

The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any jurisdiction where such offer or sale is not permitted.

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-251824

SUBJECT TO COMPLETION, DATED JANUARY 26, 2021

*Preliminary Prospectus Supplement
(To Prospectus dated January 8, 2021)*

\$150,000,000



COMMON STOCK

We are offering \$150,000,000 of shares of our common stock.

Our shares trade on the Nasdaq Global Market under the symbol "PSNL." On January 25, 2021, the last reported sale price of our common stock was \$46.91 per share. Assuming an offering price of \$46.91 per share, we would expect to offer 3,197,612 shares of our common stock.

We are an emerging growth company under the federal securities laws and, as such, we have elected to comply with reduced public company reporting requirements. See "Prospectus Supplement Summary—Implications of Being an Emerging Growth Company."

Investing in our securities involves a high degree of risk. See "[Risk Factors](#)" beginning on page S-9.

	<u>Price to Public</u>	<u>Underwriting Discounts and Commissions(1)</u>	<u>Proceeds to Personalis</u>
Per Share	\$	\$	\$
Total	\$	\$	\$

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional \$22,500,000 of shares of common stock from us, at the public offering price, less underwriting discounts and commissions, for 30 days after the date of this prospectus supplement.

The shares will be ready for delivery on or about _____, 2021.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

MORGAN STANLEY

BOFA SECURITIES

CITIGROUP

COWEN

BTIG

, 2021.

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT

	<u>Page</u>		<u>Page</u>
ABOUT THIS PROSPECTUS SUPPLEMENT	S-ii	MATERIAL U.S. FEDERAL INCOME TAX	
PROSPECTUS SUPPLEMENT SUMMARY	S-1	CONSEQUENCES TO NON-U.S. HOLDERS OF OUR	
RISK FACTORS	S-9	COMMON STOCK	S-64
SPECIAL NOTE REGARDING FORWARD-LOOKING		UNDERWRITING	S-68
STATEMENTS	S-59	LEGAL MATTERS	S-76
USE OF PROCEEDS	S-61	EXPERTS	S-76
CAPITALIZATION	S-62	WHERE YOU CAN FIND MORE INFORMATION	S-76
DILUTION	S-63	INCORPORATION OF CERTAIN INFORMATION BY	
		REFERENCE	S-77

PROSPECTUS

	<u>Page</u>		<u>Page</u>
About this Prospectus	i	Legal Ownership of Securities	73
Prospectus Summary	1	Selling Stockholder	77
Summary of Risk Factors	5	Plan of Distribution	78
Risk Factors	7	Legal Matters	81
Forward-Looking Statements	56	Experts	81
Use of Proceeds	58	Where You Can Find More Information	81
Description of Capital Stock	59	Incorporation of Certain Information by Reference	82
Description of Debt Securities	64		
Description of Warrants	71		

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a “shelf” registration statement on Form S-3 (File No. 333-251824) that we initially filed with the Securities and Exchange Commission (the “SEC”) on December 30, 2020, and that was declared effective by the SEC on January 8, 2021. This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

We have not, and the underwriters have not, authorized anyone to provide any information other than that contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectus that we have authorized for use in connection with this offering. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer or solicitation of an offer in such jurisdiction. The information contained in this prospectus supplement, the accompanying prospectus, any free writing prospectus that we have authorized for use in connection with this offering, including the documents incorporated by reference herein or therein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled “Where You Can Find Additional Information” and “Incorporation of Certain Information by Reference” in this prospectus supplement and in the accompanying prospectus.

We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

[Table of Contents](#)

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus supplement and accompanying prospectus to “Personalis,” “the company,” “we,” “us,” “our” and similar references refer to Personalis, Inc., a corporation under the laws of the State of Delaware, and its wholly owned subsidiaries.

This prospectus supplement, the accompanying prospectus and the information incorporated herein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement, the accompanying prospectus or any related free writing prospectus are the property of their respective owners.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus supplement or the accompanying prospectus or incorporated by reference in this prospectus supplement or the accompanying prospectus, and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus supplement, accompanying prospectus and any related free writing prospectus, including the risks of investing in our securities discussed under the heading “Risk Factors” contained in this prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus supplement and accompanying prospectus. You should also carefully read the information incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus supplement and accompanying prospectus are a part.

Personalis, Inc.

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 pursued business within the population sequencing market, and we have provided whole genome sequencing services under contract with the U.S. Department of Veterans Affairs (the “VA”) Million Veteran Program (the “VA MVP”), which has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. In September 2020, we announced receipt of a new task order from the VA MVP with an approximate value of up to \$31 million. The cumulative value of task orders received from the VA MVP since inception is approximately \$175 million, approximately \$132.5 million of which we had recognized as revenue as of December 31, 2020.

In August 2020, we launched NeXT Liquid Biopsy, which is a 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, NeXT Dx, which is based on our NeXT Platform, that we envision being used initially by both leading clinical cancer centers as well as biopharmaceutical companies. Most recently, in December 2020, we launched two new capabilities that are integrated into our NeXT Platform: our Systemic HLA Epitope Ranking Pan Algorithm (“SHERPA”) machine learning-based tool for the comprehensive identification and characterization of cancer neoantigens, as well as our Neoantigen Presentation Score (“NEOPS”) for predicting cancer immunotherapy response. SHERPA enables the development of new neoantigen-based diagnostic biomarkers, such as our NEOPS, and novel personalized therapies.

We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe the capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases and in support of our NeXT Liquid Biopsy. To date, we have sequenced more than 150,000 human samples, of which more than 100,000 were whole human genomes.

Personalis: The Genomics Engine for Next-Generation Cancer Therapies

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

- **Immunotherapies:** Over the past decade, a number of drugs have emerged based on the discovery that the immune system plays a key role in addressing cancer. Checkpoint inhibitors, a specific type of immunotherapy, have generated substantial 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 a broad set of 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 to 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 could 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. If drugs that used our platform in the clinical trials to form the basis for approval are approved, 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 the clinical utility of our platform as a diagnostic for advanced cancer therapies. Separately, we are also acquiring samples and building a database which we expect will hold value for our biopharmaceutical customers and may ultimately allow us to discover new mechanisms of cancer treatment.

Market Opportunities

We estimate the market opportunity for our current and planned products to be approximately \$40 billion as follows:

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

Of these 2.2 million patients, about 200,000 enroll in pharmaceutical clinical trials according to data from the U.S. National Library of Medicine, ClinicalTrials.gov, January 2019, and the remaining cancer patients presumably undergo normal clinical care. As part of that standard care, these patients go through therapy selection and eventual monitoring. For therapy selection, we estimate that each of the approximately 2.0 million cancer patients would have a tissue biopsy sequenced and tested for approximately \$3,000, which is the approved CMS reimbursement rate, equaling a potential market opportunity of \$6 billion per year.

Cancer mutations identified in this initial tissue-biopsy based test can then be used for subsequent monitoring using cell free DNA. For monitoring, we estimate that each patient would have a liquid biopsy sequenced and tested four times per year at an estimated cost of \$2,840 per test, based on publicly-available data on comparable tests. Our NeXT Dx Test addresses this market for tissue biopsy testing. Clinical versions of products we have in development may address this liquid-biopsy based monitoring opportunity. This number of patients, number of tests per patient and price per test equate to a potential market opportunity of approximately \$22.72 billion per year.

- **Clinical Trial Patients:** For each of the 200,000 clinical trial patients, we estimate that an initial tissue sample will be sequenced once for \$3,000, which is the approved CMS reimbursement rate, followed by liquid biopsy sample testing at eight different time points per year for monitoring, based on the frequency of monitoring in a recent immuno-oncology drug trial, at an estimated cost of \$4,000 per sequencing test, based on our historical standard pricing for tissue samples and anticipated pricing for liquid biopsy samples. Therefore, we estimate the potential market size to be approximately \$7 billion for tissue- and liquid-based sequencing of these clinical trial patients.
- **Population Sequencing:** According to publicly-available industry information and presentations, the potential market for population sequencing services is over \$2 billion per year. Our whole genome sequencing products address this market.

Our Products

Refer to our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that are incorporated by reference herein for a full description of our products and services. In August 2020, we launched NeXT Liquid Biopsy, which analyzes all of the approximately 20,000 human genes versus the more narrowly focused liquid biopsy assays that are currently available. In December 2020, we launched two new capabilities that are integrated into our NeXT Platform: our SHERPA machine learning-based tool for the comprehensive identification and characterization of cancer neoantigens, as well as our NEOPS for predicting cancer immunotherapy response. SHERPA enables the development of new neoantigen-based diagnostic biomarkers, such as our NEOPS, and novel personalized therapies. We are also currently developing NeXT Personal, a liquid biopsy platform that will provide personalized tumor tracking for patients, utilizing up to hundreds or even thousands of genetic variants.

Recent Updates

On January 11, 2021, we reported unaudited preliminary revenue for the fourth quarter and full year ended December 31, 2020. Our financial closing procedures for the quarter and year ended December 31, 2020 are not yet complete and, as a result, our final results upon completion of our closing procedures may vary from the preliminary results presented below. These preliminary results should not be viewed as a substitute for our full interim or annual financial statements prepared in accordance with generally accepted accounting principles in the United States, or GAAP, although these financial statements will not be available until after the completion of this offering. Further, our preliminary estimated results are not necessarily indicative of the results to be expected for any future period. See the sections titled “Special Note Regarding Forward-Looking Statements” and “Risk Factors” in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein for additional information regarding factors that could result in differences between the preliminary estimated amounts of certain of our unaudited financial data presented below and the actual financial data we will report for the quarter or year ended December 31, 2020. The preliminary results for the quarter and year ended December 31, 2020 presented below have been prepared by, and are the responsibility of, management. Deloitte & Touche LLP, our independent registered public accounting firm, has not audited, reviewed, compiled or performed any procedures with respect to such preliminary results.

We estimate revenue of approximately \$20.2 million for the fourth quarter of 2020 compared to \$18.2 million in the fourth quarter of 2019, an increase of 11%. For the full year 2020, we estimate revenue of approximately \$78.6 million compared to \$65.2 million for 2019, an increase of 21%. The following are additional fourth quarter highlights:

- Preliminary revenue from biopharma and all other customers was an estimated \$7.6 million in the fourth quarter of 2020 compared to \$4.4 million in the fourth quarter of 2019, a 73% increase.
- Preliminary revenue from the VA MVP was an estimated \$12.6 million in the fourth quarter of 2020 compared to \$13.8 million in the fourth quarter of 2019, a decrease of 9%.
- Preliminary net loss was estimated to be between \$11.9 million and \$13.2 million in the fourth quarter of 2020 compared to \$6.6 million in the fourth quarter of 2019, an increase of between 79% and 99%.
- Preliminary cash, cash equivalents, and short-term investments were estimated to be \$203.3 million as of December 31, 2020.

In addition, our operating expenses grew substantially during the fourth quarter of 2020, and are expected to continue to grow as we invest in the growth of our business.

Corporate History and Information

We were incorporated under the laws of the state of Delaware in February 2011 under the name Personalis, Inc. Our principal executive offices are located at 1330 O’Brien Drive, Menlo Park, California 94025. Our telephone number is (650) 752-1300. Our website address is <https://www.personalis.com>. The information contained in, or accessible through, our website does not constitute part of this prospectus supplement, should not be relied on in determining whether to make an investment decision, and the inclusion of our website address in this prospectus supplement is an inactive textual reference only. Our common stock is listed on the Nasdaq Global Market under the symbol “PSNL.”

As of December 31, 2020, we had 235 employees, of which 234 were full-time employees. Of these full-time employees, 96 were in research and development, 60 in laboratory operations, 44 in commercial operations and 34 in general and administrative functions. 227 of our full-time employees are located in the United States (including 208 who are based out of our corporate headquarters in Menlo Park, California), six of our full-time employees are located in Europe and one of our full-time employees is located in China. As of December 31, 2020, more than 95 of our employees had completed a Ph.D. or other advanced science or medical degree.

Implications of Being an Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”) and therefore we have taken, and intend to continue to take, advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions for up to five years from our initial public offering, which occurred in June 2019, or until we are no longer an “emerging growth company,” whichever is earlier. In addition, the JOBS Act provides that an “emerging growth company” can delay adopting new or revised accounting standards until 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.

The Offering

Common stock offered by us	\$150.0 million of shares of our common stock.
Common stock to be outstanding immediately after this offering	41,987,801 shares of common stock (or 42,467,442 shares of common stock if the underwriters exercise in full their option to purchase additional shares of common stock from us), which is based on an aggregate offering of \$150.0 million of shares of our common stock by us at an assumed public offering price of \$46.91 per share of common stock (the last reported sale price of our common stock on the Nasdaq Global Market on January 25, 2021).
Option to purchase additional common stock from us	We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to \$22.5 million of additional shares of common stock.
Use of proceeds	<p>We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$140.6 million or \$161.7 million if the underwriters exercise their option to purchase additional shares in full.</p> <p>We currently intend to use the net proceeds we receive from this offering for working capital and general corporate purposes, which may include, among other things, funding research and development programs, hiring additional personnel, infrastructure and facilities expansion, and capital expenditures. See “Use of Proceeds” on page S-61 of this prospectus supplement.</p>
Risk factors	See “Risk Factors” and the other information included in this prospectus supplement and accompanying prospectus and in the documents incorporated by reference hereby and thereby for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Nasdaq Global Market trading symbol	“PSNL”.

The number of shares of common stock to be outstanding after the offering is based on the number of shares outstanding as of September 30, 2020. As of that date, we had 38,790,189 shares of common stock outstanding, excluding:

- 5,340,464 shares of common stock underlying options outstanding at a weighted average exercise price of \$6.01 per share;
- 647,210 shares of common stock underlying restricted stock units outstanding; and
- 3,414,560 shares of common stock available for future grant under our equity incentive plans, including our employee stock purchase plan.

Unless otherwise indicated, all information in this prospectus supplement assumes:

- No exercise of outstanding options after September 30, 2020;
- No vesting of outstanding restricted stock units after September 30, 2020; and
- No exercise by the underwriters of their option to purchase additional shares of our common stock from us.

SUMMARY OF RISK FACTORS

Investing in our securities involves a high degree of risk. The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors contained under the heading “Risk Factors” in this prospectus supplement beginning on page S-9, as well as in any free writing prospectuses we have authorized for use in connection with this offering. These risks include, but are not limited to, the following:

Operational, Strategic and Business Risks

- We have a history of losses and we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenues to achieve or sustain profitability.
- If we are unable to increase sales of our current services or products or successfully develop and commercialize other services or products, or are unable to successfully compete with our competitors, we may fail to generate sufficient revenues to achieve profitability and sustain our business.
- Our operations and employees face risks related to health crises, such as the ongoing COVID-19 pandemic, that could adversely affect our operations and the business or operations of our customers or other third parties with whom we conduct business, our financial condition, and our operating results.
- A limited number of customers account for a substantial portion of our revenues and accounts receivable; in particular, we derive a substantial portion of our revenues from our largest customer, the VA MVP.
- We rely on a limited number of suppliers, or in some cases, a sole supplier, for some laboratory instruments and materials, and we may not be able to replace or immediately transition to alternative suppliers if necessary.
- We will need to invest in our infrastructure in advance of increased demand for our services; our failure to accurately forecast demand would negatively impact our business and ability to achieve or sustain profitability.
- If our facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.
- If we cannot continue timely developing and improving our services and products to keep pace with rapid advances in technology, medicine, and science our operating results and competitive position could be harmed.
- Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in or inability to achieve regulatory approval, commercialization, or payor coverage, any of which could adversely affect our business.
- The loss of key members of our executive management team or the inability to hire, retain, or motivate highly skilled personnel could adversely affect our business.
- We may not be able to manage our growth effectively, which could prevent execution of our business strategy.
- We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute stockholders’ ownership, or cause us to incur debt or significant expense.
- Expansion into China and other international markets will subject us to increased regulatory oversight and regulatory, economic, social, health and political uncertainties.

