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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____.
Commission File Number **001-38943**

Personalis, Inc.
(Exact name of Registrant as specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001	**PSNL**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☐

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant, as of June 28, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $71,600,000 based on the closing price reported for such date on the Nasdaq Global Market.

88,263,269 shares of common stock were issued and outstanding as of February 21, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2025 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The Registrant's definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

PERSONALIS, INC.

Form 10-K
For the Year Ended December 31, 2024

TABLE OF CONTENTS

		Page
	Note Regarding Forward-Looking Statements	3
	PART I	
Item 1.	Business	6
Item 1A.	Risk Factors	16
Item 1B.	Unresolved Staff Comments	55
Item 1C.	Cybersecurity	55
Item 2.	Properties	56
Item 3.	Legal Proceedings	56
Item 4.	Mine Safety Disclosures	56
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	57
Item 6.	[Reserved]	57
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	58
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	68
Item 8.	Financial Statements and Supplementary Data	69
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	100
Item 9A.	Controls and Procedures	100
Item 9B.	Other Information	100
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	100
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	101
Item 11.	Executive Compensation	102
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	102
Item 13.	Certain Relationships and Related Transactions, and Director Independence	102
Item 14.	Principal Accountant Fees and Services	103
	PART IV	
Item 15.	Exhibits, Financial Statement Schedules	104
Item 16.	Form 10-K Summary	106
	Signatures	107

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the evolution of cancer therapies and market adoption of our services and products;
- estimates of our total addressable market, future revenue and the timing thereof, expenses, use of cash and other resources, cost savings, capital requirements, and our needs for additional financing and our ability to obtain financing when needed;
- future reimbursement and reimbursement rulings;
- our business strategies, including our aim to focus on certain indications and the timing thereof;
- the benefits of our products and services, including their ability to increase the probability of clinical trial success;
- our ability to enter into and compete effectively in existing and new markets, with existing competitors and new market entrants;
- our ability to manage and grow our business by expanding our sales to existing customers or introducing our services and products to new customers;
- our sales, marketing and commercialization plans and strategies, including the expected benefits of and activities to be performed under our Commercialization and Reference Laboratory Agreement with Tempus AI, Inc. ("Tempus");
- our future business with the U.S. Department of Veterans Affairs' Million Veteran Program, Natera, Inc., Moderna, Inc. ("Moderna"), and other collaboration partners and customers;
- our belief that approval of personalized cancer therapies by the U.S. Food and Drug Administration may drive benefits to our business;
- our ability to benefit from the scaling of our infrastructure and capacity at our headquarters facility in Fremont;
- the impact our collaboration agreements and key opinion leaders may have on the broader use of our products in the future;
- the potential impacts of inflation, macroeconomic conditions, and geopolitical conflicts on our business and operations;
- our ability to establish and maintain intellectual property protection for our services and products or avoid claims of infringement;
- our success in defending and enforcing our intellectual property rights, including patents;
- potential effects of government regulation;
- our ability to hire and retain key personnel;
- the impact of our previous reductions in force on our operations and operating results; and
- our ability to maintain proper and effective internal controls.

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

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

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

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

Summary of Risk Factors

The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors below under Item 1A, "Risk Factors."

Operational, Strategic and Business Risks

- We have a history of losses and we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or sustain profitability.
- If we are unable to increase sales of our current services or successfully develop and commercialize other services or products, or if we are unable to execute our sales and marketing strategy for our services or unable to gain sufficient acceptance in the market, or if we are unable to generate sufficient reimbursement or coverage by insurance or governmental payors for our products, we may fail to generate sufficient revenue to achieve profitability and sustain our business.
- We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our revenue and accounts receivable; in particular, we currently derive a substantial portion of our revenue from two of our largest customers, Natera and Moderna, and in the past have derived a substantial portion of our revenue from other large customers.
- Building our clinical laboratory business is subject to a number or reimbursement challenges and we may not be able to establish the medical necessity of our tests for coverage or reimbursement rates that cover our costs.
- We are pursuing a partner-centric strategy and have key relationships with Tempus, Myriad Genetics, Inc, Moderna, and Merck & Co., Inc., among others. These and any other partnering and/or collaboration agreements that we have entered into or may enter into in the future may not be successful, or may terminate, which could adversely impact our business or affect our ability to develop and commercialize our services and products.
- We rely on a limited number of suppliers, or in some cases, a sole supplier, for some laboratory instruments and materials, and we may not be able to replace or immediately transition to alternative suppliers should we need to do so.
- We have a single facility and if it becomes damaged or inoperable, or we are required to vacate our facility, our ability to sell and provide our services and pursue research and development efforts may be jeopardized.
- If we cannot develop services and products to keep pace with rapid advances in technology, medicine, and science our operating results and competitive position could be harmed.
- Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in achieving, 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 future growth effectively, which could make it difficult to execute our business strategy.
- We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute stockholders' ownership, or cause us to incur debt or significant expense.

Regulatory, Legal and Cybersecurity Risks

- Our tests may be subject to regulatory action if regulatory agencies or authorities determine that our tests do not appropriately comply with statutory and regulatory requirements enforced by the FDA, or equivalent foreign regulatory authorities and/or CLIA requirements for quality laboratory testing or equivalent foreign requirements.
- Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and we may be subject to regulatory action if we or our service or product offerings do not comply with applicable requirements.
- Our internal information technology systems, or those of our third-party vendors, contractors, or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could adversely affect our business.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the cost of our offerings, limit their use or adoption, and otherwise negatively affect our operating results and business.
- Our employees may engage in misconduct or other improper activities, such as noncompliance with regulatory standards and requirements, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery laws, which could cause significant liability for us and harm our reputation.

- Changes in health care policy could increase our costs, decrease our revenue, and impact sales of and reimbursement for our tests. When we grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.
- Competitors could take legal action against us for statements that are made by the company and/or its representatives, which may require us to spend significant time and money, including damages, and could limit our ability to market our tests.

Intellectual Property Risks

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

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

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

PART I

Item 1. Business.

Company Background

Personalis develops, markets, and sells advanced cancer genomic tests and services. Our services are used by pharmaceutical companies for translational research, biomarker discovery, the development of personalized cancer therapies, and for clinical trials. Our tests are used by physicians to detect residual or recurrent cancer in patients, monitor cancer response to therapy, and uncover insights for therapy selection. We also provide whole exome and whole genome sequencing services for other diagnostic companies and population sequencing initiatives.

We perform our testing services in a large-scale, high quality, Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified and College of American Pathologists (“CAP”) accredited, laboratory located in our 100,000 square foot headquarters in Fremont, California. We were incorporated under the laws of the state of Delaware in 2011 under the name Personalis, Inc. and became a publicly-traded company in 2019.

Products

For pharmaceutical and biopharmaceutical companies

NeXT Personal

NeXT Personal is a tumor-informed liquid biopsy test for detection of minimal residual disease ("MRD"), therapy response and recurrence monitoring, in solid tumor cancers. It delivers industry-leading, ultra-high sensitivity, which we believe allows for detection of cancer earlier than other technologies. NeXT Personal helps answer these questions: Who are the right patients to enroll into a clinical trial? How are patients responding to the investigational therapy? Can circulating tumor DNA ("ctDNA") potentially be used as an endpoint in clinical trials?

ImmunoID NeXT

ImmunoID NeXT is a tissue-based service that combines whole exome and whole transcriptome sequencing data with advanced analytics to provide a multi-dimensional view of the tumor and the tumor microenvironment from a single sample. It is designed to enable the development of more efficacious cancer (immuno) therapies and the next-generation of composite biomarkers to better predict patient response. ImmunoID NeXT helps answer these questions: What are the markers and composite biomarkers in the tumor and the tumor microenvironment that contribute to therapy response and resistance? What are the neoantigens in the tumor that can be used in individualized neoantigen therapy (INT)?

