FINISH REAG	[***]	[***]
15027866	NX#-TD,TAGMENT DNA BUFFER,FINISH REAG	[***]	[***]
RS-122-2001	Kit, TruSeq RNA SMP Prep Kit-v2, 48,SetA	[***]	[***]
RS-122-2002	Kit, TruSeq RNA SMPle Prep Kit-v2	[***]	[***]
AB0011	FusionPlex® Heme v2, for Illumina®	[***]	[***]
AB0009	FusionPlex® Oncology Research	[***]	[***]
FC-130-1003	TruSeq® CTM AMPLCN IDXKit 96 IDX,384 SMP	[***]	[***]
FC-130-1007	TruSq® IDX PLT Fixture&Collar Kt 2 Each	[***]	[***]
FC-130-1005	TruSeq® Index Plate Fixture Kit	[***]	[***]
FC-130-1006	TruSeq CSTM Amplicon FLTRPlate 1 Plate)"	[***]	[***]
RS-200-1001	TruSeq™ RNA EPH Reagent Tube	[***]	[***]
FC-131-1024	NXTR® XT DNA SMP Prep Kit (24 SMP)	[***]	[***]
FC-121-9999	TruSeq® FFPE DNA Library PrepQC Kit	[***]	[***]
OP-101-1001	TruSight® Tumor 15 Kit	[***]	[***]
20029226	TST One Expanded - Oligos (36 Spl)	[***]	[***]
FC-133-1001	NXTR® XT LIB Prep KT PulseNet (96 SMP)	[***]	[***]
OP-101-1002	TruSight® Tumor 15	[***]	[***]
OP-101-1004	TruSight Tumor 170	[***]	[***]
RH-200-1001	VeriSeq NIPT SMP Prep Kit(48 SMP)	[***]	[***]
RH-200-1002	VeriSeq NIPT SMP Prep Kit(96 SMP)	[***]	[***]
FC-151-1002	TruSeq Methyl Capture EPIC Kit (12 smp)	[***]	[***]
FC-151-1003	TruSeq Methyl Capture EPIC Kit (48 smp)	[***]	[***]
20028825	TG TruSeq Nano DNA HT SMPPrep Kt 96 SMP	[***]	[***]
FC-141-2007	TruSight One Expanded Seq Panel (36 smp)	[***]	[***]
RS-303-1002	TruSight RNA Pan-Cancer Panel 48smp-SetA	[***]	[***]
RS-303-1003	TruSight RNA Pan-Cancer Panel 48smp-SetB	[***]	[***]
RS-304-1002	TruSight® RNA Fusion Panel 48SMP - Set A	[***]	[***]
RS-304-1003	TruSight® RNA Fusion Panel 48SMP - Set B	[***]	[***]
20028821	TruSight Tumor 170 Kit - NextSeq v2.5	[***]	[***]
20000902	SeqLab TruSeq DNA PCR-Free LibraryPrepHT	[***]	[***]
20000903	SeqLab TruSeq Nano DNA Library Prep HT	[***]	[***]
20028216	TruSight Onco 500 DNA/RNA Kt,NSQ(24 Spl)	[***]	[***]
20028215	TruSight Onco 500 DNA/RNA Kt (24 Spl)	[***]	[***]
20028214	TruSight Onco 500 DNA Kt, NSQ (48 Spl)	[***]	[***]