Regulatory, Legal and Cybersecurity Risks

- Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and we may be subject to regulatory action if we or our service or product offerings do not comply with applicable requirements.
- Our internal information technology systems, or those of our third-party vendors, contractors, or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could adversely affect our business.
- The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability.
- Our employees may engage in misconduct or other improper activities, such as noncompliance with regulatory standards and requirements, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery laws, which could cause significant liability for us and harm our reputation.

[Table of Contents](#)

- Changes in health care policy could increase our costs, decrease our revenues, and impact sales of and reimbursement for our tests. If we decide to grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.
- The exit of the United Kingdom from the EU could lead to regulatory divergence and require us to incur additional expenses in order to develop, manufacture, and commercialize our products and services.

Intellectual Property Risks

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

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

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

Risks Related to This Offering

- Management will have broad discretion as to the use of the proceeds from this offering; we may not use the proceeds effectively.
- If you purchase shares of common stock in this offering, you will experience immediate dilution in your investment.
- You may experience further dilution if we issue additional equity securities in future fundraising transactions, and any debt securities we issue would have rights, preferences and privileges senior to those of holders of our common stock and may restrict our operations.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors described below and all other information contained or incorporated by reference in this prospectus supplement and accompanying prospectus, including our financial statements and the related notes, as may be updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (“Exchange Act”) and in any free writing prospectus that we have authorized for use in connection with this offering before acquiring shares of our common stock. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects, which may cause the trading price of our common stock to decline and you could lose all or part of your investment.

Operational, Strategic and Business Risks

We have a history of losses, and as our costs increase, we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenues to achieve or sustain profitability.

We have incurred net losses since our inception. For the nine months ended September 30, 2020 we had a net loss of \$27.9 million, and 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 September 30, 2020, we had an accumulated deficit of \$168.5 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.

[Table of Contents](#)

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 commercial team, including sales and business development personnel;
- the recruitment, hiring, and retention of our commercial team personnel;
- 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 customers or other third parties with whom we conduct business.

Our business could be adversely impacted by the effects of a health crisis, such as the ongoing COVID-19 pandemic, that could cause significant disruption in the operations of our customers and third-party suppliers upon whom we rely. Our laboratory facilities, executive team, and most of our employees are located in the San Francisco Bay Area. In the event of a health crisis that becomes widespread in or around the San Francisco Bay Area, we may proactively, or be ordered by government officials to, take precautionary measures such as suspending our lab operations, implementing alternative work arrangements for our employees, and limiting our employees' travel activities.

Our operations have been impacted by the ongoing COVID-19 pandemic. While the state and county reopening and health orders applicable to us allow for continued operation of so-called Essential Businesses, which includes certain critical healthcare operations and services, we have substantially closed our office facilities and limited access to our laboratory facilities, to protect our employees and to comply with the provisions described within the orders. We provided temporary increased pay to certain laboratory personnel in the second quarter for their work during the COVID-19 pandemic. Such increased pay was not provided in the third or fourth quarters, but we may decide to resume increased pay in the future. The previous shelter-in-place order and current reopening and health orders have negatively impacted productivity, disrupted our business, and slowed research and development activities due to us limiting access to our laboratory space that would otherwise be used by our research and development group, and, to the extent such orders remain in place, they may continue to cause such effects on our operations. The reopening and health orders may disrupt the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we are aware of increased demand in the market for certain consumables used in COVID-19 test kits. We use such consumables in our operations, and we may face difficulties in acquiring such consumables if our suppliers prioritize orders related to COVID-19. Several of our customers, including the VA MVP, were delayed in sending us samples in the

[Table of Contents](#)

second and third quarters due to the inability to collect or ship samples during the COVID-19 pandemic, and these and additional customers may be disrupted from collecting samples or sending purchase orders and samples to us in the future. 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. If our laboratory employees were to contract COVID-19, we may significantly curtail our laboratory operations or pause operations altogether until the imminent health risk to our employees subsided. Such disruptions in our operations, and our customers' and suppliers' operations, may continue to adversely affect revenues and operating results.

The global COVID-19 pandemic continues to rapidly evolve and to present serious health risks. While authorities in some areas have lifted or relaxed certain of the restrictions described above, in some cases they have subsequently re-imposed various restrictions after observing an increased rate of COVID-19 cases; for example, in December 2020, state and local authorities in California reinstated shelter-in-place orders in light of the increasing rate of COVID-19 cases and shortage of intensive care unit beds across the state. Furthermore, there is no guarantee when or if all such restrictions will be eliminated, such that we and our customers, manufacturers and suppliers will be able to safely resume operations consistent with our pre-COVID-19 operations. Vaccines against COVID-19 have been approved by the FDA and other regulatory authorities, but there is uncertainty as to when these vaccines will be widely available to our employees and the population at large and how quickly and to what extent the vaccines will impact the COVID-19 pandemic.

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

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 or potential competitors, including Adaptive Biotechnologies Corporation, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Freenome, Inc., Genosity, Inc., Guardant Health, Inc., Inivata Limited, Invitae Corporation, Mount Sinai Genomics, Inc. which does business under the name Sema4, Natera, Inc., NanoString Technologies, Inc., NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Roche Molecular Systems, Inc., and Tempus, Inc., may have more widespread brand recognition or substantially greater financial or technical resources, development or production capacities, or marketing capabilities than we do. They may be able to devote greater resources to the development, promotion and sale of their products and services than we do or sell their products and services at prices designed to win more significant levels of market share. In addition, our present or potential competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, more well-established and well-financed companies. For example, in September 2020, Illumina, Inc. ("Illumina") announced it had entered into an agreement to acquire GRAIL, Inc. ("GRAIL"), a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology, which we view as a potential competitor. 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. Our customers and potential customers may request, or in some cases have requested, that we consider developing and seeking FDA approval for companion diagnostic tests to accompany those customers’ therapeutic product candidates, and it may be necessary for us to do so in order to successfully compete for the business of these customers. If we do not successfully develop FDA-approved companion diagnostics, we may be at a competitive disadvantage and may be unable to increase market acceptance and sales of our other product offerings, which would prevent us from increasing or sustaining our revenues or achieving or sustaining profitability. If we were to develop one or more FDA-approved companion diagnostics, we would incur increased research and development expenses, and such activities may also divert our resources or the attention of our management and may create competing internal priorities for us.

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

We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our revenues and accounts receivable.

Like other genomic profiling companies that sell to the pharmaceutical industry, we have substantial 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 71% and 75% of our revenues for the three and nine months ended September 30, 2020. Our top five customers, including the VA MVP, accounted for 85% and 88% of our revenues for the three and nine months ended September 30, 2020, respectively. There are inherent risks whenever a large percentage of revenues are concentrated with a limited number of customers. Our predictions regarding the future level of demand for our services that will be generated by these customers may be wrong. 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 factors, 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. Some of our customers have in the past suspended or terminated clinical trials or projects, received less funding than expected, experienced declining or delayed sales, or otherwise decided to reduce or eliminate their use of our services, and these and other customers may also do so in the future. As a result, we could be pressured to reduce the prices we charge for our services, which would have an adverse effect on our margins and financial position, and which would likely negatively affect our 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. Similarly, if the VA MVP was eliminated, awarded its contract to one of our competitors, further reduced the size of our contract or failed to renew our contract in the future, then our revenues, cash position, and results of operations would be materially adversely impacted. Further, if any of our other significant 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 or if the VA MVP conducts a competitive bid process for the next contract and we do not win, 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 contracted orders from the VA MVP in September 2017, 2018, 2019, and 2020. The VA MVP may initiate a competitive bidding process for its next DNA sequencing and data analysis services contract. We may not win any potential new contract in such bidding process, the value of such contract or the VA MVP contracted orders thereunder may be lower than our current contract and historical contracted orders from the VA MVP, and/or the scope or nature of the services required under such new contract may change such that we are unable to serve the VA MVP in the future.

The VA MVP's contracted orders for DNA sequencing and data analysis services have fluctuated in value over time and are subject to the availability of funding, enrollment of veterans in the VA MVP study, and the VA MVP's continued demand for our services among other factors. For example, the VA MVP contracted order received in September 2020 has a value of up to approximately \$31 million, whereas the VA MVP contracted order received in September 2019 had a value of up to approximately \$38.1 million. We have no certainty that funding will be made available for our services, or that the VA MVP will award any future contracts, contract renewals or contracted orders to us. If the priorities of the VA, the VA MVP, or the U.S. government change, including in response to the COVID-19 pandemic for example, funding for our services may be limited or not available, and our business, financial condition, and operating results and cash flows would be materially harmed. Similarly, if we do not win future VA MVP contracts and renewals (whether due to being outbid by a competitor or the VA MVP's decision to terminate for convenience or failure to renew for whatever reason), 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. Furthermore, we only recognize revenue under our VA MVP contract upon the receipt and processing of samples, and the timing and number of VA MVP samples we receive has been and could in the future be negatively affected by factors beyond our control, which has resulted, and may result in the future, in delaying our ability to process and recognize revenue for such samples. For example, the revenue we recognized during the contract year that began in September 2019 significantly exceeded the value of the VA MVP contracted order we received in September 2019 because we

[Table of Contents](#)

continued to receive after such date, and subsequently processed, samples under VA MVP contracted orders that remained unfulfilled as of September 2019 due to the time required for the VA to select optimal samples from its collection for research and then provide us those samples. Therefore, period-to-period comparisons of our operating results relating to VA MVP contracted orders may not be meaningful and, even if we win a potential new VA MVP contract and order with a value comparable to that of the September 2019 contracted order, the revenue we recognize under such potential new contract and order may be less than the revenue we recognized during the 2019-2020 contract year, and may also be less than the revenue we expect to recognize during the 2020-2021 contract year because we expect during the current contract year to finish processing most or all of the samples under VA MVP contracted orders that remained unfulfilled as of September 2020, in addition to samples received under the September 2020 contracted order. The timing and number of VA MVP samples may also have been or be negatively affected by the current COVID-19 pandemic. For example, in March 2020, the VA MVP announced that it was suspending sample collection due to the COVID-19 pandemic. In addition, we believe the COVID-19 pandemic may have been a contributing factor to the reduction in value of the September 2020 VA MVP contracted order compared to the September 2019 contracted order, as the VA MVP delayed new enrollment and also may have needed to divert resources to respond to the pandemic, and the COVID-19 pandemic may also negatively impact the value of any potential new VA MVP contract or order.

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

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

Our customers' clinical trials are expensive, can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and early clinical trials. Many of the biopharmaceutical companies that are our customers do not have products approved for commercial sale and are not profitable. These customers must continue to raise capital in order to continue their development programs and to potentially continue as our customers. If our customers' clinical trials fail or they are unable to raise sufficient capital to continue investing in their clinical programs, our 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.

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

We rely on a limited number of suppliers for sequencers and other equipment and materials that we use in our laboratory operations. For example, we rely on Illumina as the sole supplier of sequencers and various associated reagents, and 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. In September 2020, Illumina announced it had entered into an agreement to acquire GRAIL, a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology. Any disruption in Illumina's operations, or our inability to negotiate an extension to our agreements with Illumina on acceptable terms, or at all, or any competitive pressure resulting from Illumina's anticipated acquisition of GRAIL, could negatively 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.

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 and expanding laboratory capacity. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup, and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software, and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facilities to accommodate such

required expansion. We expect that much of this growth will be in advance of increased demand for our services. Our current and projected future expense levels are to a large extent fixed and are largely based on our current investment plans and our estimates of future test volume. As a result, if 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 facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our genomic analysis conducted in our laboratories. We do not have any clinical reference or research and development laboratory facilities other than our facilities 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 pandemic, we have limited access to our office and laboratory facilities in Menlo Park to protect the health and safety of our employees and to comply with applicable state and local orders. Northern California has recently experienced serious fires and the San Francisco Bay Area is considered to lie in an area with earthquake risk. The inability to sell or to perform our sequencing and analysis services, disruptions in our operations, or the backlog of samples that could develop if our facilities are inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. The limited access to our laboratory facilities as a result of the COVID-19 pandemic has resulted, and may in the future result, in a loss in productivity, including delays to research and development programs. Furthermore, our facilities and the equipment we use to perform our services and our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples as the basis for the development of our services. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

Our 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 have also been and could in the future be flaws in the databases, third-party tools or algorithms we use, or in the software that handles automated parts of our classification protocol. If we receive poor quality or degraded samples, our tests may be unable to accurately detect gene variants or we may fail to or incompletely or incorrectly identify the significance of gene variants, which could have a significant adverse impact on our business.

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 could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring, or prognosis of patients with cancer. New cancer therapies typically have only a few years of clinical data associated with them, and much of that data may not be disclosed by the pharmaceutical company that conducted the clinical trials. This could limit our ability to develop services and products based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the clinical utility of our services and our planned future services and products to new treatments, sales of our services could decline, which would have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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, 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

[Table of Contents](#)

one or more of these key employees, or if one or more of these key employees were to become unable to perform his or her duties due to contracting COVID-19, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Each member of our executive management team has an employment agreement; however, the existence of an employment agreement does not guarantee retention of members of our executive management team, and we may not be able to retain those individuals. We do not maintain “key person” life insurance on any of our employees.

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

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

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

Our performance, including our research and development programs and laboratory operations, largely depends on our continuing ability to identify, hire, develop, motivate, and retain highly skilled personnel for all areas of our organization. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future, including bioinformatic scientists, bioinformatic engineers, software engineers, statisticians, variant curators, clinical laboratory scientists, 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 facilities, laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as our test volume grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and management controls, as well as our reporting systems and procedures. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

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

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

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

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

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

Any future collaborations, including any strategic alliances or any collaborations to develop companion diagnostic tests, 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:

- we would incur increased research and development expenses, and such activities may also divert management attention and resources and/or create competing internal priorities for us, which could prevent us from successfully conducting other parts of our business or collaborating with others;

[Table of Contents](#)

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our services or products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive services or products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities for our collaborator;
- collaborators could independently develop, or develop with third parties, services or products that compete directly or indirectly with our services or products;
- collaborators with marketing, manufacturing, and distribution rights to one or more services or products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- a large percentage of our revenues may be concentrated with the collaborators if the collaborations are successful and we may experience further losses if they are or later become unsuccessful;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future services or products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future services or products;
- collaborators may own or co-own intellectual property covering our services or products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- collaborators' activities or use of our services or deliverables may create additional regulatory obligations and could lead to side effects or adverse events in patients, exposing us to potential liability or regulatory review; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

Our planned expansion into China entails substantial risks.