For cancer patients

NeXT Personal Dx

NeXT Personal Dx is a tumor-informed liquid biopsy test for the detection of MRD. We believe NeXT Personal Dx is the first ultra-sensitive test on the market to detect MRD and monitor therapy response in patients with solid tumor cancers. NeXT Personal Dx has been shown to potentially detect cancer recurrence ahead of traditional imaging and is designed to aid decision making throughout a patient's cancer journey. NeXT Personal Dx involves the initial whole genome sequencing of matched tumor and normal samples from a patient in order to create a personalized detection assay for that patient based on the biology of the patient's cancer and the subsequent use of that personalized assay to test one or more samples of the patient's blood/plasma. NeXT Personal Dx helps answer these questions: Does the patient still have cancer after curative intent treatment? How is the patient's cancer responding to therapy? And, importantly, has the cancer potentially recurred?

NeXT Dx

NeXT Dx is a comprehensive tumor profiling test that is used to help select therapy for a cancer patient and identify potential clinical trials for a patient. It analyzes a patient’s exome and transcriptome with matched tumor-normal analysis. We believe it improves chances of finding an effective therapy or help a doctor find an appropriate clinical trial. NeXT Dx helps answer the question: What are the tumor mutations with actionable therapies and clinical trials for the patient?

For diagnostics companies and population sequencing initiatives

WES

We perform whole exome sequencing ("WES") of cancer tissue and matched blood samples for diagnostic companies as an input to their products.

WGS

We perform whole genome sequencing ("WGS") on human samples for research projects, such as population sequencing initiatives.

Markets and Distribution

Our customers include pharmaceutical companies, biopharmaceutical companies, diagnostics companies, universities, non-profits, government entities, and patients. We sell through a small direct sales force, organized by geography. In November 2023, we entered into an agreement with Tempus AI, Inc. ("Tempus") to co-commercialize NeXT Personal Dx in the clinical diagnostics market. In December 2024, we agreed to expand the relationship to include biopharma industry customers. Under this expanded relationship, Tempus can offer our NeXT Personal MRD product to pharmaceutical and biotech customers who wish to bundle our tumor-informed MRD testing with other Tempus offerings in a given study.

The principal markets for our products are in the United States, Europe (including the U.K.), and rest of the world, including Asia-Pacific, which accounted for 96%, 3%, and 1%, respectively, of our revenue for the year ended December 31, 2024.

Clinical Evidence and Reimbursement

Generating clinical evidence is critical for driving adoption of our tests in the clinical market (i.e., for cancer patients) and establishing reimbursement by Medicare and private insurance companies. To this end, one of our key strategies is working with a growing number of leading cancer centers and world-class academic research institutions to build and publish the clinical evidence-base to support our products and services in our key indications. Because of the ultra-high sensitivity of our technology, we are initially focusing on three indications: breast cancer, lung cancer, and immunotherapy (IO) monitoring. We currently have collaborations with Cancer Research UK, University College London, and the Francis Crick Institute (the TRACERx study); Institut Curie, The Royal Marsden; the Vall d'Hebron Institute of Oncology (VHIO); the University of California, San Diego, Duke University; Vanderbilt University and Johns Hopkins University (the PREDICT study); the Dana-Farber Cancer Institute; the University of Texas M.D. Anderson Cancer Center; University Medical Center Hamburg-Eppendorf (also known as UKE); and Criterium and the Academic Breast Cancer Consortium.

Furthermore, generating clinical evidence is crucial to obtaining reimbursement coverage from Medicare and other payors. One of our 2025 goals is to submit for Medicare reimbursement for NeXT Personal Dx upon publication of compelling clinical evidence, and receive Medicare coverage, in at least two of our three key indications. In January 2024, we received a final Medicare coverage determination for our NeXT Dx offering, extended retroactively to August 29, 2023. We estimate that approximately half of new solid tumor cancer cases will be diagnosed in patients covered by Medicare.

Competition

Our principal competition comes from commercial and academic organizations that employ various approaches to produce information that is similar to the information that we generate for our customers. Some of our present or potential competitors include Adela, Inc., BostonGene Corporation, Caris Life Sciences, Inc., DELFI Diagnostics, Inc., Exact Sciences Corporation, Foresight Diagnostics Inc. (“Foresight”), Foundation Medicine, Inc., Freenome, Inc., Fulgent Genetics, Inc., Geneseeq Technology Inc., GRAIL, Inc., Guardant Health, Inc., Haystack Oncology, Inc., which was acquired by Quest Diagnostics Incorporated in June 2023, Laboratory Corporation of America Holdings, MedGenome Inc., Myriad Genetics, Inc., Natera, Inc. ("Natera"), NeoGenomics, Inc., Novogene Corporation, Predicine, Inc., Roche Molecular Systems, Inc., SAGA Diagnostics AB, Tempus, and Veracyte, Inc.

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

We believe that we compete favorably because of our differentiated technology, such as our ultra-sensitive approach for MRD that is able to detect cancer recurrence many months before imaging or other technologies, comprehensive data and variant calling we provide to our biopharmaceutical customers, high-quality results, and exceptional service.

Intellectual Property

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

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

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

- personalized genetic testing assays, including claims directed to methods for using sequencing data to create a personalized genetic test to monitor cancer progression, identify neoantigen candidates for personalized cancer therapy treatment, or detect the recurrence of disease at the earliest possible timepoint;
- liquid biopsy methods, including claims directed to methods of analyzing sequenced nucleic acids obtained from a patient sample in comparison with nucleic acids representing the reference genome, obtained from a blood sample, to identify disease, or recommend a drug treatment;
- clinical interpretation and neoantigen identification and prediction methods, including claims directed to methods of ranking genes associated with a phenotype and inheritance pattern or identifying neoantigens expressed in a disease sample that may be used for targeted treatments; and
- hybrid exome-genome technologies, including claims directed to methods for combining exome and/or whole genome sequencing data generated from a sample, along with the identification of other variants to identify or detect disease;
- our Accuracy and Content Enhanced ("ACE") assay and NeXT platform technology, including claims directed to methods for enriching nucleic acids from a sample based on differences in various genomic features, such as GC-content, molecular size, presence of genetic variations or rearrangements, identification of biomedically interpretable variants, epigenetic modifications, and/or species-origin (e.g., human and non-human).

As of December 31, 2024, we own 30 issued U.S. patents and 16 issued foreign patents. Issued U.S. patents in our portfolio of company-owned patents are expected to expire between 2033 and 2038, excluding any additional term for patent term adjustments or patent term extensions. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2042.

Supply of Materials

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

Customer Concentration

We currently derive a significant portion of our revenue from Moderna, Inc. ("Moderna") by providing genomic testing in its ongoing clinical trials evaluating a personalized cancer therapy and Natera, Inc. ("Natera") under our partnership to provide advanced tumor analysis for use in Natera's MRD testing offerings. Natera accounted for 30% and 43% and Moderna accounted for 28% and 5% of our revenue for the years ended December 31, 2024 and 2023, respectively. We previously derived a significant portion of our revenue from the U.S. Department of Veterans Affairs Million Veteran Program ("VA MVP"), which is a large-scale population sequencing initiative. VA MVP accounted for 9% and 13% of our revenue for the years ended December 31, 2024 and 2023, respectively. Our top five customers, including the VA MVP, Moderna and Natera, accounted for 81% and 74% of our revenue for the years ended December 31, 2024 and 2023, respectively.

Segments

We manage our business as one operating segment, which is providing advanced cancer genomic tests and services for precision oncology applications, personalized testing, and other tests. We derive revenue primarily in the United States and manage our business activities on a consolidated basis. Our chief executive officer (“CEO”) is our chief operating decision maker (“CODM”) who reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire company.