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Catalog #	Product Description	List Price (USD)	Customer Price (USD)
20028213	TruSight Onco 500 DNA Kt (48 Spl)	[***]	[***]
20005170	TruSight HLA v2 (24 samples Automated)	[***]	[***]
20005718	TruSeq Custom Amplicon Kit Dx	[***]	[***]
FC-452-1001	ForenSeq™ Human Sequencing Control	[***]	[***]
FC-141-1006	TruSight One SEQ Panel(9 SMPles)	[***]	[***]
AB0003	FusionPlex® Sarcoma, for Illumina®	[***]	[***]
AB0001	FusionPlex® Alk Ret Ros1 v2	[***]	[***]
20032629	TST170 Kit-NextSeq v2.5(24spl)+PierianDx	[***]	[***]
20032628	TST170 Kit (24 Samples)+PierianDx	[***]	[***]
20032627	TSO500 DNA/RNA Kit NextSeq (24)PierianDx	[***]	[***]
20032626	TSO500 DNA/RNA Kit (24Spl)+PierianDx	[***]	[***]
20032625	TSO500 DNA Kit NextSeq (48Spl)+PerianDx	[***]	[***]
20032624	TSO500 DNA Kit (48 samples)+PierianDx	[***]	[***]
FC-141-1007	TruSight One SEQ Panel(36 SMPles)"	[***]	[***]
FC-141-1010	TrSt-Crd-Sq-Kt(MSQ®,12 spls,v2 Ch)	[***]	[***]
FC-141-1011	TrSt-Crd-Sq-Kt(NSQ®,48 spls,Mid OTP)	[***]	[***]
20029551	TST Hereditary Cancer – oligos (48 spl)	[***]	[***]
20029550	TruSeq Neuro - oligos (48 spl)	[***]	[***]
FC-131-2001	NXTR® XT IDX Kt v2 Set A 96 IDXS,384 SMP	[***]	[***]
FC-131-2002	NXTR® XT IDX Kt v2 Set B 96 IDXS,384 SMP	[***]	[***]
FC-131-2003	NXTR® XT IDX Kt v2 Set C 96 IDXS,384 SMP	[***]	[***]
FC-131-2004	NXTR® XT IDX Kt v2 Set D 96 IDXS,384 SMP	[***]	[***]
20029274	TG Library Prep Partner Kit	[***]	[***]
FC-142-1001	TruSight HLA Seq Panel (24 smp)	[***]	[***]
FC-451-1001	ForenSeq™ Index Adapter Fixture	[***]	[***]
20029229	TST Cardio - Oligos (48 Spl)	[***]	[***]
20029227	TST One - Oligos (36 Spl)	[***]	[***]
	SBS and Cluster Generation Sequencing Co		
FC-401-4003	HiSeq® SBS Kit v4 (250 Cycle)	[***]	[***]
FC-402-4023	HiSeq® Rapid SBS Kit v2 (500 cycles)	[***]	[***]
FC-402-4021	HiSeq® Rapid SBS Kit v2 (200 cycles)	[***]	[***]
FC-402-4022	HiSeq® Rapid SBS Kit v2 (50 cycles)	[***]	[***]
GD-401-3001	TruSeq® SR Cluster Kit v3 – cBot™ - HS	[***]	[***]
PE-401-3001	TruSeq® PE Cluster Kit v3 – cBot™ - HS	[***]	[***]
FC-401-3001	TruSeq SBS KIT v3 - HS (200 CYCLES)	[***]	[***]

Catalog #	Product Description	List Price (USD)	Customer Price (USD)
FC-401-3002	TruSeq SBS KIT v3 - HS (50 CYCLES)	[***]	[***]
FC-401-4002	HiSeq® SBS Kit v4 (50 Cycle)	[***]	[***]
PE-402-4002	HiSeq® Rapid PE Cluster Kit v2	[***]	[***]
GD-402-4002	HiSeq® Rapid SR Cluster Kit v2	[***]	[***]
GD-401-4001	HiSeq® SR Cluster Kit v4 – cBot™	[***]	[***]
20006992	High Throughput HiSeq SBS Kit (150 cyc)	[***]	[***]
20006991	High Throughput HiSeq PE Cluster Kit	[***]	[***]
PE-401-4001	HiSeq® PE Cluster Kit v4 – cBot™	[***]	[***]
15056112	HiSeq® Rapid SBS Kit - FunnelBottle Caps	[***]	[***]
15037576	HiSeq® Flowcell Gaskets 4 Pack	[***]	[***]
	SBS and Cluster Generation Sequencing Co		
DX-502-1003	Index Adapter Replacement Caps	[***]	[***]
FC-901-1003	KIT,BRIDGE MANIFOLD,CLUSTER STATION	[***]	[***]
FC-800-1001	TruSeq® Nano DNA Accessory Kit	[***]	[***]
PE-121-1003	TruSEQ Dual IDX SEQ PRMR Kit, Paired End	[***]	[***]
FC-121-1003	TruSEQ Dual IDX SEQ PRMR Kt, Single Read	[***]	[***]
FC-110-3001	PhiX CONTROL V3 KIT	[***]	[***]
GD-304-2001	TruSq v2 cBot Multi-PRMR Re-Hybrdztn Kt	[***]	[***]
SY-401-2015	KIT,CBOT MANIFOLD,HiSEQ	[***]	[***]
GD-403-4001	HSQ® Multi-PRMR Rehybridization Kit v4	[***]	[***]
20015892	HT1 Buffer	[***]	[***]
20012552	MiSeqDx Reagent Kit v3	[***]	[***]
20005160	cBot 2 Barcoded Strip Tubes (8 well)	[***]	[***]
15073345	Streck cell free DNA BCT (CE)	[***]	[***]
GD-310-1001	HSQ® 3k/4k cBot Multi-PRMR ReHYBRID Kit	[***]	[***]
MS-102-9999	MiSeq® Disposable Wash Tubes	[***]	[***]
GD-404-1001	HiSeq® Rapid Rehybridization Kit	[***]	[***]
CT-403-2001	HiSeq® Rapid Duo cBot™ SampleLoading Kit	[***]	[***]
FC-110-3002	NextSeq™ PhiX Control Kit	[***]	[***]