In June 2020, we announced a partnership with a clinical genomics and life sciences company headquartered in China as a means to expand business operations into China in the near term. Our first wholly owned subsidiary was formed in Shanghai in October 2020. Our expansion and investment plans are subject to substantial risks which may include, but are not limited to: the inability to protect our intellectual property rights under Chinese law, which may not offer as high a level of protection as U.S. law; unexpectedly long negotiation

periods with Chinese suppliers and customers; quality issues related to supplies sourced from local vendors; unexpectedly high labor costs due to a tight labor supply; foreign investment restrictions; and difficulty in repatriating funds and selling or transferring assets. Our investments in China also expose us to additional foreign currency exchange risk. In addition, as tensions have escalated between the U.S. and China, we believe there is an enhanced risk that our planned investments in China may be subject to unforeseen risks or restrictions, which may include expropriation of the investments by the Chinese government. These and other risks may result in our not realizing a return on, or losing some, or all, of our planned investments in China, which could have a material adverse effect on our financial condition and financial performance.

Personal privacy, cyber security, and data protection are becoming increasingly significant issues in China. For example, the State Council of the People's Republic of China adopted the Regulations of the People's Republic of China on Administration of Human Genetic Resources, which went into effect on July 1, 2019. The regulations establish a framework for the collection, preservation, utilization, and supply abroad of human genetic resources of China. The regulations also establish a framework for the use of data and other information generated from use of human genetic resources of China. The regulations also provide that foreign organizations, individuals and entities established or controlled by them are prohibited to collect or preserve China's human genetic resources or transport them abroad. Due to the lack of detailed interpretations and implementations, it is not clear whether the agency in China responsible for enforcing the regulations will grant the necessary approvals for use by us and our partners of our NeXT Platform or our other current or future products in research or clinical projects involving China's human genetic resources or information generated therefrom. The Chinese government separately has various regulations relating to the collection, use, storage, disclosure, and security of data, among other things. We cannot assure you that we will be able to comply with all of these regulatory requirements. Any failure to comply with relevant regulations and policies could result in significant cost and liability to us and could adversely affect our business and results of operations. Any additional new regulations or the amendment or modification of previously implemented regulations, or the failure to receive any necessary approvals for use of our products in connection with such projects, could require us and our partners to change our business plans and incur additional costs, and could limit our ability to generate revenues in China.

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

We may in the future expand our business and operations into international jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals and marketing and selling products and services. For example, in June 2020, we announced our intention to expand into China. As we expand internationally, our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, increased government regulation, social instability, local or regional health crises, and political, economic or diplomatic developments in the future. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations in such jurisdictions to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, anti-bribery and anti-corruption laws may conflict with some local customs and practices in foreign jurisdictions. Our international operations may subject us to heightened scrutiny under the FCPA, the United Kingdom (the "U.K.") Bribery Act and similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws. As a result of our policy to comply with the FCPA, the U.K. Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws. Further, notwithstanding our compliance programs, there can be no assurances that our policies will prevent our employees or agents from violating these laws or protect us from any such violations. Additionally, we cannot predict the nature, scope or impact of any future regulatory requirements that may apply to our international operations or how foreign governments will

interpret existing or new laws. Alleged, perceived, or actual violations of any such existing or future laws by us or due to the acts of others, may result in criminal or civil sanctions, including contract cancellations or debarment, and damage to our reputation, any of which could have a material adverse effect on our business.

Regulatory, Legal and Cybersecurity Risks

Our tests may be subject to regulatory action if regulatory agencies determine that our tests do not appropriately comply with statutory and regulatory requirements enforced by the U.S. Food and Drug Administration, and/or CLIA requirements for quality laboratory testing.

The laws and regulations governing the marketing of clinical laboratory tests are extremely complex and in many instances there are no significant regulatory or judicial interpretations of these laws and regulations. The Federal Food, Drug and Cosmetic Act (the “FDC Act”) defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. Some of our tests may be considered by the FDA to be in vitro diagnostic products that are subject to regulation as medical devices. Among other things, pursuant to the FDC Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices.

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

[Table of Contents](#)

non-binding draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA indicated that it did not intend to implement its proposed framework until the draft guidance documents are finalized. The FDA was expected to finalize its proposal for the oversight of LDTs before the end of 2016, but in November 2016, the FDA announced that it would halt finalizing of the guidance documents and continue to work with stakeholders, the incoming administration, and Congress on the approach to LDT regulation. This announcement was followed by the issuance of an information discussion paper on January 13, 2017, in which the FDA outlined a substantially revised “possible approach” to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it is not enforceable and does not represent the FDA’s “formal position.” It is unclear at this time if or when the FDA will finalize its plans to end enforcement discretion for LDTs, and even then, whether the new regulatory requirements are expected to be phased-in over time. However, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.

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

Additionally, the Centers for Medicare & Medicaid Services (“CMS”), and certain state agencies regulate the performance of LDTs (as authorized under CLIA and state law, respectively). Our tests are developed in compliance with CLIA requirements. However, if our laboratory fails to comply with the prescribed quality requirements for laboratory testing or other requirements for CLIA, we could lose CLIA certification. That in turn would impact our ability to operate our laboratory and provide results to our customers, which could negatively impact our business operations.

The IVDR includes limited exemptions for LDTs, but such exemptions only apply to laboratories that are part of health institutions established in the EEA, and so any services undertaken outside of the EEA (for example at our facilities in the U.S.) will not be covered by such exemptions. In any event, such exemptions are limited in their scope, and only apply if a number of conditions are met, including that the health institution justifies that the “target patient group’s specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market” and do not cover devices that are manufactured on an “industrial scale”. Even where an exemption is applicable, such IVDs will still be subject to certain requirements under the IVDR. It is therefore unlikely that our tests will benefit from any exemption on the basis of being LDTs and will have to comply with the IVDR in full if we offer such tests to customers in the EEA (and Northern Ireland) (whether directly or via intermediaries).

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

If the FDA determines that our tests and associated software do not fall within the definition of an LDT, or there are regulatory or legislative changes, we may be required to obtain premarket clearance for our tests and

[Table of Contents](#)

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

If premarket review of our tests is required, the premarket review process may involve, among other things, successfully completing additional clinical trials. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical

[Table of Contents](#)

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;

Table of Contents

- 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

[Table of Contents](#)

review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood necessary for us to perform our tests that may limit our ability to make our tests available outside of the U.S. Complying with licensure requirements in new jurisdictions may be expensive and/or time-consuming, may subject us to significant and unanticipated delays, or may be in conflict with other applicable requirements.

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

Failure to comply with the IVDR may result in a range of enforcement actions. Penalties under the IVDR are devolved to national governments, but the IVDR requires that such measures are “effective, proportionate, and dissuasive.” Initial indications suggest that penalties for breaches of the IVDR are likely to include fines and, potentially, prison sentences.

Although we market our tests as LDTs that are currently subject to the FDA’s exercise of enforcement discretion, if we fail to operate within the conditions of that exercise of enforcement discretion, 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.

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

In the ordinary course of our business, we collect, process, and store proprietary, confidential, and sensitive information, including protected health information (“PHI”), personally identifiable information (“PII”), credit card and other financial information, intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We depend on information technology and telecommunications systems for significant elements of our operations and we have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business

[Table of Contents](#)

processes and functional areas, including, for example, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit, and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors, as we have outsourced elements of our operations to third parties and as a result a number of third-party vendors and other contractors and consultants have access to our proprietary, confidential, and sensitive information.

We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of business-critical information, including research and development information, patient data, commercial information, and business and financial information. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to our customers, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, and managing the administrative aspects of our business. For example, in the first quarter of 2018, we experienced downtime in our information technology systems in connection with the adoption of certain new information technology, and our results of operations in the first and second quarters of 2018 were adversely affected as a result. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

Notwithstanding the implementation of security measures, given the size and complexity of our internal information technology systems and those of our third-party vendors and other contractors and consultants, and the increasing amounts of proprietary, confidential, and sensitive information that they maintain, such information technology systems are potentially vulnerable to breakdown, service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third-party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (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 accidental actions or omissions by trusted insiders, cyber-attacks or cyber intrusions, including by computer hackers, viruses, 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; in particular, during the COVID-19 pandemic we have observed an increase in attempted attacks against our data systems. Additionally, in connection with the ongoing COVID-19 pandemic, most of our personnel are working remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more personnel accessing sensitive and critical information from remote locations. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, hostile foreign governments or agencies, or cybersecurity researchers. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our services 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

[Table of Contents](#)

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.

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.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen.

Any such access, breach, or other loss of information could result in legal claims or proceedings, liability under domestic or foreign privacy, data protection, and data security laws such as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and penalties. Notice of certain security 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.

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

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to \$250,000 and permit injured parties to sue for damages. Similarly, the California Consumer Privacy Act ("CCPA") allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures. The 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.

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

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

For example, the EU adopted the General Data Protection Regulation (EU) 2016/679 ("GDPR"), which imposes onerous and comprehensive privacy, data protection, and data security obligations onto data controllers and processors, including, as applicable, contractual privacy, data protection, and data security commitments, expanded disclosures to data subjects about how their personal information is used, honoring individuals' data protection rights, limitations on retention of personal information, additional requirements pertaining to sensitive information (such as health data) and pseudonymized (i.e., key-coded) data, data breach notification requirements, and higher standards for obtaining consent from data subjects. Penalties for non-compliance with the GDPR can be significant and include fines in the amount of the greater of €20 million or 4% of global turnover and restrictions or prohibitions on data processing, which could limit our ability to do business in the EU, reduce demand for our services, and adversely impact our business and results of operations. The GDPR also provides that EU member states may introduce further conditions, including limitations, to make their own further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share European data, or could cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices.

[Table of Contents](#)

European privacy, data protection, and data security laws, including the GDPR, generally restrict the transfer of personal information from the U.K., EEA and Switzerland to the U.S. and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. There is uncertainty on how to implement such safeguards and how to conduct such transfers in compliance with the GDPR, and certain safeguards may not be available or applicable with respect to some or all of the personal information processing activities necessary to research, develop and market our products and services. One of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks. However, the EU-U.S. Privacy Shield framework was invalidated in July 2020 in a decision by the Court of Justice of the EU and the Swiss-U.S. Privacy Shield Framework was declared as inadequate by the Swiss Federal Data Protection and Information Commissioner. The decision by the Court of Justice and the announcement by the Swiss Commissioner both raised questions about whether one of the primary alternatives to the Privacy Shield frameworks, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the U.S. or most other countries. Authorities in the U.K. may similarly invalidate use of the EU-U.S. Privacy Shield and raise questions on the viability of the Standard Contractual Clauses. In November 2020, EU regulators proposed a new set of Standard Contractual Clauses, which impose additional obligations and requirements with respect to the transfer of EU personal data to other jurisdictions, which may increase the legal risks and liabilities under the GDPR and local EU laws associated with cross-border data transfers, and result in material increased compliance and operational costs. If we are unable to implement a valid solution for personal information transfers to the U.S. and other countries, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe to the U.S. or other countries may decrease demand for our products and services as our customers that are subject to the GDPR may seek alternatives that do not involve personal information transfers out of Europe. At present, there are few, if any, viable alternatives to the Privacy Shield and the Standard Contractual Clauses.

In addition, it is unclear whether the transfer of personal information from the EU to the U.K. will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the U.K. and the EU, transfers of personal information from the EEA to the U.K. are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an adequacy finding with respect to the U.K. before the end of that period, the U.K. will be considered a "third country" under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers lawful under the GDPR. Additionally, although U.K. privacy, data protection and data security law is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

Regulation of privacy, data protection, and data security has also become more stringent in the U.S. New laws are also being considered at both the state and federal levels, and legislatures of states such as California have already passed and enacted privacy legislation. For example, the CCPA, which took effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy, data protection and data security legislation in the U.S., which could increase our potential liability and adversely affect our business. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA imposes additional obligations relating to consumer data on companies doing business in California beginning January 1, 2022, with implementing regulations expected on or before July 1, 2022, and enforcement beginning July 1, 2023. The CPRA significantly modifies the CCPA and will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish

restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law.

Compliance with U.S. and foreign privacy, data protection, and data security laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We typically rely on our customers to obtain valid and appropriate consents from data subjects whose genetic samples and data we process on such customers' behalf. Given that we do not typically obtain direct consent from such data subjects and we do not audit our customers to ensure that they have obtained the necessary consents required by law, the failure of our customers to obtain consents that are valid under applicable law could result in our own non-compliance with privacy laws. Such failure to comply with U.S. and foreign privacy, data protection, and data security laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data protection, and data security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

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

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with government regulations, including federal and state healthcare fraud and abuse laws and regulations, to misuse information, including patient information, and to report financial information or data accurately or disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from government healthcare programs, contractual damages, refunding of payments received by us, reputational harm, additional reporting, or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

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

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program. A person or entity does not need to have actual knowledge of

the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

- the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim under the False Claims Act;
- the “Anti-Markup Rule” and similar state laws, among other things, prohibit a physician or supplier billing the Medicare program from marking up the price of a purchased diagnostic service performed by another laboratory or supplier that does not “share a practice” with the billing physician or supplier. Penalties may apply to the billing physician or supplier if Medicare or another payer is billed at a rate that exceeds the performing laboratory’s charges to the billing physician or supplier, and the performing laboratory could be at risk under false claims laws, described below, for causing the submission of a false claim;
- the 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”), with certain exceptions, to report annually to CMS information related to (i) payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members, which will be expanded beginning in 2022, to require applicable manufacturers to report information regarding payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives during the previous year;
- 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 U.S. may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and reputational harm and divert our management’s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, integrity oversight and reporting obligations, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We could be adversely affected by violations of the Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the U.K.’s Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

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

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

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

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several 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 eliminating 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the

[Table of Contents](#)

case, although it is uncertain when or how the Supreme Court will rule. 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 ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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 established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare 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. In January 2020, CMS announced that data reporting for clinical diagnostic laboratory tests is delayed by one year. Moreover, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, enacted in March 2020, further delays the reporting period by an additional year. Therefore, data that was originally supposed to be reported between January 1, 2020 and March 31, 2020 must now be reported between January 1, 2022 and March 31, 2022. Covered laboratories must report data from the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests will then resume on a three year cycle beginning in 2025. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our products in development. In addition, CMS updated the statutory phase-in provisions such that, for 2020, the rates for clinical diagnostic laboratory tests may not be reduced by more than 10% of the rates for 2019. Pursuant to the CARES Act, the statutory phase-in of payment reductions has been extended through 2024 with a 0% reduction cap for 2021 and a 15% reduction cap for each of 2022, 2023, and 2024. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

Further, it is possible that additional governmental action is taken to address the COVID-19 pandemic. We also anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and private payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from payers, including commercial payers and government payers.

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

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

The 2017 tax reform law, as modified by 2020 tax legislation, and possible future changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law comprehensive tax legislation (the “Tax Cuts and Jobs Act”) that significantly revised the Internal Revenue Code of 1986, as amended (the “Code”). Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, on March 27, 2020, the CARES Act was enacted, which includes changes to the tax provisions that benefit business entities and makes certain technical corrections to the Tax Cuts and Jobs Act. On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspends the use of California net operating losses and limits the use of California research tax credits for tax years beginning in 2020 and before 2023. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act, or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation.

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

We are subject to taxation in numerous U.S. states and territories, as well as various non-U.S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various 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 and the CARES Act, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as “Brexit.” Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K.

[Table of Contents](#)

was subject to a transition period until December 31, 2020 (the “Transition Period”), during which EU rules continued to apply. A deal that outlines the future trading relationship between the U.K. and the EU was agreed in December 2020 and has been approved by each EU member state and the U.K.