Regulatory Environment

Coverage and Reimbursement

Our ability to commercialize diagnostic tests based on our technology will depend in large part on the extent to which coverage and reimbursement for our tests can be achieved. Coverage and reimbursement of new products and services is uncertain, and whether we can obtain coverage and adequate reimbursement is unknown. In the U.S., there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage is

separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs. Additionally, the coverage and reimbursement status of newly-approved or cleared laboratory tests, including our NeXT Personal Dx offering, is uncertain. The commercial success of our current and future products in both domestic and international markets may depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors.

Federal and State Laboratory Licensing Requirements

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of or assessment of health. CLIA requires that a laboratory hold a certificate applicable to the type of laboratory examinations it performs and that it complies with, among other things, standards covering operations, personnel, facilities administration, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. Because we are a CAP accredited laboratory, the Centers for Medicare & Medicaid Services (“CMS”) does not perform this survey and inspection and relies on our CAP survey and inspection. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory that is certified as “high complexity” under CLIA may develop, manufacture, validate, and market proprietary tests referred to as laboratory developed tests (“LDTs”). CLIA requires analytical validation including accuracy, precision, specificity, sensitivity, and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that nonresident laboratories, or out-of-state laboratories, maintain an in-state laboratory license to perform tests on samples from patients who reside in that state. As a condition of state licensure, these state laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures or facility requirements, or prescribe record maintenance requirements. Because our laboratory is located in the state of California, we are required to and do maintain a California state laboratory license. We also maintain licenses to conduct testing in other states where nonresident laboratories are required to obtain state laboratory licenses, including Maryland, Pennsylvania, Rhode Island, and New York. Other states may currently have or adopt similar licensure requirements in the future, which may require us to modify, delay, or stop its operations in those states.

Regulatory framework for medical devices in the United States

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

Although the FDA regulates medical devices, including IVDs, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and FDA regulations with respect to LDTs, which are a subset of IVDs that are intended for clinical use and developed, validated, and offered within a single laboratory for use only in that laboratory. We currently market our diagnostic tests as LDTs.

On April 29, 2024, the FDA published final regulations to make explicit that IVD products are devices under the FDC Act, removing much of the FDA’s historical enforcement discretion for most LDTs. In conjunction with this final rule, the FDA proposed to phase out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. This final rule also provides that FDA intends to exercise enforcement discretion and generally not enforce premarket review and quality system requirements (except for requirements under Part 820, subpart M (records)) for currently marketed IVDs offered as LDTs that were first marketed prior to April 29, 2024 and intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by the New York State Clinical Lab Evaluation Program (“NYS CLEP”). Additionally, pursuant to the final rule, the FDA will gradually end its general enforcement discretion approach in five stages over a four-year period for other LDTs not approved by NYS CLEP and not already on market. Each stage of the proposed phaseout period would subject LDTs to a set of regulatory requirements.

If the FDA determines that our tests are subject to enforcement as medical devices, we could be subject to enforcement action, including administrative and judicial sanctions, and additional regulatory controls and submissions for our tests, all of which could be

burdensome. We and/or our collaborators may also be required to submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices.

If the FDA determines that our tests and associated software do not fall within the definition of an LDT, or there are other regulatory or legislative changes, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, we may be required to obtain premarket clearance for our tests and associated software under Section 510(k) of the FDC Act or approval of a PMA. We would also be subject to ongoing regulatory requirements such as registration and listing requirements, medical device reporting requirements, and quality control requirements. The regulatory requirements to which our tests are subject would depend on the FDA's classification of our tests. The FDA has issued regulations classifying medical devices into one of three regulatory control categories (Class I, Class II, or Class III) depending on the degree of regulation that the FDA finds necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet both pre- and post-market. On January 31, 2024, FDA announced its intent to initiate a reclassification process for most IVDs that are currently Class III (high risk), the majority of which are infectious disease and companion diagnostic IVDs, into Class II (moderate risk). This reclassification would allow manufacturers of certain types of IVDs to seek marketing clearance through the less burdensome Class II 510(k) premarket notification pathway rather than the Class III premarket approval (PMA) pathway, the most stringent type of FDA medical device review.

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.

One classification regulation that could be relevant to one or more of our tests is a classification for genetic health risk ("GHR") assessment tests, codified at 21 C.F.R. § 866.5950. If our tests fall under the 21 C.F.R. § 866.5950 classification regulation for GHR tests, or under another Class II classification that is subject to a premarket notification requirement, we would be required to obtain marketing clearance for such tests. Further, if considered to fall under the 21 C.F.R. § 866.5950 classification for GHR tests, our tests would be required to adhere to specified special controls, such as labeling and testing specifications and information about the test to be posted on the manufacturer's website.

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

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

- restrictions on manufacturing processes;
- restrictions on product marketing;
- warning letters;
- withdrawal or recall of products from the market;

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

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

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

Federal and State Fraud and Abuse Laws

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

The AKS prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing, or ordering, any good, facility, item, or service that is reimbursable, in whole or in part, under a federal healthcare program.

The Stark Law and similar state laws, including California's Physician Ownership and Referral Act, generally prohibit, among other things, clinical laboratories and other entities from billing a patient or any governmental or commercial payor for any diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has a direct or indirect investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

The federal civil and criminal false claims laws including the FCA, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government, and the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies. Under the FCA, private citizens can bring claims on behalf of the government through qui tam actions. We must also operate within the bounds of the fraud and abuse laws of the states in which we do business which may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.

The Eliminating Kickbacks in Recovery Act

The Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and is similar to the federal Anti-Kickback Statute in that it creates criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing unless a specific exception applies. Unlike the federal Anti-Kickback Statute, EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). Additionally, most of the safe harbors available under the federal Anti-Kickback Statute are not reiterated under EKRA, and certain EKRA safe harbors conflict with the safe harbors available under the federal Anti-Kickback Statute. Therefore, compliance with a federal Anti-Kickback safe harbor does not guarantee protection under EKRA. Because EKRA is a new law, there is very little additional guidance to

indicate how and to what extent it will be interpreted, applied and enforced by the government. Currently, there is no proposed regulation interpreting or implementing EKRA, nor any public guidance released by a federal agency concerning EKRA.

Other Federal and State Healthcare Laws

In addition to the requirements discussed above, several other healthcare laws could have an effect on our business. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") fraud and abuse provisions created federal civil and criminal statutes that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense, and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, biologicals, and medical devices or supplies that require premarket approval by or notification to the FDA, and for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP"), with certain exceptions, to report annually to CMS information related to (i) payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members.

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

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

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

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

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General (the "OIG"), and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the Anti-Kickback Statute. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting, or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

HIPAA and HITECH

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

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

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

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

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

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

U.S. Healthcare Reform

In the United States, there have been a number of legislative and regulatory changes at the federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), became law. This law substantially changed the way health care is financed by both commercial payors and government payors, and significantly impacted our industry. The ACA contained a number of provisions expected to impact the clinical laboratory industry, such as changes governing enrollment in state and federal health care programs, reimbursement changes, and fraud and abuse.

Further, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA 2022") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the health reform measures of the current administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032, 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 ("APMs"), and the Merit-based Incentive Payment System ("MIPS"). Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments.

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

test, which will be used to establish revised Medicare reimbursement rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Beginning on January 1, 2018, CMS has begun using reported private payor pricing to periodically revise payment rates under the CLFS. Based on current law, between January 1, 2025 and March 31, 2025, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2025 to 2027 CLFS rates. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our current tests or those in development. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), as amended by Section 221 of the Continuing Appropriations and Extensions Act, 2025 the statutory phase-in of the payment reductions has been extended through 2025 with a 0% reduction cap for 2021-2025 and a 15% reduction cap for 2026 through 2028. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

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

Human Capital

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

- Patient-centric
- Teachers
- Learners
- Execution-oriented
- Inclusive

At a foundational level, employees receive training related to workplace safety and emergency preparedness, awareness and expectations of inclusion, required data protection, and other regulatory matters. We offer competitive total rewards programs, ongoing training and development, and a commitment to the safety and health of our employees. We also practice a commitment to diversity by including broader outreach and sourcing for candidates for new roles as well as education and a visible commitment to diversity and inclusion internally.