* Fixed Price is active for this material.
Post Pricing Message: Payment Terms for the account is Net 60

III. CONDITIONS OF SALE

By submitting an order, Customer accepts and agrees that the Terms and Conditions is the sole and exclusive agreement between Customer and Illumina with respect to the Illumina products and/or services as described above and accepts all other terms of this quotation.
NOTWITHSTANDING THE FOREGOING, IF ILLUMINA AND CUSTOMER HAVE ENTERED INTO A VALID AND ENFORCEABLE AGREEMENT GOVERNING THE ILLUMINA PRODUCTS AND/OR SERVICES DESCRIBED ABOVE, THE ORDER OF PRECEDENCE BETWEEN THE AGREEMENT AND THE TERMS AND CONDITIONS SHALL BE AS FOLLOWS: IN THE EVENT OF A CONFLICT

BETWEEN THE TERMS OF THE AGREEMENT AND THE TERMS AND CONDITIONS, OR IF THE AGREEMENT INCLUDES ADDITIONAL TERMS NOT ADDRESSED IN THE TERMS AND CONDITIONS, THE AGREEMENT SHALL GOVERN WITH RESPECT TO SUCH TERMS.
Illumina does not supply plastics such as microplates or pipette tips for use in the listed assays and these are not included in the consumables pricing provided; however, as a result of the highly multiplexed nature of all assays, plastics alone contribute minimally to the final cost.

Customer and Illumina agree as follows:

- Customer's purchase of the products referenced in this Quotation is not conditioned on future performance characteristics or applications, whether or not realized.
- Unless otherwise agreed by Illumina in writing, Illumina will not assist Customer in developing, testing, or validating unsupported applications.
- Illumina will not replace any consumables or reagent kits if the cause of any performance failure is due to unsupported applications.
- Illumina is unable to provide any assurances or guarantee that the performance of the products referenced in this Quotation will match published specifications when used for unsupported applications.

IV. SHIP HOLD

In cases where this Quotation does not include a pre-defined ship schedule, the following ship hold terms shall apply:

- All orders must have a defined ship schedule. The initial ship date must be no later than three (3) months from the date the purchase order is received by Illumina (as provided in the Order Confirmation) and the entire order must be shipped complete within twelve (12) months from Illumina's receipt of the purchase order.
- Any exceptions to these ship hold terms must be agreed to in writing by Illumina and the Customer must pre-pay at least fifty percent (50%) of the purchase order amount of the affected shipments.
- Customers may request two (2) shipment delays for any single purchase order. The total months of delayed shipment for shipments associated with a single purchase order shall not exceed six (6) months.
- If Customer has requested a delayed shipment, Illumina reserves the right to change the lead time necessary to initiate Customer's first shipment (which may be longer than the lead time quoted at the time of the order placement).
- If Customer cannot take shipment in accordance with these terms, Illumina reserves the right to cancel the order in its entirety without any liability to the Customer.

V. HOW TO ORDER

RUO & DX Goods, Instruments and Warranty Coverage (including BlueGnome)

For all consumable orders: Please submit your order online through MyIllumina (http://my.illumina.com).	For all other orders: Please submit your institutional Purchase Order and a complete copy of this quotation to the attention of: Illumina Customer Service customerservice@illumina.com Phone: +1.858.202.4566 Toll Free: +1.800.809.ILMN (4566) Fax: +1.858.202.4766

VI. EXPIRATION OF OFFER

The offer contained in this document is revocable at the sole discretion of Illumina if not executed by Customer and a purchase order received by Illumina before 5:00 pm Pacific Time on the expiration date shown on page 1 of this quotation.

Terms and Conditions of Sale

http://www.illumina.com/content/dam/illumina-marketing/documents/terms-conditions/united-states/usa-terms-and-conditions-of-sale-general.pdf. Additionally, if Customer is purchasing Illumina professional consulting services as relate to instruments, Customer environment or workflows (in all cases, excluding instrument warranty services) ("Professional Services"), Customer agrees such Professional Services are exclusively governed by the Terms and Conditions - Services (Professional Services) located here: http://www.illumina.com/content/dam/illumina-marketing/ documents/company/terms-and-conditions-services.pdf

Exhibit 21.1

SUBSIDIARY OF PERSONALIS, INC.

Name of Subsidiary	Jurisdiction of Incorporation
Personalis (UK) Ltd.	United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-232233 on Form S-8 of our report dated March 25, 2020, relating to the consolidated financial statements of Personalis, Inc. and subsidiary (the "Company"), appearing in the Annual Report on Form 10-K of the Company for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

San Jose, California
March 25, 2020

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)) 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) 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

   (c) 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: March 25, 2020

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)) 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) 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

   (c) 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: March 25, 2020

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, 2019 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: March 25, 2020

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, 2019 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: March 25, 2020

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