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

Should the U.K. or Great Britain further diverge from the EU from a regulatory perspective (for example, by not mirroring the provisions of the IVDR), tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Intellectual Property Risks

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

Our commercial success will depend in part on our avoiding infringement of patents and infringement, misappropriation or other violations of other proprietary rights of third parties, including for example the intellectual property of competitors. There is extensive intellectual property litigation involving the biotechnology and pharmaceutical industries and genetic sequencing technology. 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 U.S. and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the U.S. can remain confidential until patents issue. Therefore, patent applications covering our products, services, or technologies could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products, services, technologies, and their use. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent’s prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a

[Table of Contents](#)

pending application may be incorrect, which may negatively impact our ability to market our products and services. Further, we may incorrectly determine that our technologies, products, or services are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or services.

Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our technologies, products, and services. Regardless of the merit of third parties' claims against us for infringement, misappropriation or violations of their intellectual property rights, such third parties may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, even if such claims are resolved in our favor, could cause us to incur substantial expenses and be a substantial diversion of our employee resources even if we are ultimately successful. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources 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 a suit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products, services or technologies we may develop and any other technologies covered by the asserted third-party patents and any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement; obtain one or more licenses from third parties in order to continue developing and marketing our products and technology, which may not be available on commercially reasonable terms (if at all) or may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; pay substantial royalties and other fees; and redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, or be prohibited from commercializing certain tests, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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 U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the AIA, the U.S. 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 U.S. 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 U.S. 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 U.S. may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S., and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, and services are obtained, once the patent life has expired, we may be open to competition from competitive products. Our issued patents will expire on dates ranging from 2033 to 2038, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2040. In addition, although upon issuance in the U.S. a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products and services, our competitive position, business, financial condition, results of operations, and prospects will be adversely affected.

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

We have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, the patent process is expensive, time consuming and complex, and we may not be able to apply for patents on certain aspects of our services, products, and other technologies in a timely fashion, at a reasonable cost, in all jurisdictions or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.

Moreover, the patent position of biotechnology companies can be highly uncertain because it involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the U.S. or elsewhere.

[Table of Contents](#)

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;

[Table of Contents](#)

- any issued patents that we own or may license will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop or in-license additional proprietary technologies that are patentable;
- pending patent applications that we own or may license will lead to issued patents;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

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

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

It is also possible that we fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, *inter partes* review proceedings, or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the U.S. allow for various post-grant opposition proceedings, such as *inter partes* review proceedings, 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 U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product. 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

[Table of Contents](#)

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

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

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our products and provision of our services, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, license agreements, collaboration agreements, supply agreements, consulting agreements, or other similar agreements with our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how, and other confidential information increases the risk that such trade secrets and know-how become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or know-how, or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

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

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

Filing, prosecuting, maintaining, defending, and enforcing patents on our products, services, and technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. Competitors may use our

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

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

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

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

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

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

[Table of Contents](#)

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

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

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

A portion of the products or technologies licensed, developed, and/or distributed by us incorporate so-called “open source” software and we may incorporate open source software into other products in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products or provide our services that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their products. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could have a material adverse effect on our business, financial condition, and results of operations.

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

We license certain intellectual property that is important to our business, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. For example,

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

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

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

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

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

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

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 September 30, 2020, we had approximately \$20.6 million in customer deposits, including \$17.6 million from one customer. However, as of that date, we had \$206.1 million of cash and cash equivalents, and short-term investments. We are generally not required by our contracts to retain these deposits in cash or otherwise and we have generally used these deposits to make capital expenditures and fund our operations. When a customer that has prepaid us for future services cancels its contract with us or reduces the level of services that it expects to receive, we are 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.

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

We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations, and research and development activities. Additionally, if we decide to grow our business by developing in vitro diagnostic tests, our capital expenditures and operating expenses would significantly increase. We may seek to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued may also provide for rights, preferences, or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement, if available, could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms.

If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or sales and marketing initiatives. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruption to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the ongoing COVID-19 pandemic. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to us. While we believe our existing cash and cash equivalents, and short-term investments 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.

[Table of Contents](#)

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

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

- actual or anticipated fluctuations in our operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research reports by securities analysts or changed recommendations for our stock;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP, as our largest customer;
- the timing and amount of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business or issues we may face with regulators;
- additions or departures of key management or other personnel;
- inability to obtain additional funding;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments related to our intellectual property or other matters, including litigation;
- the long-term macroeconomic effects of the COVID-19 pandemic, including potential global, regional or national economic slowdowns, recessions, depressions or other economic downturns; and
- general economic, industry, and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors.

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

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our 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 MVP and other large customers are not obliged to deliver tissue samples or other specimens to us at any particular time or at all. The rate at which we receive tissue samples or other specimens can vary dramatically from quarter to quarter, and is difficult or impossible for us to accurately forecast. Our receipt and processing of tissue samples and other specimens from our customers leads to our recognition of revenue, and as such the variable rates of delivery of customer samples will lead to variations in our revenues from quarter to quarter. For example, we often see fluctuations in receipt and processing of samples and revenues in the fourth quarter due, in part, to the concentration of holidays in late November and in December and some of our biopharmaceutical customers have fiscal years ending in December, which we believe may impact the timing of samples or payments provided by such customers. Fluctuations in quarterly results may adversely impact the value of our common stock. Factors that may cause fluctuations in our quarterly financial results include, without limitation, those listed elsewhere in this “Risk Factors” section. We also may face competitive pricing pressures, and we may not be able to maintain our pricing in the future, which would adversely affect our operating results.

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

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

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

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of September 30, 2020, we had 38,790,189 shares of common stock outstanding, all of which shares were eligible as of such date for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, upon issuance, shares of common stock subject to outstanding options under our stock option plans as of September 30, 2020 will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, certain holders of shares of our common stock have the right to require us to register these shares under the Securities Act pursuant to an investors’ rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse effect on the market price of our common stock.

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

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

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

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

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

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

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

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

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

As of December 31, 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,

as modified by the CARES Act, federal net operating losses incurred in tax years beginning in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses for tax years beginning after 2020 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, as modified by the CARES Act. In addition, under 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 have experienced ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, for California income tax purposes, California net operating losses and California research tax credits will be suspended and limited, respectively, for tax years beginning after 2019 but before 2023.

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

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

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

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

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

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

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

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

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

The requirements of being a public company consume substantial resources, may result in litigation and 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 may be required to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

[Table of Contents](#)

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.

As a public company, it may be increasingly expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, as a result of our disclosure obligations as a public company, we have reduced strategic flexibility as compared to our competitors that are privately-held companies, and are under pressure to focus on short-term results, which may materially and adversely affect our ability to achieve long-term profitability.

We are 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 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;

[Table of Contents](#)

- 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 the 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 U.S. 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.

Risks Related to This Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

If you purchase shares of common stock in this offering, you will experience immediate dilution in your investment.

Purchasers of common stock in this offering will pay a price per share in this offering that exceeds the net tangible book value per share of our common stock. Assuming that an aggregate of 3,197,612 shares of common stock are sold by us at a public offering price of \$46.91 per share, the last reported sale price of our common shares on the Nasdaq Global Market on January 25, 2021, for aggregate net proceeds to us of approximately \$140.6 million and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, if you purchase shares of our common stock in this offering, you will experience immediate dilution of \$38.71 per share, representing the difference between the assumed public offering price and our as adjusted net tangible book value per share as of September 30, 2020, after giving effect to this offering. See the section below titled “Dilution” on page S-63 for a more detailed illustration of the dilution you would incur if you purchase common stock in this offering.

You may experience further dilution if we issue additional equity securities in future fundraising transactions, and any debt securities we issue would have rights, preferences and privileges senior to those of holders of our common stock and may restrict our operations.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering. Further, we have a significant number of stock options and restricted stock units outstanding. The exercise of outstanding stock options or vesting of restricted stock units may result in further dilution of your investment. Additionally, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents we have filed with the SEC that are incorporated by reference contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the evolution of cancer therapies and market adoption of our services;
- estimates of our total addressable market, future revenue, expenses, capital requirements, and our needs for additional financing;
- our ability to enter into and compete in new market segments;
- 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;
- our expectation regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act; and
- our ability to maintain proper and effective internal controls.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss in greater detail many of these risks under the heading “Risk Factors” contained in this prospectus supplement, in any free writing prospectuses we may authorize for use in connection with this offering, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which are incorporated by reference into this prospectus supplement and accompanying prospectus in their entirety. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

[Table of Contents](#)

Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this prospectus supplement and accompanying prospectus together with the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we may authorize for use in connection with this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the sale of common stock by us in this offering of approximately \$140.6 million, or \$161.7 million if the underwriters exercise their option to purchase additional shares in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We will retain broad discretion over the use of the net proceeds from this offering. We currently intend to use the net proceeds we receive from this offering for working capital and general corporate purposes, which may include, among other things, funding research and development programs, hiring additional personnel, infrastructure and facilities expansion, and capital expenditures.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, short-term investments, and capitalization as of September 30, 2020:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale by us of \$150.0 million of shares of our common stock in this offering at an assumed public offering price of \$46.91 per share, the closing price of our common stock on the Nasdaq Global Market Exchange on January 25, 2021, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us as described under “Use of Proceeds.”

You should read the data set forth in the table below in conjunction with (a) our consolidated financial statements, including the related notes, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” from our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and (b) our condensed consolidated financial statements, including the related notes, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” from our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, which are incorporated by reference into this prospectus supplement and accompanying prospectus.

(In thousands, except share and per share amounts)	As of September 30, 2020	
	Actual	As Adjusted
Cash and cash equivalents	\$ 133,245	\$ 273,844
Short-term investments	\$ 72,818	\$ 72,818
Stockholders’ equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; 0 shares issued and outstanding, actual and as adjusted	\$ —	\$ —
Common stock, \$0.0001 par value, 200,000,000 shares authorized; 38,790,189 shares issued and outstanding, actual; 41,987,801 shares issued and outstanding as adjusted	4	4
Additional paid-in capital	327,027	512,626
Accumulated other comprehensive income	37	37
Accumulated deficit	(168,528)	(168,528)
Total stockholders’ equity	203,540	344,139
Total capitalization	\$ 203,540	\$ 344,139

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of September 30, 2020. As of that date, we had 38,790,189 shares of common stock outstanding, excluding:

- 5,340,464 shares of common stock underlying options outstanding at a weighted average exercise price of \$6.01 per share;
- 647,210 shares of common stock underlying restricted stock units outstanding; and
- 3,414,560 shares of common stock available for future grant under our equity incentive plans, including our employee stock purchase plan.

DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price and the adjusted net tangible book value per share of our common stock after this offering.

Net tangible book value on September 30, 2020, was approximately \$203.5 million, or \$5.25 per share. “Net tangible book value” is total assets minus the sum of liabilities and intangible assets. “Net tangible book value per share” is net tangible book value divided by the total number of shares outstanding. Net tangible book value per share after this offering gives effect to the sale of \$150.0 million of shares of our common stock in this offering at the assumed public offering price of \$46.91 per share, the closing price of our common stock on the Nasdaq Global Market on January 25, 2021, after deducting estimated underwriting discounts commissions and estimated offering expenses payable by us.

Our as adjusted net tangible book value as of September 30, 2020, after giving effect to this offering as described above, would have been approximately \$344.1 million, or \$8.20 per share of common stock. This represents an immediate increase in net tangible book value of \$2.95 per share to our existing stockholders and an immediate dilution in net tangible book value of \$38.71 per share to investors participating in this offering. The following table illustrates this dilution per share to investors participating in this offering:

Assumed public offering price per share		\$46.91
Net tangible book value per share as of September 30, 2020	\$ 5.25	
Increase in net tangible book value per share attributable to new investors in offering	\$ 2.95	
As adjusted net tangible book value per share after giving effect to the offering	\$ <u>8.20</u>	
Dilution per share to new investors		\$38.71

If the underwriters fully exercise their option to purchase additional shares, as adjusted net tangible book value after this offering would increase to approximately \$8.60 per share, and there would be an immediate dilution of approximately \$38.31 per share to investors participating in this offering.

The number of shares of common stock to be outstanding after the offering is based on the number of shares outstanding as of September 30, 2020. As of that date, we had 38,790,189 shares of common stock outstanding, excluding:

- 5,340,464 shares of common stock underlying options outstanding at a weighted average exercise price of \$6.01 per share;
- 647,210 shares of common stock underlying restricted stock units outstanding; and
- 3,414,560 shares of common stock available for future grant under our equity incentive plans, including our employee stock purchase plan.

To the extent that any outstanding options are exercised or restricted stock units vest, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or equity-linked securities, the issuance of these securities could result in further dilution to our stockholders.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership, and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local, or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service, or IRS, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder’s particular circumstances, including the alternative minimum tax, the Medicare contribution tax on net investment income, and the special tax accounting rules under Section 451(b) of the Code. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- “controlled foreign corporations;”
- “passive foreign investment companies;”
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING,

OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS. YOU SHOULD ALSO CONSULT WITH YOUR TAX ADVISOR WITH RESPECT TO POTENTIAL CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in our Form S-1 Registration Statement under the section titled “Dividend Policy,” we have not paid and do not anticipate paying dividends. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled “—Gain on Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and Sections 1471 through 1474 of the Code (commonly referred to as FATCA), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our paying agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) including a U.S. taxpayer identification number and certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder’s U.S. trade or business (and are attributable to such holder’s permanent establishment in the United States if required by an

[Table of Contents](#)

applicable tax treaty), the non-U.S. holder will generally be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation ("USRPHC") for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our worldwide real property interests. We believe that we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were dividends that were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This

[Table of Contents](#)

information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Foreign Entities

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA applies to dividends paid on our common stock and, subject to the proposed Treasury Regulations described below, also applies to gross proceeds from sales or other dispositions of our common stock. The U.S. Treasury Department released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

UNDERWRITING

Morgan Stanley & Co. LLC, BofA Securities, Inc., Citigroup Global Markets Inc. and Cowen and Company, LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below:

<u>Underwriter</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	
BofA Securities, Inc.	
Citigroup Global Markets Inc.	
Cowen and Company, LLC	
BTIG, LLC	
Total	<u><u> </u></u>

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter’s initial amount reflected in the above table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional shares of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us:	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

[Table of Contents](#)

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$. We have agreed to reimburse the underwriters for expenses up to \$37,500 relating to clearance of this offering with the Financial Industry Regulatory Authority and compliance with state securities or “blue sky” laws.

The shares are listed on the Nasdaq Global Market under the trading symbol “PSNL.”

We and our directors and executive officers have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, during the period ending 60 days after the date of this prospectus (the “restricted period”):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock. These restrictions also do not apply to us in certain circumstances including in connection with the issuance of up to 5% of our shares of common stock outstanding immediately following the closing of this offering in acquisitions or other similar strategic transactions.