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

As of January 31, 2025, we had 229 employees, of which 228 were full-time employees. Of these full-time employees, 83 were in research and development, 67 in laboratory operations, 40 in commercial operations and 38 in general and administrative functions. 226 of our full-time employees were located in the United States, with the remaining two located in Europe (including the U.K.). As of January 31, 2025, more than 40% of our employees had completed a Ph.D. or other advanced science or medical degree.

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

Environment

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

Available Information

Our website is located at https://www.personalis.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including their exhibits, proxy and information statements, and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also use the investor relations page on our website as a channel of distribution for important company information, including press releases, analyst coverage and financial information regarding us, as well as corporate governance information. We also use our and our Chief Executive Officer's X (formerly Twitter) accounts (@personalisinc; @C_HallBiotech) and our Chief Executive Officer's LinkedIn accounts (https://www.linkedin.com/company/personalis-inc/; https://www.linkedin.com/in/christopher-hall-a982a0/) as channels of distribution for important company information. Information on our website or our social media accounts is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

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

Operational, Strategic and Business Risks

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

We have incurred net losses since our inception. For the years ended December 31, 2024 and 2023, we had net losses of $81 million and $108 million, respectively. As of December 31, 2024, we had an accumulated deficit of $550 million. To date, we have not generated sufficient revenue to achieve profitability, and we may never achieve or sustain profitability. In addition, we expect to continue to incur net losses for the foreseeable future, and we expect our accumulated deficit to continue to increase as we focus on scaling our business and operations. Our efforts to sustain and grow our business may be more costly than we expect, and we may not be able to increase our revenue sufficiently to offset our higher operating expenses. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations, and cash flows, and could cause the market price of our common stock to decline.

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

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

In addition, as a growing genomics company, we have engaged in targeted sales and marketing activities for our services. Although we have had revenue from sales of our services since 2013, our services may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or permit us to become profitable. We will need to further establish and grow the market for our services through the expansion of our current relationships and development of new relationships with biopharmaceutical customers and through gaining acceptance in medical communities. 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:

- generation of sufficient reimbursement or coverage by insurance or governmental payors for our products;
- our ability to demonstrate the utility and value of our services to our customers and potential customers;
- the success of our commercial team, including sales and business development personnel;
- the recruitment, hiring, and retention of our commercial team personnel;
- whether our customers and potential customers accept that our services are sufficiently sensitive and specific;
- our ability to educate our customers and potential customers of the utility of the comprehensiveness of our services and of testing patients at multiple time points;
- our ability to continue to fund sales and marketing activities;
- whether our services are considered superior to those of our competitors;
- any negative publicity regarding our or our competitors' services resulting from defects or errors;
- our success obtaining and maintaining patent and trade secret protection for our services and technologies; and

- our success enforcing and defending intellectual property rights and claims.

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

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

Our principal competition comes from commercial and academic organizations that employ various approaches 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 educate our customers and potential customers on the benefits of our comprehensive tests compared to simpler panels provided by our competitors. For example, the information that we provide may be more challenging or require additional resources for our customers to interpret than the information provided by our competitors' less comprehensive assays. In addition, our suppliers or competitors may announce the development of new products, services or features that results in our customers' or potential customers' decision to reduce, postpone or cancel orders from us while they wait to determine which products, services or features are or will be perceived as technologically superior, more commercially successful or adopted as standards in the industry; such decisions by our customers or potential customers may be influenced by their concerns regarding the potential obsolescence of data generated using our services and features if our services or features are or will not be perceived as technologically superior, commercially successful or adopted as standards in the industry.

Some of our present or potential competitors, including Adela, Inc., BostonGene Corporation, Caris Life Sciences, Inc., DELFI Diagnostics, Inc., Exact Sciences Corporation, Foresight Diagnostics Inc. ("Foresight"), Foundation Medicine, Inc., Freenome, Inc., Fulgent Genetics, Inc., Geneseeq Technology Inc., GRAIL, Inc., Guardant Health, Inc., Haystack Oncology, Inc., which was acquired by Quest Diagnostics Incorporated in June 2023, Laboratory Corporation of America Holdings, MedGenome Inc., Myriad Genetics, Inc., Natera, NeoGenomics, Inc., Novogene Corporation, Predicine, Inc., Roche Molecular Systems, Inc., SAGA Diagnostics AB, Tempus, and Veracyte, Inc. may have more widespread brand recognition or substantially greater financial or technical resources, development or production capacities, or marketing capabilities than we do. They may be able to devote greater resources to the development, promotion and sale of their products and services than we do or sell their products and services at prices designed to win more significant levels of market share. Also, we have had, and may have in the future, customer or supply relationships with our present or potential competitors. For example, we have an agreement with Natera to provide advanced tumor analysis for use in Natera's MRD testing offerings. During the year ended December 31, 2024, revenue under our agreement accounted for 30% of our total revenue. See "—We currently derive a substantial portion of our revenue from DNA sequencing and data analysis services that we provide to Natera. We expect our commercial relationship with Natera to wind down by mid-2025 and, if we are unable to grow our customer base and diversify our revenue concentration, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed." In addition, our present or potential competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, more well-established and well-financed companies. We may also have disputes with our present or potential competitors. See "—Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price, any of which could have a material adverse effect."

Others may develop lower-priced, less complex products and services that pharmaceutical companies could view as functionally equivalent to our current or planned future services, which could force us to lower the price of our services and impact our operating margins and our ability to achieve and maintain profitability. In addition, companies or governments that control access to genetic testing and related services through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. In addition, technological innovations that result in the creation of enhanced products or diagnostic tools that are more sensitive or specific than ours may enable other clinical laboratories, hospitals, physicians, or medical providers to provide specialized products or services similar to ours in a more patient-friendly, efficient, or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, or if we cannot maintain successful customer or supply relationships with Natera, Illumina or other present or potential competitors, we may be unable to ensure or increase market acceptance and sales of our current or planned future services, which could prevent us from increasing or sustaining our revenue or achieving or sustaining profitability.

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

we would incur increased research and development expenses, and such activities may also divert our resources or the attention of our management and may create competing internal priorities for us. In addition, we have limited experience developing diagnostics, have never developed an FDA-approved companion diagnostic, and may be unable to successfully compete against companies with more experience developing and commercializing companion diagnostics.

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

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

Like other genomic profiling companies that sell to the pharmaceutical industry, we have substantial customer concentration. We currently derive a significant portion of our revenue from Natera, which accounted for 30% and 43% of our revenue for the years ended December 31, 2024 and 2023, respectively. We also derive a significant portion of our revenue from Moderna, which accounted for 28% and 5% of our revenue for the years ended December 31, 2024 and 2023, respectively. We previously derived a significant portion of our revenue from the VA MVP, which more recently accounted for 9% and 13% of our revenue for the years ended December 31, 2024 and 2023, respectively. Our top five customers, including Natera, Moderna, and the VA MVP, accounted for 81% and 74% of our revenue for the years ended December 31, 2024 and 2023, respectively. There are inherent risks whenever a large percentage of revenue is concentrated with a limited number of customers. While we have attempted to grow our customer base and diversify our revenue concentration beyond Natera, Moderna, and the VA MVP, we may not be able to successfully do so in the future. Our predictions regarding the future level of demand for our services that will be generated by these customers may be wrong. In addition, revenue from our larger customers have historically fluctuated and may continue to fluctuate based on the commencement and completion of clinical trials or other projects, the timing of which may be affected by market conditions or other factors, some of which may be outside of our control. Some of our customers have in the past suspended or terminated clinical trials or projects, received less funding than expected, experienced declining or delayed sales, or otherwise decided to reduce or eliminate their use of our services, and these and other customers may also do so in the future. As a result, we could be pressured to reduce the prices we charge for our services, which would have an adverse effect on our margins and financial position, and which would likely negatively affect our revenue and results of operations. In particular, if we do not win future VA MVP renewals with a value comparable to that of our historical contracted orders, it may have a material adverse effect on our revenue, cash position, and results of operations. See "—We have derived a substantial portion of our current revenue from DNA sequencing and data analysis services that we provided to one of our largest customers, the VA MVP. If the VA MVP's demand for and/or funding for our DNA sequencing and data analysis services continues to be substantially reduced, or if our new contract with the VA MVP were to be terminated, our business, financial condition, revenue and other operating results, and cash flows will be materially harmed." Similarly, if the VA MVP was eliminated, awarded its contract to one of our competitors, further reduced the size of our contract or failed to renew our contract in the future, then our revenue, cash position, and results of operations would be materially adversely impacted. Likewise, if Natera, Moderna or any of our other significant customers were to reduce or cease their use of our services, then our revenue, cash position, and results of operations may be materially adversely impacted. Further, if any of our significant customers were to stop payment for our services, it would have a material adverse effect on our accounts receivable, increasing our credit risk. The failure of these customers to pay their balances, or any customer to pay future outstanding balances, would result in an operating expense and reduce our cash flows.