The restrictions described in the immediately preceding paragraph do not apply to our directors, or executive officers in certain circumstances, including (i) transactions by any person other than us relating to shares of our common stock or other securities acquired in this offering or in open market transactions after the closing of this offering, provided that no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) would be required or voluntarily made in connection with subsequent sales of the common stock or other securities acquired in such open market transactions; (ii) transfers of our common stock as bona fide gifts, by will, to an immediate family member or to certain trusts provided that no filing under Section 16(a) of the Exchange Act would be required or voluntarily made; (iii) distributions of our common stock to another corporation, partnership, limited liability company, trust, or other business entity that is an affiliate, or to an entity controlled or managed by an affiliate provided that no filing under Section 16(a) of the Exchange Act would be required or voluntarily made; (iv) distributions of our common stock to the stockholders, partners, or members of such holders provided that no filing under Section 16(a) of the Exchange Act would be required or voluntarily made; (v) the exercise of options or other equity awards granted under a stock incentive plan or other equity award plan described in this prospectus supplement, or the exercise of warrants outstanding described in this prospectus supplement; (vi) transfers of our common stock to us for the net exercise of options, settlement of warrants granted pursuant to our equity incentive plans, or to cover tax withholding for grants pursuant to our equity incentive plans, provided that any filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (vi); (vii) the establishment by such holders of trading plans under Rule 10b5-1 under the Exchange Act provided that such plan does not provide for the transfer of common stock during the restricted period; (viii) transfers of our common stock pursuant to a domestic order, divorce settlement, or other court order; (ix) transfers of our

[Table of Contents](#)

common stock to us pursuant to any right to repurchase or any right of first refusal we may have over such shares; (x) transfers of our common stock pursuant to a bona fide third-party tender offer, merger, consolidation, or other similar transaction that is approved by our board of directors; (xi) any transfer or sale of common stock pursuant to a trading plan that was established pursuant to Rule 10b5-1 under the Exchange Act prior to the date of the lockup agreement; (xii) the sale of shares of common stock issued upon settlement of restricted stock units to cover (i) the satisfaction of the maximum tax withholding obligation arising from the vesting of such restricted stock unit and the related issuance of such shares and (ii) any applicable fees or commissions due to or required to be collected by our administrative agent for our equity incentive plans *provided* that during the restricted period, any filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (xii); and (xiii) sales to the underwriters pursuant to the underwriting agreement.

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain, or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the underwriters' option described above. The underwriters can close out a covered short sale by exercising the underwriters' option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the underwriters' option. The underwriters may also sell shares in excess of the underwriters' option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing, and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

[Table of Contents](#)

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial

Table of Contents

intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

We have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares in this document. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of us or the underwriters.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom, no shares of common stock have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares that either (i) has been approved by the Financial Conduct Authority, or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provision in Regulation 74 of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019, except that offers of shares may be made to the public in the United Kingdom at any time under the following exemptions under the UK Prospectus Regulation:

- to any legal entity which is a qualified investor as defined in Article 2 of the UK Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in Article 2 of the UK Prospectus Regulation); or
- in any other circumstances falling within section 86 of the Financial Services and Markets Act 2000 (“FSMA”),

provided that no such offer of shares shall require the Issuer or any representative to publish a prospectus pursuant to section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any relevant state means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

We have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of us or the underwriters. In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in Article 2 of the UK Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated)

[Table of Contents](#)

falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the FSMA.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, Personalis, Inc., or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (“FINMA”), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (“DFSA”). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (“ASIC”), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the “Corporations Act”), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

[Table of Contents](#)

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation, or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations, and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the “SFA”)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

[Table of Contents](#)

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person, which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)), the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor), whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA, except:

- (a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i) (B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law; or
- (d) as specified in Section 276(7) of the SFA.

LEGAL MATTERS

Cooley LLP will pass upon the validity of the securities offered by this prospectus supplement. Davis Polk & Wardwell LLP, Menlo Park, California, is representing the underwriters in this offering.

EXPERTS

The financial statements incorporated in this Prospectus Supplement by reference from the Company's Annual Report on Form 10-K have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement is part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and does not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus supplement and accompanying prospectus for a copy of such contract, agreement or other document. Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. The information on the SEC's web site is not part of this prospectus supplement or accompanying prospectus, and any references to this web site or any other web site are inactive textual references only.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information in this prospectus supplement supersedes information in the accompanying prospectus supplement or incorporated by reference that we filed with the SEC prior to the date of this prospectus supplement, while information that we file later with the SEC will automatically update and supersede the information in this prospectus supplement and accompanying prospectus. We incorporate by reference into this prospectus supplement and accompanying prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-38943):

- our Annual Report on [Form 10-K](#), for the year ended December 31, 2019, filed with the SEC on March 25, 2020;
- the information specifically incorporated by referenced into our Annual Report on Form 10-K for the year ended December 31, 2019 from our [Definitive Proxy Statement](#) filed with the SEC on April 3, 2020;
- our Quarterly Report on [Form 10-Q](#), for the quarter ended March 31, 2020, filed with the SEC on May 7, 2020;
- our Quarterly Report on [Form 10-Q](#), for the quarter ended June 30, 2020, filed with the SEC on August 6, 2020;
- our Quarterly Report on [Form 10-Q](#), for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020;
- our Current Report on Form 8-K filed with the SEC on [May 20, 2020](#);
- our Current Report on Form 8-K filed with the SEC on [August 12, 2020](#); and
- the description of our common stock set forth in our registration statement on [Form 8-A](#), filed with the SEC on June 17, 2019, including any amendment or report filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus supplement and accompanying prospectus, which will become a part of this prospectus supplement and accompanying prospectus from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus supplement and the accompanying prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later-filed document modify or replace such earlier statements. We will furnish without charge to each person, including any beneficial owner, to whom a prospectus supplement and the accompanying prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference into this prospectus supplement and accompanying prospectus but not delivered with the prospectus supplement and the accompanying prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to:

Personalis, Inc.
1330 O'Brien Drive
Menlo Park, California 94025
Attn: Secretary
(650) 752-1300

PROSPECTUS



\$300,000,000

Common Stock

Preferred Stock

Debt Securities

Warrants

and

1,774,240 Shares of

Common Stock

Offered by the Selling Stockholder

We may, from time to time, offer and sell up to \$300,000,000 of any combination of the securities described in this prospectus, either individually or in combination, at prices and on terms described in one or more supplements to this prospectus. We may also offer common stock or preferred stock upon conversion of debt securities, or common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon exercise of warrants. In addition, the selling stockholder to be named in the applicable prospectus supplement may offer and sell up to an aggregate of 1,774,240 shares of our common stock, from time to time, on the terms described in this prospectus or in an applicable prospectus supplement. We will not receive any of the proceeds from the sale of the shares offered by the selling stockholder hereunder. To the extent that any selling stockholder resells any securities, the selling stockholder may be required to provide you with this prospectus and a prospectus supplement identifying and containing specific information about the selling stockholder and the terms of the securities being offered.

This prospectus describes some of the general terms that may apply to an offering of our securities. We will provide the specific terms of these offerings and securities in one or more supplements to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as the documents incorporated by reference, before buying any of the securities being offered.

This prospectus may not be used to consummate a sale of securities unless accompanied by a prospectus supplement.

We and the selling stockholder may sell the securities through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information on the methods of sale, you should refer to the section entitled "[Plan of Distribution](#)" in this prospectus on page 78 and in the applicable prospectus supplement. If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable discounts or commissions and over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Our common stock is listed on the Nasdaq Global Market under the symbol "PSNL." On December 29, 2020, the last reported sale price of our common stock on the Nasdaq Global Market was \$38.52 per share. The applicable prospectus supplement will contain information, where applicable, as to other listings, if any, on the Nasdaq Global Market or other securities exchange of the securities covered by the prospectus supplement.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "[Risk Factors](#)" contained in this prospectus on page 7, in our most recent [Annual Report on Form 10-K](#) and [Quarterly Report on Form 10-Q](#) incorporated by reference into this prospectus, in the applicable prospectus supplement and in any free writing prospectuses we have authorized for use in connection with a specific offering, and under similar headings in the other documents that are incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We are an "emerging growth company" under the federal securities laws and are subject to reduced public company reporting requirements.

The date of this prospectus is January 8, 2021.

TABLE OF CONTENTS

	Page
About this Prospectus	i
Prospectus Summary	1
Summary of Risk Factors	5
Risk Factors	7
Forward-Looking Statements	56
Use of Proceeds	58
Description of Capital Stock	59
Description of Debt Securities	64
Description of Warrants	71
Legal Ownership of Securities	73
Selling Stockholder	77
Plan of Distribution	78
Legal Matters	81
Experts	81
Where You Can Find More Information	81
Incorporation of Certain Information by Reference	82

You should rely only on the information contained in, or incorporated by reference into, this prospectus and the applicable prospectus supplement, along with the information contained in any free writing prospectuses we have authorized for use in connection with a specific offering. We have not authorized anyone to provide you with different information. We are not making an offer to sell or seeking an offer to buy securities under this prospectus or the applicable prospectus supplement and any related free writing prospectus in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus, the applicable prospectus supplement or any related free writing prospectus, and the documents incorporated by reference herein and therein, are accurate only as of their respective dates, regardless of the time of delivery of this prospectus, the applicable prospectus supplement or any related free writing prospectus, or any sale of a security.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration process under the Securities Act of 1933, as amended, or the Securities Act. Under this shelf registration statement, we may sell from time to time in one or more offerings up to a total dollar amount of \$300,000,000 of common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in combination with other securities as described in this prospectus. In addition, under this shelf process, the selling stockholder to be named in a supplement to this prospectus may, from time to time, offer and sell up to 1,774,240 shares of our common stock, as described in this prospectus, in one or more offerings. This prospectus provides you with a general description of the securities we and the selling stockholder may offer.

Each time we or the selling stockholder sell any type or series of securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information

[Table of Contents](#)

relating to these offerings. We may also add, update or change in a prospectus supplement or free writing prospectus any of the information contained in this prospectus or in the documents we have incorporated by reference into this prospectus. This prospectus, together with the applicable prospectus supplement, any related free writing prospectus and the documents incorporated by reference into this prospectus and the applicable prospectus supplement, will include all material information relating to the applicable offering. You should carefully read both this prospectus and the applicable prospectus supplement and any related free writing prospectus, together with the additional information described under “Where You Can Find More Information,” before buying any of the securities being offered.

This prospectus may not be used to consummate a sale of securities unless accompanied by a prospectus supplement.

Neither we nor the selling stockholder have authorized anyone to provide you with any information other than contained in, or incorporated by reference into, this prospectus and the applicable prospectus supplement, along with the information contained in any free writing prospectuses we or the selling stockholder have authorized for use in connection with a specific offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should not assume that the information contained in or incorporated by reference in this prospectus or any prospectus supplement or in any such free writing prospectus is accurate as of any date other than their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates.

This prospectus contains and incorporates by reference market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe that these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. Although we are not aware of any misstatements regarding the market and industry data presented in this prospectus and the documents incorporated herein by reference, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading “Risk Factors” contained in the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section entitled “Where You Can Find More Information.”

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “Personalis,” “the company,” “we,” “us,” “our” and similar references refer to Personalis, Inc., a corporation under the laws of the State of Delaware.

This prospectus and the information incorporated herein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus, any applicable prospectus supplement or any related free writing prospectus are the property of their respective owners.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus or incorporated by reference herein and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading “Risk Factors” contained in this prospectus, the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements and related notes, and the exhibits to the registration statement of which this prospectus is a part, before making your investment decision.

PERSONALIS, INC.

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 pursued business within the population sequencing market, and we have provided whole genome sequencing services under contract with the U.S. Department of Veterans Affairs (the “VA”) Million Veteran Program (the “VA MVP”), which has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. In September 2020, we announced receipt of a new task order from the VA MVP with an approximate value of up to \$31 million. The cumulative value of task orders received to date from the VA MVP has increased to approximately \$175 million.

In August 2020, we launched a 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.

Company Information

We were incorporated under the laws of the state of Delaware in February 2011 under the name Personalis, Inc. Our principal executive offices are located at 1330 O’Brien Drive, Menlo Park, California 94025. Our telephone number is (650) 752-1300. Our website address is <https://www.personalis.com>. The information contained in, or accessible through, our website does not constitute part of this prospectus, should not be relied on in determining whether to make an investment decision, and the inclusion of our website address in this prospectus is an inactive textual reference only.

The Personalis logo and other trademarks or service marks of Personalis, Inc. appearing in this prospectus are the property of Personalis, Inc. Other trademarks, service marks or trade names appearing in this prospectus are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

[Table of Contents](#)

Risks Associated with our Business

Our business is subject to numerous risks, as described under the heading “Risk Factors” contained in the applicable prospectus supplement and in any free writing prospectuses we have authorized for use in connection with a specific offering, and under similar headings in the documents that are incorporated by reference into this prospectus.

Description of Securities We May Offer

We may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in combination, with a total dollar amount up to \$300,000,000 from time to time under this prospectus, together with the applicable prospectus supplement and any related free writing prospectus, at prices and on terms to be determined at the time of any offering. We may also offer common stock, preferred stock and/or debt securities upon the exercise of warrants. In addition, the selling stockholder to be named in a supplement to this prospectus may offer or sell, from time to time, up to 1,774,240 shares of our common stock. This prospectus provides you with a general description of the securities we may offer. Each time we or the selling stockholder offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate principal amount or aggregate offering price;
- maturity;
- original issue discount;
- rates and times of payment of interest or dividends;
- redemption, conversion, exercise, exchange or sinking fund terms;
- ranking;
- restrictive covenants;
- voting or other rights;
- conversion or exchange prices or rates and, if applicable, any provisions for changes to or adjustments in the conversion or exchange prices or rates and in the securities or other property receivable upon conversion or exchange; and
- a discussion of material United States federal income tax considerations, if any.

The applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change any of the information contained in this prospectus or in the documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

We or the selling stockholder may sell the securities directly to investors or to or through agents, underwriters or dealers. We and the selling stockholder, and our or their agents, underwriters or dealers reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities to or through agents, underwriters or dealers, we will include in the applicable prospectus supplement:

- the names of those agents, underwriters or dealers;
- applicable fees, discounts and commissions to be paid to them;

[Table of Contents](#)

- details regarding over-allotment options, if any; and
- the net proceeds to us, if any.

Common Stock

We may issue shares of our common stock from time to time. The selling stockholder may offer shares of our common stock to the extent such shares were issued and outstanding, or issuable upon exercise or conversion of securities issued and outstanding, prior to the original date of filing of the registration statement to which this prospectus relates. Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. 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 from time to time by our board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock. Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the 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 in the future. In this prospectus, we have summarized certain general features of the common stock under “Description of Capital Stock—Common Stock.” We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to any common stock being offered.

Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Our board of directors will determine the designations, voting powers, preferences and rights of the preferred stock, as well as the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, preemptive rights, terms of redemption or repurchase, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series, or the designation of such series, any or all of which may be greater than the rights of our common stock. Convertible preferred stock will be convertible into our common stock or exchangeable for other securities. Conversion may be mandatory or at your option and would be at prescribed conversion rates.

If we sell any series of preferred stock under this prospectus, we will fix the designations, voting powers, preferences and rights of such series of preferred stock, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock that we are offering before the issuance of the related series of preferred stock. In this prospectus, we have summarized certain general features of the preferred stock under “Description of Capital Stock—Preferred Stock.” We urge you to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Debt Securities

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsecured and

[Table of Contents](#)

unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all of our senior indebtedness. Convertible or exchangeable debt securities will be convertible into or exchangeable for our common stock or our other securities. Conversion or exchange may be mandatory or optional (at our option or the holders' option) and would be at prescribed conversion or exchange rates.