We currently derive a substantial portion of our revenue from DNA sequencing and data analysis services that we provide to Natera. We expect our commercial relationship with Natera to wind down by mid-2025 and, if we are unable to grow our customer base and diversify our revenue concentration, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed.

In February 2021, we entered into a partnership in the field of personalized oncology with Natera, pairing our NeXT tumor profiling and diagnostic services and products with Natera's personalized ctDNA test Signatera™ for treatment monitoring and MRD assessment. Under this non-exclusive agreement, Natera is responsible for validating the design of, and commercialization of, Signatera personalized ctDNA assays using matched tumor and normal exome sequence data from us. The agreement covers MRD testing for both clinical use and research use. Since that time, Natera's sample volumes have increased such that we currently derive a significant portion of our revenue from sales of our DNA sequencing and data analysis services to Natera under our agreement. For example, in 2024, revenue under our agreement accounted for 30% of our total revenue. In December 2024, we amended our agreement to extend minimum volume commitments through the second quarter of 2025. Upon expiration of the term of the amended agreement, we expect our commercial relationship with Natera to terminate as we are aware that Natera plans to bring such services in-house in lieu of purchasing such services from us. We are also aware of at least one third party supplier of DNA sequencing and analysis services, such that Natera has elected, and may continue to elect in the future, to send a portion (or all) of its samples to its other supplier(s) instead of us, which it is not contractually prohibited from doing, given the non-exclusive nature of our agreement. Our agreement with Natera requires us to achieve certain quality and turnaround time metrics for Natera samples. Recently, the volumes of samples sent to us by

Natera have fluctuated significantly and may continue to do so for the remainder of the term of the agreement, which could cause us to experience difficulty in achieving such metrics from time to time, or to meet our other obligations under our agreement.

Additionally, Natera or other customers may allege that any failures to achieve the required metrics are a breach of our agreement and seek to terminate our agreement prior to its expiration and/or pursue any remedies available to it under the agreement, at law or in equity. Relatedly, we have incurred expenses in connection with our scale-up activities under our agreement with Natera, and we may incur additional expenses in the future to increase our laboratory's capacity to process increased sample volumes from our other customers. Our activities under our agreement with Natera have had, and activities with our other customers may in the future have, an impact on our business, including diversion of our resources and the attention of our management, including with respect to our internal research and development objectives and projects for our other customers, collaborators and/or partners. If we are unable to successfully increase our laboratory's capacity and manage any such competing objectives and/or projects for other customers, we may be unable to meet the quality and timing requirements of our agreement with Natera or our other customers, collaborators and/or partners. We may also be unable to successfully research, develop, launch and/or commercialize our services or service capabilities. Furthermore, our NeXT Personal test is a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify MRD and recurrence in patients previously diagnosed with cancer. If NeXT Personal or any of our other services is seen as competing with Signatera or any of Natera's other services, we will still be required to fulfill our obligations to Natera under our agreement, although Natera may elect to send a portion (or all) of its samples to its other supplier(s) and/or bring such services in-house. If the volume of samples received under our agreement with Natera were to be significantly reduced or eliminated, or if our agreement with Natera were to be terminated or not renewed after expiration, and we are unable to grow our customer base and diversify our revenue concentration timely, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed.

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

We have derived a substantial portion of our revenue from sales of our DNA sequencing and data analysis services to the VA MVP. In September 2017, we entered into a one-year contract with three one-year optional renewal periods with the VA for the VA MVP, pursuant to which we received contracted orders from the VA MVP in September 2017, 2018, 2019, 2020, and 2021. In September 2022, we entered into a new contract with the VA MVP to continue providing them WGS services and received an initial task order with a value of up to $10.0 million (the "2022 VA MVP Agreement"). The performance period under the new contract includes a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. In September 2024, we received a third task order with a value of up to $7.5 million. There is no guarantee that the VA MVP will exercise any subsequent renewal option.

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

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

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

Our customers, other than the VA MVP and Natera, are primarily biopharmaceutical companies that use our services to support clinical trials, including Moderna. Our future success is substantially dependent on our ability to maintain our customer relationships and to establish new ones. Many factors have the potential to impact our customer relations, including the type of support our customers and potential customers require and our ability to deliver it, our customers' satisfaction with our services, and other factors that may be beyond our control. Furthermore, our customers may decide to decrease or discontinue their use of our services due to changes in research and product development plans (including as a result of a public health crisis), failures in their clinical trials (which failures are statistically much more likely to occur than not at some point in the clinical development process, notwithstanding any enhanced patient stratification from the use of our proprietary tests and algorithms), financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control.

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

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

Building our clinical laboratory business is subject to a number of reimbursement challenges and we may not be able to establish the medical necessity of our tests for coverage or reimbursement rates that cover our costs.

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

In January 2024, we announced that we received a final Medicare coverage determination for our NeXT Dx offering, extended retroactively to August 29, 2023. While we estimate that approximately half of new solid tumor cancer cases will be diagnosed in patients covered by Medicare, the Medicare coverage determination may not be indicative of our ability to obtain coverage with other payors. Even if favorable coverage and reimbursement status is attained for one or more of our products, less favorable coverage policies and reimbursement rates may be implemented in the future.

We are pursuing a partner-centric strategy and have key relationships with Tempus, Myriad, Moderna and Merck, among others. These and any other partnering and/or collaboration arrangements that we have entered into or may enter into in the future may not be successful, or may terminate, which could adversely impact our business or affect our ability to develop and commercialize our services and products.

Any current or future collaborations, including any strategic alliances or any collaborations to develop companion diagnostic tests, that we have entered (for example, our strategic alliances with Moderna and Merck; and our collaborations with Tempus; Myriad; ClearNote Health, Inc.; Cancer Research UK, University College London, and the Francis Crick Institute (the TRACERx study); Institut Curie; The Royal Marsden; the Vall d'Hebron Institute of Oncology (VHIO); the University of California, San Diego; Duke University; Vanderbilt University and Johns Hopkins University (the PREDICT study); the Dana-Farber Cancer Institute; the University of Texas M.D.