Any debt securities issued under this prospectus will be issued under one or more documents called indentures, which are contracts between us and a national banking association or other eligible party, as trustee. In this prospectus, we have summarized certain general features of the debt securities under "Description of Debt Securities." We urge you, however, to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of debt securities being offered, as well as the complete indenture and any supplemental indentures that contain the terms of the debt securities. A form of indenture has been filed as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

Warrants

We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. We may issue warrants independently or in combination with common stock, preferred stock and/or debt securities offered by any prospectus supplement. In this prospectus, we have summarized certain general features of the warrants under "Description of Warrants." We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to the particular series of warrants being offered, as well as any warrant agreements and warrant certificates, as applicable, that contain the terms of the warrants. We have filed forms of the warrant agreements and forms of warrant certificates containing the terms of the warrants that may be offered as exhibits to the registration statement of which this prospectus is a part. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

Any warrants issued under this prospectus may be evidenced by warrant certificates. Warrants also may be issued under an applicable warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if applicable, in the prospectus supplement relating to the particular series of warrants being offered.

Use of Proceeds

Except as described in any applicable prospectus supplement or in any free writing prospectus we have authorized for use in connection with a specific offering, we currently intend to use the net proceeds from the sale of our securities offered by us hereunder, if any, for working capital, capital expenditures and other general corporate purposes. See the section entitled "[Use of Proceeds](#)" on page 58 of this prospectus.

We will not receive any proceeds from the sale of shares of our common stock by any selling stockholder.

Selling Stockholder

The selling stockholder is an entity that acquired shares of our common stock in open market transactions in June 2020 and in our public offering in August 2020. See the section entitled "[Selling Stockholder](#)" on page 77 of this prospectus.

SUMMARY OF RISK FACTORS

Investing in our securities involves a high degree of risk. The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors contained under the heading “Risk Factors” in this prospectus on page 7, as well as in the applicable prospectus supplement and in any free writing prospectuses we have authorized for use in connection with a specific offering.

Operational, Strategic and Business Risks

- We have a history of losses and we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenues to achieve or sustain profitability.
- If we are unable to increase sales of our current services or successfully develop and commercialize other services or products, or are unable to successfully compete with our competitors, we may fail to generate sufficient revenues to achieve profitability and sustain our business.
- Our operations and employees face risks related to health crises, such as the ongoing COVID-19 pandemic, that could adversely affect our operations and the business or operations of our customers or other third parties with whom we conduct business, our financial condition, and our operating results.
- A limited number of customers account for a substantial portion of our revenues and accounts receivable; in particular, we derive a substantial portion of our revenues from our largest customer, the VA MVP.
- We rely on a limited number of suppliers, or in some cases, a sole supplier, for some laboratory instruments and materials, and we may not be able to replace or immediately transition to alternative suppliers if necessary.
- We will need to invest in our infrastructure in advance of increased demand for our services; our failure to accurately forecast demand would negatively impact our business and ability to achieve or sustain profitability.
- If our facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.
- If we cannot continue timely developing and improving our services and products to keep pace with rapid advances in technology, medicine, and science our operating results and competitive position could be harmed.
- Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in or inability to achieve regulatory approval, commercialization, or payor coverage, any of which could adversely affect our business.
- The loss of key members of our executive management team or the inability to hire, retain, or motivate highly skilled personnel could adversely affect our business.
- We may not be able to manage our growth effectively, which could prevent execution of our business strategy.
- We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute stockholders’ ownership, or cause us to incur debt or significant expense.
- Expansion into China and other international markets will subject us to increased regulatory oversight and regulatory, economic, social, health and political uncertainties.

Regulatory, Legal and Cybersecurity Risks

- Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and we may be subject to regulatory action if we or our service or product offerings do not comply with applicable requirements.
- Our internal information technology systems, or those of our third-party vendors, contractors, or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could adversely affect our business.

[Table of Contents](#)

- Our employees may engage in misconduct or other improper activities, such as noncompliance with regulatory standards and requirements, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery laws, which could cause significant liability for us and harm our reputation.
- Changes in health care policy could increase our costs, decrease our revenues, and impact sales of and reimbursement for our tests. If we decide to grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.

Intellectual Property Risks

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

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

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

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties described below, under the heading “Risk Factors” contained in the applicable prospectus supplement and any related free writing prospectuses we have authorized for use in connection with a specific offering, and discussed under the section entitled “Risk Factors” contained in our most recent Annual Report on Form 10-K and in our most recent Quarterly Report on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus in their entirety, together with other information in this prospectus, the documents incorporated by reference and any free writing prospectus that we may authorize for use in connection with this offering.

The risks described in these documents are not the only ones we face, but those that we consider to be material. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled “Forward-Looking Statements.”

Operational, Strategic and Business Risks

We have a history of losses, and as our costs increase, we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenues to achieve or sustain profitability.

We have incurred net losses since our inception. For the nine months ended September 30, 2020 we had a net loss of \$27.9 million, and 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 September 30, 2020, we had an accumulated deficit of \$168.5 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

[Table of Contents](#)

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 commercial team, including sales and business development personnel;
- the recruitment, hiring, and retention of our commercial team personnel;
- 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 customers or other third parties with whom we conduct business.

Our business could be adversely impacted by the effects of a health crisis, such as the ongoing COVID-19 pandemic, that could cause significant disruption in the operations of our customers and third-party suppliers upon whom we rely. Our laboratory facilities, executive team, and most of our employees are located in the San Francisco Bay Area. In the event of a health crisis that becomes widespread in or around the San Francisco Bay Area, we may proactively, or be ordered by government officials to, take precautionary measures such as suspending our lab operations, implementing alternative work arrangements for our employees, and limiting our employees' travel activities.

Our operations have been impacted by the ongoing COVID-19 pandemic. While the state and county reopening and health orders applicable to us allow for continued operation of so-called Essential Businesses, which includes certain critical healthcare operations and services, we have substantially closed our office facilities and limited access to our laboratory facilities, to protect our employees and to comply with the provisions described within the orders. We provided temporary increased pay to certain laboratory personnel in the second quarter for their work during the COVID-19 pandemic. Such increased pay was not provided in the

[Table of Contents](#)

third or fourth quarters, but we may decide to resume increased pay in the future. The previous shelter-in-place order and current reopening and health orders have negatively impacted productivity, disrupted our business, and slowed research and development activities due to us limiting access to our laboratory space that would otherwise be used by our research and development group, and, to the extent such orders remain in place, they may continue to cause such effects on our operations. The reopening and health orders may disrupt the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we are aware of increased demand in the market for certain consumables used in COVID-19 test kits. We use such consumables in our operations, and we may face difficulties in acquiring such consumables if our suppliers prioritize orders related to COVID-19. Several of our customers were delayed in sending us samples in the second and third quarters due to the inability to collect or ship samples during the COVID-19 pandemic, and these and additional customers may be disrupted from sending purchase orders and samples to us in the future. 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. If our laboratory employees were to contract COVID-19, we may significantly curtail our laboratory operations or pause operations altogether until the imminent health risk to our employees subsided. Such disruptions in our operations, and our customers' and suppliers' operations, may continue to adversely affect revenues and operating results.

The global COVID-19 pandemic continues to rapidly evolve and to present serious health risks. While authorities in some areas have lifted or relaxed certain of the restrictions described above, in some cases they have subsequently re-imposed various restrictions after observing an increased rate of COVID-19 cases; for example, in December 2020, state and local authorities in California reinstated shelter-in-place orders in light of the increasing rate of COVID-19 cases and shortage of intensive care unit beds across the state. Furthermore, there is no guarantee when or if all such restrictions will be eliminated, such that we and our customers, manufacturers and suppliers will be able to safely resume operations consistent with our pre-COVID-19 operations. Vaccines against COVID-19 have been approved by the FDA and other regulatory authorities, but there is uncertainty as to when these vaccines will be widely available to our employees and the population at large and how quickly and to what extent the vaccines will impact the COVID-19 pandemic.

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

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 or potential competitors, including Adaptive Biotechnologies Corporation, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Freenome, Inc., Genosity, Inc., Guardant Health, Inc., Inivata Limited, Invitae Corporation, Mount Sinai Genomics, Inc. which does business under the name Sema4, Natera, Inc., NanoString Technologies, Inc., NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Roche Molecular Systems, Inc., and Tempus, Inc., may have more widespread brand recognition or substantially greater financial or technical resources, development or

production capacities, or marketing capabilities than we do. They may be able to devote greater resources to the development, promotion and sale of their products and services than we do or sell their products and services at prices designed to win more significant levels of market share. In addition, our present or potential competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, more well-established and well-financed companies. For example, in September 2020, Illumina, Inc. (“Illumina”) announced it had entered into an agreement to acquire GRAIL, Inc. (“GRAIL”), a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology, which we view as a potential competitor. 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 Tafenlar® from GlaxoSmithKline. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests, such as the ones we currently offer as part of our services, would be considered an off-label use and this may limit our access to this market segment. Our customers and potential customers may request, or in some cases have requested, that we consider developing and seeking FDA approval for companion diagnostic tests to accompany those customers’ therapeutic product candidates, and it may be necessary for us to do so in order to successfully compete for the business of these customers. If we do not successfully develop FDA-approved companion diagnostics, we may be at a competitive disadvantage and may be unable to increase market acceptance and sales of our other product offerings, which would prevent us from increasing or sustaining our revenues or achieving or sustaining profitability. If we were to develop one or more FDA-approved companion diagnostics, we would incur increased research and development expenses, and such activities may also divert our resources or the attention of our management and may create competing internal priorities for us.

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 and services aimed at identifying treatment options will be developed and that these products and services may compete with our services. In addition, competitors may develop their own versions of our current or planned future services in countries where we did not apply for or receive patents and compete with us in those countries, including encouraging the use of their products or services by biopharmaceutical companies in other countries.

We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our revenues and accounts receivable.

Like other genomic profiling companies that sell to the pharmaceutical industry, we have substantial 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 71% and 75% of our revenues for the three and nine months ended September 30, 2020. Our top five customers, including the VA MVP, accounted for 85% and 88% of our revenues for the three and nine months ended September 30, 2020, respectively. There are inherent risks whenever a large percentage of revenues are concentrated with a limited number of customers. Our predictions regarding the future level of demand for our services that will be generated by these customers may be wrong. 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 factors, 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. Some of our customers have in the past suspended or terminated clinical trials or projects, received less funding than expected, experienced declining or delayed sales, or otherwise decided to reduce or eliminate their use of our services, and these and other customers may also do so in the future. As a result, we could be pressured to reduce the prices we charge for our services, which would have an adverse effect on our margins and financial position, and which would likely negatively affect our 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. Similarly, if the VA MVP was eliminated, awarded its contract to one of our competitors, further reduced the size of our contract or failed to renew our contract in the future, then our revenues, cash position, and results of operations would be materially adversely impacted. Further, if any of our other significant 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 or if the VA MVP conducts a competitive bid process for the next contract and we do not win, 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 contracted orders from the VA MVP in September 2017, 2018, 2019, and 2020. The VA MVP may initiate a competitive bidding process for its next DNA sequencing and data analysis services contract. We may not win any potential new contract in such bidding process, the value of such contract or the VA MVP contracted orders thereunder may be lower than our current contract and historical contracted orders from the VA MVP, and/or the scope or nature of the services required under such new contract may change such that we are unable to serve the VA MVP in the future.

The VA MVP’s contracted orders for DNA sequencing and data analysis services have fluctuated in value over time and are subject to the availability of funding, enrollment of veterans in the VA MVP study, and the VA MVP’s continued demand for our services among other factors. For example, the VA MVP contracted order received in September 2020 has a value of up to approximately \$31 million, whereas the VA MVP contracted order received in September 2019 had a value of up to approximately \$38.1 million. We have no certainty that funding will be made available for our services, or that the VA MVP will award any future contracts, contract renewals or contracted orders to us. If the priorities of the VA, the VA MVP, or the U.S. government change, including in response to the COVID-19 pandemic for example, funding for our services may be limited or not available, and our business, financial condition, and operating results and cash flows would be materially

[Table of Contents](#)

harm. Similarly, if we do not win future VA MVP contracts and renewals (whether due to being outbid by a competitor or the VA MVP's decision to terminate for convenience or failure to renew for whatever reason), 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. Furthermore, we only recognize revenue under our VA MVP contract upon the receipt and processing of samples, and the timing and number of VA MVP samples we receive has been and could in the future be negatively affected by factors beyond our control, which has resulted, and may result in the future, in delaying our ability to process and recognize revenue for such samples. For example, the revenue we recognized during the contract year that began in September 2019 significantly exceeded the value of the VA MVP contracted order we received in September 2019 because we continued to receive after such date, and subsequently processed, samples under VA MVP contracted orders that remained unfulfilled as of September 2019 due to the time required for the VA to select optimal samples from its collection for research and then provide us those samples. Therefore, period-to-period comparisons of our operating results relating to VA MVP contracted orders may not be meaningful and, even if we win a potential new VA MVP contract and order with a value comparable to that of the September 2019 contracted order, the revenue we recognize under such potential new contract and order may be less than the revenue we recognized during the 2019-2020 contract year, and may also be less than the revenue we expect to recognize during the 2020-2021 contract year because we expect during the current contract year to finish processing most or all of the samples under VA MVP contracted orders that remained unfulfilled as of September 2020, in addition to samples received under the September 2020 contracted order. The timing and number of VA MVP samples may also have been or be negatively affected by the current COVID-19 pandemic. In addition, we believe the COVID-19 pandemic may have been a contributing factor to the reduction in value of the September 2020 VA MVP contracted order compared to the September 2019 contracted order, as the VA MVP delayed new enrollment and also may have needed to divert resources to respond to the pandemic, and the COVID-19 pandemic may also negatively impact the value of any potential new VA MVP contract or order.

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

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

[Table of Contents](#)

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.

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

We rely on a limited number of suppliers for sequencers and other equipment and materials that we use in our laboratory operations. For example, we rely on Illumina as the sole supplier of sequencers and various associated reagents, and 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. In September 2020, Illumina announced it had entered into an agreement to acquire GRAIL, a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology. Any disruption in Illumina's operations, or our inability to negotiate an extension to our agreements with Illumina on acceptable terms, or at all, or any competitive pressure resulting from Illumina's anticipated acquisition of GRAIL, could negatively 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.

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 and expanding laboratory capacity. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup, and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software, and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facilities to accommodate such required expansion. We expect that much of this growth will be in advance of increased demand for our services. Our current and projected future expense levels are to a large extent fixed and are largely based on our current investment plans and our estimates of future test volume. As a result, if 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 facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our genomic analysis conducted in our laboratories. We do not have any clinical reference or research and development laboratory facilities other than our facilities 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 pandemic, we have limited access to our office and laboratory facilities in Menlo Park to protect the health and safety of our employees and to comply with applicable state and local orders. Northern California has recently experienced serious fires and the San Francisco Bay Area is considered to lie in an area with earthquake risk. The inability to sell or to perform our sequencing and analysis services, disruptions in our operations, or the backlog of samples that could develop if our facilities are inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. The limited access to our laboratory facilities as a result of the COVID-19 pandemic has resulted, and may in the future result, in a loss in productivity, including delays to research and development programs. Furthermore, our facilities and the equipment we use to perform our services and our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples as the basis for the development of our services. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

[Table of Contents](#)

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

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

Errors, including if our tests fail to accurately detect gene variants, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business. We classify variants in accordance with guidelines that are subject to change and subject to our interpretation. There have also been and could in the future be flaws in the databases, third-party tools or algorithms we use, or in the software that handles automated parts of our classification protocol. If we receive poor quality or degraded samples, our tests may be unable to accurately detect gene variants or we may fail to or incompletely or incorrectly identify the significance of gene variants, which could have a significant adverse impact on our business.

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 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, and Aaron Tachibana, our Chief Financial Officer. The collective efforts of each of these persons and others working with them as a team are critical to us as we continue to develop our technologies, services, products, and research and development programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, or if one or more of these key employees were to become unable to perform his or her duties due to contracting COVID-19, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Each member of our executive management team has an employment agreement; however, the existence of an employment agreement does not guarantee retention of members of our executive management team, and we may not be able to retain those individuals. We do not maintain “key person” life insurance on any of our employees.

[Table of Contents](#)

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

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

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

Our performance, including our research and development programs and laboratory operations, largely depends on our continuing ability to identify, hire, develop, motivate, and retain highly skilled personnel for all areas of our organization. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future, including bioinformatic scientists, bioinformatic engineers, software engineers, statisticians, variant curators, clinical laboratory scientists, 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 facilities, laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as our test volume grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and management controls, as well as our reporting systems and procedures. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We may also pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. As an organization, we have limited experience with respect to acquisitions as well as the formation of strategic alliances and joint ventures. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, and their consideration may be distracting to our management or

prevent us from pursuing other opportunities. In addition, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future such transactions by us also could result in significant write-offs, the incurrence of debt and contingent liabilities, exposure to additional liability, exposure to additional revenue concentration, additional regulatory obligations and exposure to additional potential liability, any of which could harm our operating results and future prospects. If we make any acquisitions in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Integration of an acquired company or business also may require management resources that otherwise would be available for ongoing development of our existing business.

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

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

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

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

Any future collaborations, including any strategic alliances or any collaborations to develop companion diagnostic tests, 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:

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

[Table of Contents](#)

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

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

Our planned expansion into China entails substantial risks.

In June 2020, we announced a partnership with a clinical genomics and life sciences company headquartered in China as a means to expand business operations into China in the near term. Our first wholly owned subsidiary was formed in Shanghai in October 2020. Our expansion and investment plans are subject to substantial risks which may include, but are not limited to: the inability to protect our intellectual property rights under Chinese law, which may not offer as high a level of protection as U.S. law; unexpectedly long negotiation periods with Chinese suppliers and customers; quality issues related to supplies sourced from local vendors; unexpectedly high labor costs due to a tight labor supply; foreign investment restrictions; and difficulty in repatriating funds and selling or transferring assets. Our investments in China also expose us to additional foreign currency exchange risk. In addition, as tensions have escalated between the U.S. and China, we believe there is an enhanced risk that our planned investments in China may be subject to unforeseen risks or restrictions, which may include expropriation of the investments by the Chinese government. These and other risks may result in our not realizing a return on, or losing some, or all, of our planned investments in China, which could have a material adverse effect on our financial condition and financial performance.

Personal privacy, cyber security, and data protection are becoming increasingly significant issues in China. For example, the State Council of the People's Republic of China adopted the Regulations of the People's Republic of China on Administration of Human Genetic Resources, which went into effect on July 1, 2019. The

regulations establish a framework for the collection, preservation, utilization, and supply abroad of human genetic resources of China. The regulations also establish a framework for the use of data and other information generated from use of human genetic resources of China. The regulations also provide that foreign organizations, individuals and entities established or controlled by them are prohibited to collect or preserve China's human genetic resources or transport them abroad. Due to the lack of detailed interpretations and implementations, it is not clear whether the agency in China responsible for enforcing the regulations will grant the necessary approvals for use by us and our partners of our NeXT Platform or our other current or future products in research or clinical projects involving China's human genetic resources or information generated therefrom. The Chinese government separately has various regulations relating to the collection, use, storage, disclosure, and security of data, among other things. We cannot assure you that we will be able to comply with all of these regulatory requirements. Any failure to comply with relevant regulations and policies could result in significant cost and liability to us and could adversely affect our business and results of operations. Any additional new regulations or the amendment or modification of previously implemented regulations, or the failure to receive any necessary approvals for use of our products in connection with such projects, could require us and our partners to change our business plans and incur additional costs, and could limit our ability to generate revenues in China.

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

We may in the future expand our business and operations into international jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals and marketing and selling products and services. For example, in June 2020, we announced our intention to expand into China. 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.

Regulatory, Legal and Cybersecurity Risks

Our tests may be subject to regulatory action if regulatory agencies determine that our tests do not appropriately comply with statutory and regulatory requirements enforced by the U.S. Food and Drug Administration, and/or CLIA requirements for quality laboratory testing.

The laws and regulations governing the marketing of clinical laboratory tests are extremely complex and in many instances there are no significant regulatory or judicial interpretations of these laws and regulations. The Federal Food, Drug and Cosmetic Act (the "FDC Act") defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

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

If we are required to conduct clinical trials, we and any third-party contractors we engage would be required to comply with 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.

[Table of Contents](#)

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.

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, integrity, and availability 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, 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 accidental actions or omissions by trusted insiders, cyber-attacks or cyber intrusions, 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; in particular, during the COVID-19 pandemic we have observed an increase in attempted attacks against our data systems. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, hostile foreign governments or agencies, or cybersecurity researchers. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our services 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.

[Table of Contents](#)

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. 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") imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It also 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 can 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.

Although there are legal mechanisms to allow for the transfer of personal data from the UK, EEA and Switzerland to the United States, uncertainty about compliance with such data protection laws remains and such mechanisms may not be available or applicable with respect to the personal data processing activities necessary to research, develop and market our products and services. For example, legal challenges in the EU to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the EU-U.S. and Swiss-U.S. Privacy Shield Frameworks. Specifically, on July 16, 2020, the Court of Justice of the European Union invalidated Decision 2016/1250 on the adequacy of the protection provided by the EU-U.S. Privacy Shield Framework. To the extent that we or any of our vendors, contractors, or consultants relied on the EU-U.S. Privacy Shield Framework, we will not be able to do so in the future, which could increase our costs and limit our ability to process personal data from the EU in the United States. The same decision also cast doubt on the ability to use one of the primary alternatives to the Privacy Shield, namely, the European Commission's Standard Contractual Clauses, to lawfully transfer personal data from EU to the United States and most other countries. At present, there are few, if any, viable alternatives to the Privacy Shield and the Standard Contractual Clauses.

Further, Brexit has created uncertainty with regard to data protection regulation in the UK. In particular, while the Data Protection Act of 2018 that implements and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the UK, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a "third country" under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under the GDPR and other privacy laws implemented by EU Member States and the UK in connection with any measures we take to comply with such laws.

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 typically rely on our customers to obtain valid and appropriate consents from data subjects whose genetic samples and data we process on such customers' behalf. Given that we do not typically obtain direct consent from such data subjects and we do not audit our customers to ensure that they have obtained the necessary consents required by law, the failure of our customers to obtain consents that are 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.

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 or 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.

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 laws, among other things, prohibit a physician or supplier billing the Medicare program from marking up the price of a purchased diagnostic service performed by another laboratory or supplier that does not “share a practice” with the billing physician or supplier. Penalties may apply to the billing physician or supplier if Medicare or another payer is billed at a rate that exceeds the performing laboratory’s charges to the billing physician or supplier, and the performing laboratory could be at risk under false claims laws, described below, for causing the submission of a false claim;
- the 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 (including certain other healthcare professionals) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;

[Table of Contents](#)

- 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.

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.

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

The coverage and reimbursement status of newly approved or cleared laboratory tests, including our Next Dx test, is uncertain. If we decide to seek reimbursement for our Next Dx test or other in vitro diagnostic tests we may develop, and if such tests are inadequately covered by insurance 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.

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;

[Table of Contents](#)

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research; and
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed several 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 eliminating 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. 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 ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. The CARES Act, which was signed into law in March 2020, is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA"), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates, and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare 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. In January 2020, CMS announced that data reporting for clinical diagnostic laboratory tests is delayed by one year. Therefore, data that was supposed to be reported between January 1, 2020 and March 31, 2020 must now be

reported between January 1, 2021 and March 31, 2021. Covered laboratories must report data from the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests will then resume on a three year cycle beginning in 2024. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our products in development. In addition, CMS updated the statutory phase-in provisions such that, for 2020, the rates for clinical diagnostic laboratory tests may not be reduced by more than 10% of the rates for 2019. Additionally, there will be a 15% reduction cap for each of 2021, 2022, and 2023. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

Further, it is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on August 6, 2020, President Trump issued an Executive Order that instructs the federal government to develop a list of “essential” medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States. 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.

The 2017 tax reform law, as modified by 2020 tax legislation, and possible future changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law comprehensive tax legislation (the “Tax Cuts and Jobs Act”) that significantly revised the Internal Revenue Code of 1986, as amended (the “Code”). Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, on March 27, 2020, the Coronavirus Aid, Relief and Economic Security (“CARES”) Act was enacted, which includes changes to the tax provisions that benefit business entities and makes certain technical corrections to the Tax Cuts and Jobs Act. On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspends the use of California net operating losses and limits the use of California research tax credits for tax years beginning in 2020 and before 2023. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act, or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation.

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

We are subject to taxation in numerous U.S. states and territories, as well as various non-U.S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various 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 and the CARES Act, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. 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.

Intellectual Property Risks

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

Our commercial success will depend in part on our avoiding infringement of patents and infringement, misappropriation or other violations of other proprietary rights of third parties, including for example the intellectual property of competitors. There is extensive intellectual property litigation involving the biotechnology and pharmaceutical industries and genetic sequencing technology. 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.

[Table of Contents](#)

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 a suit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products, services or technologies we may develop and any other technologies covered by the asserted third-party patents and any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement; obtain one or more licenses from third parties in order to continue developing and marketing our products and technology, which may not be available on commercially reasonable terms (if at all) or may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; pay substantial royalties and other fees; and redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, or be prohibited from commercializing certain tests, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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 2038, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 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

[Table of Contents](#)

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;

[Table of Contents](#)

- 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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

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

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

A portion of the products or technologies licensed, developed, and/or distributed by us incorporate so-called “open source” software and we may incorporate open source software into other products in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products or provide our services that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their products. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could have a material adverse effect on our business, financial condition, and results of operations.

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

We license certain intellectual property that is important to our business, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. For example, our agreements with third parties, such as Illumina, include certain non-exclusive license rights that are essential

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

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

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

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

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

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

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 September 30, 2020, we had approximately \$20.6 million in customer deposits, including \$17.6 million from one customer. However, as of that date, we had

[Table of Contents](#)

\$206.1 million of cash and cash equivalents, and short-term investments. We are generally not required by our contracts to retain these deposits in cash or otherwise and we have generally used these deposits to make capital expenditures and fund our operations. When a customer that has prepaid us for future services cancels its contract with us or reduces the level of services that it expects to receive, we are 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.

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 pandemic. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to us. While we believe our existing cash and cash equivalents, and short-term investments 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.

[Table of Contents](#)

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

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

- actual or anticipated fluctuations in our operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research reports by securities analysts or changed recommendations for our stock;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP, as our largest customer;
- the timing and amount of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business or issues we may face with regulators;
- additions or departures of key management or other personnel;
- inability to obtain additional funding;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments related to our intellectual property or other matters, including litigation;
- the long-term macroeconomic effects of the COVID-19 pandemic, including potential global, regional or national economic slowdowns, recessions, depressions or other economic downturns; and
- general economic, industry, and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors.

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

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our 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 MVP and other large customers are not obliged to deliver tissue samples or other specimens to us at any particular time or at all. The rate at which we receive tissue samples or other specimens can vary dramatically from quarter to quarter, and is difficult or impossible for us to accurately forecast. Our receipt and processing of tissue samples and other specimens from our customers leads to our recognition of revenue, and as such the variable rates of delivery of customer samples will lead to variations in our revenues from quarter to quarter. For example, we often see fluctuations in receipt and processing of samples and revenues in the fourth quarter due, in part, to the concentration of holidays in late November and in December and some of our biopharmaceutical customers have fiscal years ending in December, which we believe may impact the timing of samples or payments provided by such customers. Fluctuations in quarterly results may adversely impact the value of our common stock. Factors that may cause fluctuations in our quarterly financial results include, without limitation, those listed elsewhere in this “Risk Factors” section. We also may face competitive pricing pressures, and we may not be able to maintain our pricing in the future, which would adversely affect our operating results.

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

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

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

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of September 30, 2020, we had 38,790,189 shares of common stock outstanding, all of which shares were eligible as of such date for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, upon issuance, shares of common stock subject to outstanding options under our stock option plans as of September 30, 2020 will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, certain holders of shares of our common stock have the right to require us to register these shares under the Securities Act pursuant to an investors’ rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse effect on the market price of our common stock.

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

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

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

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

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

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

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

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

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

As of December 31, 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, as modified by the CARES Act, federal net operating losses incurred in tax years beginning in 2018 and in future

[Table of Contents](#)

years may be carried forward indefinitely, but the deductibility of such federal net operating losses for tax years beginning after 2020 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, as modified by the CARES Act. In addition, under 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. In addition, for California income tax purposes, California net operating losses and California research tax credits will be suspended and limited, respectively, for tax years beginning after 2019 but before 2023.

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 of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

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

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

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

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

The requirements of being a public company 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

[Table of Contents](#)

this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may be required to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment will result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected. By disclosing information in this 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.

As a public company, it may be increasingly expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, as a result of our disclosure obligations as a public company, we have reduced strategic flexibility as compared to our competitors that are privately-held companies, and are under pressure to focus on short-term results, which may materially and adversely affect our ability to achieve long-term profitability.

We are 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 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;

[Table of Contents](#)

- 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 the 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 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.

FORWARD-LOOKING STATEMENTS

This prospectus and the documents we have filed with the SEC that are incorporated by reference contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, forward-looking statements may be identified by words such as “anticipate,” “believe,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “project,” “should,” “will” or the negative of these terms or other similar expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” and elsewhere in this prospectus and in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus in their entirety, together with other information in this prospectus, the documents incorporated by reference and any free writing prospectus that we may authorize for use in connection with a specific offering. These factors include, among other things:

- 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;
- our expectation regarding the time during which we will be an emerging growth company under the JOBS Act; and
- our ability to maintain proper and effective internal controls.

[Table of Contents](#)

These risks are not exhaustive. Other sections of this prospectus may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for our management to predict all risks and uncertainties nor can we assess the impact of all such factors on our business or the extent to which any such factor, or combination of such factors, may cause actual results to differ from those contained in, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus or to conform these statements to actual results or to changes in our expectations.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and 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 upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

USE OF PROCEEDS

Except as described in any applicable prospectus supplement or in any free writing prospectuses we have authorized for use in connection with a specific offering, we currently intend to use the net proceeds from this offering for working capital and general corporate purposes, which may include, among other things, funding research and development programs, vendor payables, hiring additional personnel, and capital expenditures.

We will not receive any proceeds from the sale of shares of our common stock by any selling stockholder.

DESCRIPTION OF CAPITAL STOCK

General

As of the date of this prospectus, our amended and restated certificate of incorporation authorizes us to issue up to 210,000,000 shares of capital stock, 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.

The following summary describes the material terms of our capital stock. The description of capital stock is qualified by reference to our amended and restated certificate of incorporation and our amended and restated bylaws.

Common Stock

As of September 30, 2020, 38,790,189 shares of common stock were outstanding. 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.

Voting Rights

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.

Dividend Rights

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.

Liquidation

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.