Anderson Cancer Center; University Medical Center Hamburg-Eppendorf (also known as UKE); and Criterium and the Academic Breast Cancer Consortium) or may enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which include that:

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

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

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

We rely on a limited number of suppliers for sequencers and other equipment and materials that we use in our laboratory operations. For example, we rely on Illumina as our sole supplier of sequencers and various associated reagents and other materials used in our routine laboratory operations, and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations or our inability to negotiate pricing with Illumina on acceptable terms, or at all, could negatively impact our supply chain and laboratory operations and our ability to conduct our business and generate revenue. Additionally, COVID-19 previously disrupted Illumina's ability to fulfill our purchase orders for reagents or other materials in a timely manner and another health epidemic or pandemic may disrupt the ability of Illumina and our other suppliers to fulfill our purchase orders in a timely manner or at all. Our suppliers, including Illumina, could cease supplying these materials and equipment at any time, could increase the price of these materials or equipment (including the promotional pricing offered to us by Illumina for our 2022 VA MVP Agreement and certain other

projects) or fail to provide us with sufficient quantities of materials or equipment that meet our specifications. Our laboratory operations have been and in the future could be interrupted if we encounter delays or difficulties in securing sequencers or other equipment or materials, or if we cannot obtain an acceptable substitute. We have also experienced, and may experience in the future, delays or difficulties in upgrading to newer versions or replacements of these materials and equipment, which may have better performance or be more cost-effective than the current versions. Any such interruption, delay or difficulty could significantly affect our business, financial condition, results of operations, and reputation.

We believe that there are only a few manufacturers other than Illumina that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. Likewise, we believe that there are a limited number of manufacturers and suppliers for other reagents and materials necessary for our laboratory operations, such as the sample preparation reagents required for our ACE technology, which enables our NeXT Platform to provide more comprehensive sequencing coverage, as well as those required to create personalized liquid biopsy panels for each patient as part of our NeXT Personal assay. Although we have evaluated and may continue in the future to evaluate equipment and materials from other suppliers, the use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, would likely result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations, or could require that we revalidate our tests. Additionally, an existing supplier of ours may allege that such activities constitute a breach of its agreement with us and may cease supplying us with sufficient quantities of materials or equipment that meet our specifications, in a timely manner or at all. Moreover, an existing supplier or third party may allege that such activities, replacement equipment or materials infringe, misappropriate or otherwise violate its intellectual property, and may bring infringement or other intellectual property-related claims against us. See "—Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price, any of which could have a material adverse effect." We cannot assure you that, if we were forced to replace Illumina or another supplier on which we rely, we would be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and other materials on-line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our services, our business, financial condition, results of operations, and reputation could be adversely affected.

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

We have a single facility and if it becomes damaged or inoperable, or we are required to vacate our facility, our ability to sell and provide our services and pursue research and development efforts may be jeopardized.

We currently derive our revenue from our genomic analysis conducted in our laboratories. Currently, our only clinical reference or research and development laboratory facility is in Fremont, California. Our laboratory facility 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. Northern California continues to experience 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 laboratory facility is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. For example, from January 2023 through April 2023, we experienced substantial disruption to use of our laboratory facility due to a failure of an electrical bus duct serving that facility. Furthermore, our laboratory facility and the equipment we use to perform our services and our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples as the basis for the development of our services, and our services typically involve using biological samples provided by or on behalf of our customers or collaborators. In some cases, these samples are difficult to obtain. If the parts of our laboratory facility where we store these biological samples were damaged or compromised, or if these biological samples or the resulting data were otherwise lost, damaged or compromised due to equipment malfunction, human error or other causes, our ability to pursue our research and development projects or provide our services, as well as our reputation, could be jeopardized. For example, we have experienced from time to time, and may experience in the future, equipment malfunctions that have resulted in lost, damaged or compromised samples or resulting data. We carry insurance for damage to our property or to our customer's property while in our possession, and we also carry insurance for the disruption of our business, but these types of insurance may not be sufficient to cover all of our potential losses or liabilities and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratory facility becomes inoperable, we would likely not be able to license or transfer our technology to other facilities with the qualifications, including state licensure and CLIA certification, that would be necessary to cover the scope of our current

and our planned future services. Even if we were to find facilities with such qualifications to perform our services, they may not be available to us on commercially reasonable terms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our success in implementing our business strategy depends largely on the skills, experience, and performance of key members of our executive management team and others in key management positions. The collective efforts of each of our executives and others working with them as a team are critical to us as we continue to develop our technologies, services, products, and research and development programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. If there are changes to our leadership team, there is a risk to organizational effectiveness and employee retention as well as the potential for disruption to our business. Integrating members into new or different management roles could prove disruptive to our operations, require substantial resources and management attention and ultimately prove unsuccessful. Each member of our executive management team has an employment agreement; however, the existence of an employment agreement does not guarantee retention of members of our executive management team, and we may not be able to retain those individuals or replace them in the event we lose their services. We do not maintain "key person" life insurance on any of our employees.

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

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

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

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

We have undertaken in the past, and may in the future undertake, internal restructuring activities that could result in disruptions to our business or otherwise harm our results of operations or financial condition.

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. For example, in the first quarter of 2023 and in the fourth quarter of 2023, we implemented reductions in our workforce to reduce operating costs and improve operating efficiency that collectively affected nearly 50% of our workforce. Any restructuring activities that we may undertake in the future may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we undertake in the future will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations and disrupt our ongoing business. If any internal restructuring activities we undertake in the future fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

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

Our Fremont facility expanded our laboratory capacity and, in order to execute our business model, we will need to make additional investments to further scale our infrastructure, including purchases of additional equipment, some of which can take several months or more to procure, setup, and validate, or increases to our software and computing capacity. There is no assurance that any of these increases in scale, equipment, software, and computing capacities, or process enhancements will be successfully implemented. In addition, we have experienced, and expect to continue to experience, significant fluctuations in the timing of receipt and volume of samples from our customers and collaborators. These fluctuations have in the past adversely impacted, and may in the future adversely impact, our ability to process samples timely and in an efficient fashion, particularly when the sample volume at any given time exceeds our then current capacity.

We expanded our laboratory facility in advance of increased demand for our services. Our current and projected future expense levels are to a large extent fixed and are largely based on our current investment plans and our estimates of future test volume. As a result, if revenue does not meet our expectations we may not be able to promptly adjust or reduce our spending to levels commensurate with our revenue, or at all. 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.

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.

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

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

Our operations were previously impacted by the COVID-19 pandemic. For example, the previous shelter-in-place order and health orders negatively impacted productivity, disrupted our business, and slowed research and development activities due to us limiting access to our laboratory space that would otherwise be used by our research and development group, and, to the extent such orders return in similar or more stringent form, they may cause similar effects on our operations. COVID-19 disrupted, and a future health epidemic or pandemic may disrupt in the future, the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we use certain consumables in our operations, and we have faced, and may face in the future, difficulties in acquiring such

consumables if our suppliers prioritize orders related to a health epidemic or pandemic or if other supply chain issues arise as a result of such a public health crisis. Several of our customers were delayed in sending us samples due to the inability to collect or ship samples during the COVID-19 pandemic, and these and additional customers may be disrupted from collecting samples or sending purchase orders or samples to us in the future in the event of the emergence of another health epidemic or pandemic.

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

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

We may in the future expand our business and operations into international jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals and marketing and selling products and services. As we expand internationally, our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, increased government regulation, social instability, local or regional health crises, and political, economic or diplomatic developments in the future. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations in such jurisdictions to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, anti-bribery and anti-corruption laws may conflict with some local customs and practices in foreign jurisdictions. Our international operations may subject us to heightened scrutiny under the Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), the United Kingdom (the “U.K.”) Bribery Act and similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws. As a result of our policy to comply with the FCPA, the U.K. Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws. Further, notwithstanding our compliance programs, there can be no assurances that our policies will prevent our employees or agents from violating these laws or protect us from any such violations. Additionally, we cannot predict the nature, scope or impact of any future regulatory requirements that may apply to our international operations or how foreign governments will interpret existing or new laws. Alleged, perceived, or actual violations of any such existing or future laws by us or due to the acts of others, may result in criminal or civil sanctions, including contract cancellations or debarment, and damage to our reputation, any of which could have a material adverse effect on our business.

Regulatory, Legal and Cybersecurity Risks

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

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

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs, which are a subset of in vitro diagnostic devices that are intended for clinical use and designed, manufactured, and used entirely within a single laboratory. We currently market our tests as LDTs and, therefore, we believe that they are not currently subject to the FDA’s enforcement of its medical device regulations and the applicable FDC Act provisions.

On May 6, 2024, the FDA issued final regulations under which it intends to phase out its enforcement discretion approach to LDTs over a period of four years (the "Final Rule"). We anticipate that we may be required to obtain PMA approval for certain of our tests by October 1, 2027. We may also be subject to device registration and listing requirements, medical device reporting requirements and the requirements of the FDA’s Quality System Regulation. We may be required to conduct clinical trials to support any premarket notification or applications to FDA, which would increase the costs to our business and impair our profitability. If the FDA determines that our tests are subject to enforcement as medical devices, we could be subject to enforcement action, including administrative and judicial sanctions, and additional regulatory controls and submissions for our tests, all of which could be burdensome. We and/or our collaborators may also be required to submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices. 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."

The implementation of the Final Rule exposes us to additional regulatory controls and submissions for our tests or the possibility of enforcement action, both of which would be burdensome. In addition, we cannot be certain that the FDA will not enact rules or guidance documents that could impact our ability to purchase certain materials necessary for the performance of our tests, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting, or prohibiting the purchase of reagents necessary to perform testing.

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

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

If the FDA determines that our tests and associated software do not fall within the definition of an LDT, under the FDA's Final Rule or otherwise, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, we may be required to obtain premarket clearance for our tests and associated software under Section 510(k) of the FDC Act or approval of a premarket approval application ("PMA"). We would also be subject to ongoing regulatory requirements such as registration and listing requirements, medical device reporting requirements, and quality control requirements. If our tests are considered medical devices not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, the regulatory requirements to which our tests are subject would depend on the FDA's classification of our tests. The FDA has issued regulations classifying generic types of medical devices into one of three regulatory control categories (Class I, Class II, or Class III) depending on the degree of regulation that the FDA finds necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet both pre- and post-market. On January 31, 2024, FDA announced its intent to initiate a reclassification process for most IVDs that are currently Class III (high risk), the majority of which are infectious disease and companion diagnostic IVDs, into Class II (moderate risk). This reclassification would allow manufacturers of certain types of IVDs to seek marketing clearance through the less burdensome Class II 510(k) premarket notification pathway rather than the Class III premarket approval (PMA) pathway, the most stringent type of FDA medical device review.

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

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

If our tests are considered medical devices not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, one classification regulation that could be relevant to one or more of our tests is a classification for genetic health risk ("GHR") assessment tests, codified at 21 C.F.R. § 866.5950. If our tests are considered medical devices that are not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, and one or more of our tests is considered to fall under the 21 C.F.R. § 866.5950 classification regulation for GHR tests, or under another Class II classification that is subject to a

premarket notification requirement, we would be required to obtain marketing clearance for such tests. Further, if considered to fall under the 21 C.F.R. § 866.5950 classification for GHR tests, our tests would be required to adhere to specified special controls, such as labeling and testing specifications and information about the test to be posted on the manufacturer's website. If any of our current or pipeline tests are not considered by the FDA to be GHR tests or do not qualify for the limited exemption for a sponsor's subsequent GHR tests once the assessment system has been reviewed and cleared by FDA, or if any of our tests fall under a different non-exempt classification or are unclassified, we could be required to obtain 510(k) clearance or approval of a PMA for such test in the future.

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

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

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

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

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

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

- suspension or withdrawal of regulatory clearances or approvals;
- limitation on, or refusal to permit, import or export of our products;
- product seizures;
- injunctions; or
- imposition of civil or criminal penalties.

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

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

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

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

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance, and inspections. We have a current CLIA certificate to conduct our tests at our laboratory in Fremont, California. To renew this certificate, we are subject to survey and inspection every two years. Because we are a CAP-accredited laboratory, the Centers for Medicare & Medicaid Services ("CMS") does not perform this survey and inspection and relies on our CAP survey and inspection. We also may be subject to additional unannounced inspections.

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

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

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

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

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

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

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

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which are increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, attacks enhanced or facilitated by artificial intelligence ("AI"), software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, natural disasters, terrorism, and other similar threats. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, ability to provide our services, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. Most of our employees are working remotely at least part of the time and such remote work has increased risks to our information technology systems and data, as more of our employees

utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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

Despite the measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to our customers, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, and managing the administrative aspects of our business. For example, in 2018, we experienced downtime in our information technology systems in connection with the adoption of new information technology, and our results of operations in the first and second quarters of 2018 were adversely affected as a result. In 2024, we experienced downtime in our information technology systems due to human error in connection with an upgrade by one of our third-party vendors to one of our information technology systems. Our results of operations were not materially adversely affected in the case of the latter downtime. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products and services.

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

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Further, if the information technology systems of the third parties with whom we work become subject to security incidents, we may have insufficient recourse against such third parties, and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We employ a shared responsibility model where our customers and partners are responsible for configuring and implementing security measures related to our platform. As part of this model, we make certain security features available to users that can be implemented at their discretion or identify security areas or measures for which they are responsible. For example, users can choose whether to implement and enforce multifactor authentication to access their accounts. In certain cases where users choose not to implement, or incorrectly implement, those features or measures, misuse our services, or otherwise experience their own vulnerabilities, policy violations, credential exposure or security incidents, even if we are not the cause of a resulting customer security issue or incident, our customer and partner relationships, reputation, and revenue may be adversely impacted.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our tests and services and otherwise conduct our business in the ordinary course.

Unauthorized access, loss, or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development

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

Applicable data privacy and security obligations, including applicable federal and/or state breach notification laws and foreign equivalents, as well as public company disclosure obligations, may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulatory authorities and our stockholders, of certain security incidents or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims) and mass arbitration; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers or partners to stop using our products and services, deter new customers or partners from using our products and services, and negatively impact our ability to grow and operate our business. Whether a cybersecurity incident is reportable to our stockholders may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide.

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

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI technologies.

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

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

In the United States, federal, state, and local governments have enacted numerous data privacy, and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Penalties for failure to comply with HIPAA and HITECH include significant civil monetary penalties and criminal penalties in certain circumstances with fines up to $250,000 per violation and/or imprisonment. Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective and applicable to us, we may have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. Similarly, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA") applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including those noted below. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the CPRA expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado, Connecticut and Utah have also enacted comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal

and local levels. These state laws and the CCPA provide individuals with certain rights concerning their personal information, including the right to access, correct, or delete certain personal information, and opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely and our customers. Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information and regulators, such as the Federal Trade Commission, have indicated that use of biometric technologies (including facial recognition technologies) may be subject to additional scrutiny.

We may be subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington's My Health My Data Act broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. California also recently passed a law protecting privacy of abortion-related records and other reproductive healthcare services.

Outside the U.S., an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the General Data Protection Regulation 2016/679 ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais) (Law No. 13,709/2018), and China's Personal Information Protection Law impose strict requirements for processing personal information. Under the EU GDPR and UK GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, applies to our operations. We also receive personal information from customers in Asia and may be subject to new and emerging data privacy and security regimes in Asia, including Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

In the ordinary course of business, we may transfer personal information from Europe and other jurisdictions to the U.S. or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the EEA and the U.K. have significantly restricted the transfer of personal information to the U.S. and other countries whose data privacy and security laws they generally believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and U.K. to the U.S. in compliance with law, such as the EEA's standard contractual clauses, the U.K.'s International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (and U.K. extension thereto) (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in such framework), these mechanisms are susceptible to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the U.S. If there is no lawful manner for us to transfer personal information from the EEA, the U.K. or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Additionally, companies that transfer personal information out of the EEA and U.K. to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. EEA countries may also introduce national legislation further limiting the processing of personal genetic, biometric, or health data, which could limit our ability to collect, use and share data originating from the EEA, or could cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. The U.S. is also increasingly scrutinizing certain personal data transfers and may impose data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

In addition to data privacy and security laws, because we process some credit card payments through a third-party payment processing partner, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. For example, we also are subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from $5,000 to $100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses.