Rights and Preferences

Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. 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

As of September 30, 2020, no shares of preferred stock were outstanding. 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 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

[Table of Contents](#)

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 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 decreasing the market price of our common stock and could also have the effect of delaying, deferring or preventing a change of control or other corporate action.

We will fix the designations, voting powers, preferences and rights of the preferred stock of each series we issue under this prospectus, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering. We will describe in the applicable prospectus supplement the terms of the series of preferred stock being offered, including, to the extent applicable:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing;
- the provisions for a sinking fund;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights of the preferred stock;
- preemptive rights;
- restrictions on transfer, sale or other assignment;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of material United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable.

Options and Restricted Stock Units

As of September 30, 2020, stock options to purchase an aggregate of 3,548,764 shares of common stock were outstanding under our 2011 Equity Incentive Plan, or 2011 Plan.

As of September 30, 2020, (i) stock options to purchase an aggregate of 1,679,200 shares of common stock were outstanding under our 2019 Equity Incentive Plan, or 2019 Plan, (ii) restricted stock units covering an aggregate of 560,410 shares of common stock were outstanding under our 2019 Plan, and (iii) 2,200,594 shares remained available for future issuance under the 2019 Plan.

As of September 30, 2020, 413,266 shares remained available for future issuance under the 2019 Employee Stock Purchase Plan, or ESPP.

As of September 30, 2020, (i) stock options to purchase an aggregate of 112,500 shares of common stock were outstanding under our 2020 Inducement Plan, or 2020 Plan, (ii) restricted stock units covering an aggregate of 86,800 shares of common stock were outstanding under our 2020 Plan, and (iii) 800,700 shares remained available for future issuance under the 2020 Plan.

Warrants

As of September 30, 2020, no warrants to purchase shares of our capital stock were issued or outstanding.

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.

[Table of Contents](#)

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 Delaware General Corporation Law, or 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 is 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 does 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 are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. 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 contained in our amended and restated certificate of incorporation are inapplicable or unenforceable if they are challenged in a proceeding or otherwise.

[Table of Contents](#)

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. The transfer agent's address is 250 Royall Street, Canton, Massachusetts 02021.

Listing on the Nasdaq Global Market

Our common stock is listed on the Nasdaq Global Market under the symbol "PSNL."

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any debt securities that we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below. Unless the context requires otherwise, whenever we refer to the indenture, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the debt securities under the indenture that we will enter into with the trustee named in the indenture. The indenture will be qualified under the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act. We have filed the form of indenture as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

The following summary of material provisions of the debt securities and the indenture is subject to, and qualified in its entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the debt securities that we may offer under this prospectus, as well as the complete indenture that contains the terms of the debt securities.

General

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with “original issue discount,” or OID, for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title of the series of debt securities;
- any limit upon the aggregate principal amount that may be issued;
- the maturity date or dates;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;

Table of Contents

- if the price (expressed as a percentage of the aggregate principal amount thereof) at which such debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;
- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;
- whether the debt securities of the series shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities; and the depositary for such global security or securities;
- if applicable, the provisions relating to conversion or exchange of any debt securities of the series and the terms and conditions upon which such debt securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at our option or the holders' option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange;
- if other than the full principal amount thereof, the portion of the principal amount of debt securities of the series which shall be payable upon declaration of acceleration of the maturity thereof;
- additions to or changes in the covenants applicable to the particular debt securities being issued, including, among others, the consolidation, merger or sale covenant;
- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;
- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;
- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;

Table of Contents

- whether interest will be payable in cash or additional debt securities at our or the holders' option and the terms and conditions upon which the election may be made;
- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any and principal amounts of the debt securities of the series to any holder that is not a "United States person" for federal tax purposes;
- any restrictions on transfer, sale or assignment of the debt securities of the series; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indenture will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of our assets as an entirety or substantially as an entirety. However, any successor to or acquirer of such assets (other than a subsidiary of ours) must assume all of our obligations under the indenture or the debt securities, as appropriate.

Events of Default under the Indenture

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the following are events of default under the indenture with respect to any series of debt securities that we may issue:

- if we fail to pay any installment of interest on any series of debt securities, as and when the same shall become due and payable, and such default continues for a period of 90 days; provided, however, that a valid extension of an interest payment period by us in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of interest for this purpose;
- if we fail to pay the principal of, or premium, if any, on any series of debt securities as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to such series; provided, however, that a valid extension of the maturity of such debt securities in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of principal or premium, if any;
- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indenture, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive written notice of such failure, requiring the same to be remedied and stating that such is a notice of default thereunder, from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the trustee or the holders of at least 25% in aggregate principal

[Table of Contents](#)

amount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indenture, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act, the trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indenture or to appoint a receiver or trustee, or to seek other remedies only if:

- the holder has given written notice to the trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request;
- such holders have offered to the trustee indemnity satisfactory to it against the costs, expenses and liabilities to be incurred by the trustee in compliance with the request; and
- the trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the trustee regarding our compliance with specified covenants in the indenture.

Modification of Indenture; Waiver

We and the trustee may change an indenture without the consent of any holders with respect to specific matters:

- to cure any ambiguity, defect or inconsistency in the indenture or in the debt securities of any series;
- to comply with the provisions described above under “Description of Debt Securities—Consolidation, Merger or Sale;”
- to provide for uncertificated debt securities in addition to or in place of certificated debt securities;

Table of Contents

- to add to our covenants, restrictions, conditions or provisions such new covenants, restrictions, conditions or provisions for the benefit of the holders of all or any series of debt securities, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred upon us in the indenture;
- to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to make any change that does not adversely affect the interests of any holder of debt securities of any series in any material respect;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided above under “Description of Debt Securities—General” to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment under any indenture by a successor trustee; or
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act.

In addition, under the indenture, the rights of holders of a series of debt securities may be changed by us and the trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, we and the trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of any debt securities of any series;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any series of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

- provide for payment;
- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- pay principal of and premium and interest on any debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the trustee;
- compensate and indemnify the trustee; and
- appoint any successor trustee.

[Table of Contents](#)

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we provide otherwise in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indenture provides that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company, or DTC, or another depository named by us and identified in the applicable prospectus supplement with respect to that series. To the extent the debt securities of a series are issued in global form and as book-entry, a description of terms relating to any book-entry securities will be set forth in the applicable prospectus supplement.

At the option of the holder, subject to the terms of the indenture and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indenture and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will impose no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the trustee is under no obligation to exercise any of the powers given it by the indenture at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

[Table of Contents](#)

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indenture and the debt securities will be governed by and construed in accordance with the internal laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement and free writing prospectus, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which may consist of warrants to purchase common stock, preferred stock or debt securities and may be issued in one or more series. Warrants may be offered independently or in combination with common stock, preferred stock or debt securities offered by any prospectus supplement. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The following description of warrants will apply to the warrants offered by this prospectus unless we provide otherwise in the applicable prospectus supplement. The applicable prospectus supplement for a particular series of warrants may specify different or additional terms.

We have filed forms of the warrant agreements and forms of warrant certificates containing the terms of the warrants that may be offered as exhibits to the registration statement of which this prospectus is a part. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants. The following summaries of material terms and provisions of the warrants are subject to, and qualified in their entirety by reference to, all the provisions of the form of warrant and/or the warrant agreement and warrant certificate, as applicable, and any supplemental agreements applicable to a particular series of warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplement related to the particular series of warrants that we may offer under this prospectus, as well as any related free writing prospectus, and the complete form of warrant and/or the warrant agreement and warrant certificate, as applicable, and any supplemental agreements, that contain the terms of the warrants.

General

We will describe in the applicable prospectus supplement the terms of the series of warrants being offered, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;

Table of Contents

- a discussion of any material or special U.S. federal income tax considerations of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or
- in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. The warrants may be exercised as set forth in the prospectus supplement relating to the warrants offered. Unless we otherwise specify in the applicable prospectus supplement, warrants may be exercised at any time up to the close of business on the expiration date set forth in the prospectus supplement relating to the warrants offered thereby. After the close of business on the expiration date, unexercised warrants will become void.

Upon receipt of payment and the warrant or warrant certificate, as applicable, properly completed and duly executed at the corporate trust office of the warrant agent, if any, or any other office, including ours, indicated in the prospectus supplement, we will, as soon as practicable, issue and deliver the securities purchasable upon such exercise. If less than all of the warrants (or the warrants represented by such warrant certificate) are exercised, a new warrant or a new warrant certificate, as applicable, will be issued for the remaining warrants.

Governing Law

Unless we otherwise specify in the applicable prospectus supplement, the warrants and any warrant agreements will be governed by and construed in accordance with the laws of the State of New York.

Enforceability of Rights by Holders of Warrants

Each warrant agent, if any, will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee, depositary or warrant agent maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary’s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depositary or its participants. Consequently, for securities issued in global form, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary’s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not legal holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depositary will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any applicable trustee or depositary will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

[Table of Contents](#)

For example, once we make a payment or give a notice to the legal holder, we have no further responsibility for the payment or notice even if that legal holder is required, under agreements with its participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the legal holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of the indenture or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the legal holders contact the indirect holders is up to the legal holders.

Special Considerations For Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depositary's rules and procedures will affect these matters.

Global Securities

A global security is a security that represents one or any other number of individual securities held by a depositary. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in the applicable prospectus supplement, DTC will be the depositary for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under "Special Situations When a Global Security Will Be Terminated." As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and legal holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a legal holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

The rights of an indirect holder relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- an investor will be an indirect holder and must look to his or her own bank, broker or other financial institution for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security;
- we and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in a global security, nor do we or any applicable trustee supervise the depositary in any way;
- the depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your bank, broker or other financial institution may require you to do so as well; and
- financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities.

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations when a Global Security will be Terminated

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks, brokers or other financial institutions to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

Unless we provide otherwise in the applicable prospectus supplement, the global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or

[Table of Contents](#)

- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The applicable prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the applicable prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

SELLING STOCKHOLDER

This prospectus also relates to the possible resale by one of our stockholders, who we refer to in this prospectus as the selling stockholder, of up to 1,774,240 shares of our common stock that were issued and outstanding prior to the date of the registration statement of which this prospectus forms a part. The selling stockholder is a holder of our common stock, who purchased shares of our common stock in the open market in June 2020 and in our public offering in August 2020.

The applicable prospectus supplement will set forth the name of each selling stockholder and the number of securities beneficially owned by such selling stockholder that are covered by such applicable prospectus supplement. The applicable prospectus supplement will also disclose whether any selling stockholder has held any position or office with, has been employed by, or otherwise has had a material relationship with us during the three years prior to the date of the applicable prospectus supplement.

The selling stockholder shall not sell any shares of our common stock pursuant to this prospectus until we have identified such selling stockholder and the shares being offered for resale by such selling stockholder in a subsequent prospectus supplement. However, the selling stockholder may sell or transfer all or a portion of its shares of our common stock pursuant to any available exemption from the registration requirements of the Securities Act.

PLAN OF DISTRIBUTION

We or the selling stockholder may sell our securities covered by this prospectus in any of three ways (or in any combination):

- to or through underwriters or dealers;
- directly to one or more purchasers; or
- through agents.

We or the selling stockholder may distribute the securities:

- from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time;
- at market prices prevailing at the time of sale;
- at prices related to the prevailing market prices; or
- at negotiated prices.

Each time we or the selling stockholder offer and sell securities covered by this prospectus, we will provide a prospectus supplement or supplements that will describe the method of distribution and set forth the terms of the offering, including:

- the name or names of any underwriters, dealers or agents;
- the amounts of securities underwritten or purchased by each of them;
- the purchase price of securities and the proceeds, if any, we or the selling stockholder will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us or the selling stockholder;
- any underwriting discounts or commissions or agency fees and other items constituting underwriters' or agents' compensation;
- the public offering price of the securities;
- any discounts, commissions or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. We or the selling stockholder may determine the price or other terms of the securities offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the obligations of the underwriter, dealer or agent in the applicable prospectus supplement.

Underwriters or dealers may offer and sell the offered securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. If underwriters or dealers are used in the sale of any securities, the securities will be acquired by the underwriters or dealers for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters or dealers. Generally, the underwriters' or dealers' obligations to purchase the securities will be subject to certain conditions precedent. The underwriters or dealers will be obligated to purchase all of the securities if they purchase any of the securities, unless otherwise specified in the prospectus supplement. We may use underwriters with whom we have a material relationship. We will describe the nature of any such relationship in the prospectus supplement, naming the underwriter.

Table of Contents

We or the selling stockholder may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we or the selling stockholder pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment. We or the selling stockholder may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us or the selling stockholder at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we or the selling stockholder pay for solicitation of these contracts.

Agents, dealers and underwriters may be entitled to indemnification by us or the selling stockholder against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents, dealers or underwriters may be required to make in respect thereof. Agents, dealers and underwriters may be customers of, engage in transactions with, or perform services for us or the selling stockholder in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended. Overallotment involves sales in excess of the offering size, which create a short position. This short sales position may involve either “covered” short sales or “naked” short sales. Covered short sales are short sales made in an amount not greater than the underwriters’ over-allotment option to purchase additional securities in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing securities in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market, as compared to the price at which they may purchase securities through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the securities that could adversely affect investors who purchase securities in this offering. Stabilizing transactions permit bids to purchase the underlying security for the purpose of fixing the price of the security so long as the stabilizing bids do not exceed a specified maximum. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions.

Any underwriters who are qualified market makers on the Nasdaq Global Market may engage in passive market making transactions in our common stock, preferred stock, warrants and debt securities, as applicable, on the Nasdaq Global Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker’s bid, however, the passive market maker’s bid must then be lowered when certain purchase limits are exceeded.

In compliance with guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

[Table of Contents](#)

Similar to other purchase transactions, an underwriter's purchase to cover the syndicate short sales or to stabilize the market price of our securities may have the effect of raising or maintaining the market price of our securities or preventing or mitigating a decline in the market price of our securities. As a result, the price of our securities may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the securities if it discourages resales of the securities.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the securities. If such transactions are commenced, they may be discontinued without notice at any time.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered by this prospectus, and any supplement thereto, will be passed upon for us by Cooley LLP.

EXPERTS

The financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Neither we nor any agent, underwriter or dealer has authorized any person to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered by this prospectus.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC, including Personalis. The address of the SEC website is www.sec.gov.

We maintain a website at www.personalis.com. Information contained in or accessible through our website does not constitute a part of this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” the information we file with it, which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings (including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to the effectiveness of such registration statement) we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act until the termination of the offering of the shares covered by this prospectus (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K):

- our annual report on [Form 10-K](#) for the year ended December 31, 2019, filed with the SEC on March 25, 2020, including the information specifically incorporated by reference therein from our definitive proxy statement on [Schedule 14A](#), filed with the SEC on April 3, 2020;
- our quarterly report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on [May 7, 2020](#), our quarterly report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on [August 6, 2020](#), and our quarterly report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on [November 5, 2020](#);
- our current report on Form 8-K filed with the SEC on [May 20, 2020](#), and our current report on Form 8-K filed with the SEC on [August 12, 2020](#); and
- the description of our common stock set forth in our registration statement on [Form 8-A](#), filed with the SEC on June 17, 2019, including any amendments thereto or reports filed for the purposes of updating this description.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents.:

Personalis, Inc.
1330 O’Brien Drive
Menlo Park, California 94025
(650) 752-1300
Attn: General Counsel