We also rely on vendors to process payment card data, who may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or

statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various data privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

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

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing data privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products and services; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with government regulations, including federal and state healthcare fraud and abuse laws and regulations, to misuse information, including patient information, and to report financial information or data accurately or disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation.

We have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from government healthcare programs, contractual damages, refunding of payments received by us, reputational harm, additional reporting, or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring

of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

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

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim under the False Claims Act;
- the Anti-Markup Rule, which, among other things, prohibit a physician or supplier billing the Medicare program from marking up the price of a purchased diagnostic service performed by another laboratory or supplier that does not "share a practice" with the billing physician or supplier. Penalties may apply to the billing physician or supplier if Medicare or another payor is billed at a rate that exceeds the performing laboratory's charges to the billing physician or supplier, and the performing laboratory could be at risk under false claims laws, described below, for causing the submission of a false claim;
- the 14-Day Rule, also known as the Medicare Date of Service Rule, which prohibits a laboratory supplier from billing the Medicare program for tests performed on samples collected during or within 14 days of an inpatient hospital stay, unless an exception applies, and requires the laboratory supplier to bill the hospital in those cases. Penalties may apply to the laboratory supplier if Medicare determines that the Medicare program was inappropriately billed for testing that should have been billed to the hospital where the sample was collected;
- state client billing laws, which specify whether a person that did not perform the service is permitted to submit the claim for payment and if so, whether the non-performing person is permitted to mark up the cost of the services in excess of the price the purchasing provider paid for such services. For example, California has an anti-markup statute which prohibits providers from charging for any laboratory test that it did not perform unless the provider (a) notifies the patient, client or customer of the name, address, and charges of the laboratory performing the test, and (b) charges no more than what the provider was charged by the clinical laboratory which performed the test except for any other service actually rendered to the patient by the provider (for example, specimen collection, processing and handling) (California Business and Professions Code Section 655.5). This provision applies, with certain limited exceptions, to licensed persons such as physicians and clinical laboratories regulated under the Business and Professions Code. In addition, many states also have "direct-bill" laws, which means that the services actually performed by an individual or entity must be billed by such individual or entity, thus preventing ordering physicians from purchasing services from a laboratory and rebilling for the services they order. For example, California has a direct bill rule specific to anatomic pathology services that prohibits any provider from billing for anatomic pathology services if those services were not actually rendered by that person or under his or her direct supervision with some exemptions (California Business and Professions Code Section 655.7);
- the federal civil and criminal false claims laws, including the False Claims Act, which impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. These laws can apply to entities that provide information on coverage, coding, and reimbursement of their products and services and assistance with obtaining reimbursement to persons who bill payors. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, biologicals, and medical devices or supplies that require premarket approval by or notification to the FDA, and for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to (i) payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members;
- the HIPAA fraud and abuse provisions, which created federal civil and criminal statutes that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense, and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, known as business associates, as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and is similar to the federal Anti-Kickback Statute in that it creates criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing unless a specific exception applies. Unlike the federal Anti-Kickback Statute, EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). Additionally, most of the safe harbors available under the federal Anti-Kickback Statute are not reiterated under EKRA, and certain EKRA safe harbors conflict with the safe harbors available under the federal Anti-Kickback Statute. Therefore, compliance with a federal Anti-Kickback safe harbor does not guarantee protection under EKRA. Because EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be interpreted, applied and enforced by the government. Currently, there is no proposed regulation interpreting or implementing EKRA, nor any public guidance released by a federal agency concerning EKRA;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any payor, including private insurers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing physicians for testing that they order as discussed above; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; employing, exercising control over, licensed professionals in violation of state laws prohibiting corporate practice of medicine and other professions, and prohibitions against the splitting of professional fees with licensed professionals; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies and authorities 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, disgorgement, imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, integrity oversight and reporting obligations, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

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

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "ACA"), became law. This law substantially changed the way health care is financed by both commercial payors and government payors, 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.

Further, on August 16, 2022, the IRA 2022 was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. Efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA create considerable uncertainties for all businesses involved in healthcare, including our own. It is unclear how such future efforts to repeal and replace the ACA will impact the ACA and our business. Additional legislation may be enacted that further amends, or repeals, the ACA, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our and our customers' business.

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

based Incentive Payment System. Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payor payment rates and volumes for their tests. CMS will use this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare reimbursement rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Beginning on January 1, 2018, CMS has begun using reported private payor pricing to periodically revise payment rates under the CLFS. Based on current law, between January 1, 2025 and March 31, 2025, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2025 to 2027 Clinical Laboratory Fee Schedule rates. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our current tests or those in development.

Pursuant to the Consolidated Appropriations Act, the statutory phase-in of the payment reductions has been extended through 2025 with a 0% reduction cap for 2021-2023 and a 15% reduction cap for 2026 through 2028. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows. We also anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and private payors 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 payors, including commercial payors and government payors. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

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

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

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

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

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

tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 during which EU rules continued to apply. The U.K. and the EU have signed the EU-U.K. Trade and Cooperation Agreement which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the U.K. and EU's relationship will operate in the future. However, there are still many uncertainties. On May 26, 2022, the IVDR entered into application in the EU. However, the IVDR is not applicable in the U.K. In the U.K., IVDs are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which retains a regulatory framework similar to the framework set out by the IVDD. As a result, there will be some regulatory divergence in the U.K. from the EU in light of the fact that the CE marking process is set out in EU law, which no longer applies in the U.K. The U.K. has devised a new route to market culminating in a U.K. Conformity Assessed mark to replace the CE Mark for placing IVDs on the market in Great Britain ("G.B."). Northern Ireland will, however, continue to be covered by the regulations governing CE Marks (a CE Mark or a CE Mark and UKNI Mark will be required to place products on the Northern Ireland market). The EU legal framework, including the IVDR, remains applicable in Northern Ireland (any products placed on the market in the Northern Ireland must be compliant with EU law). However, all medical devices and IVDs must be registered with the MHRA, in order to be placed on the G.B. market.

The U.K. Government has introduced legislation permitting EU CE Marks to continue to be recognized in G.B. for medical devices. The duration of such recognition depends on the EU regulatory framework on the basis of which the medical devices were previously CE marked. The risk classification of the devices also has an impact if they were CE marked in accordance with the IVDD. The U.K. government also intends to introduce legislation establishing reinforced post-market surveillance requirements in early 2024. The World Trade Organization ("WTO") published notification of the draft Post-market Surveillance Requirements Statutory Instrument (PMS SI) on July 26, 2023. These post-market surveillance requirements are anticipated to apply from mid-2024. The U.K. government is aiming to have core aspects of the future regulatory regime for medical devices applicable from July 1, 2025. The nature of any new regulation in the U.K. is uncertain, and as such, we may experience delays in obtaining future access to the U.K. and other European markets. The U.K.'s departure from the EU has also impacted customs regulations and impacted timing and ease of shipments into the EU from the U.K.

The UK government has recently amended the MDR 2002 to extend the recognition of CE marked medical devices in Great Britain. The amendments provide that CE marks will cease to be recognized in Great Britain on June 30, 2030, at the latest. Shorter deadlines may apply depending on the regulatory framework on the basis of which the CE mark is affixed and the classification of the medical devices. In addition, CE marks may cease to have affect before the deadlines established in the amended UK MDR – if CE Certificates of Conformity expire, or if related application of EU law renders the CE Certificates of Conformity invalid at an earlier date. Accordingly, IVDs CE marked in accordance with the IVDD can be placed on the Great Britain market until May 26, 2025 if they are list A, list B, or self-testing IVDs or until June 30, 2030 if they are General IVDs which were self-assessed under the IVDD, for which the EU Declaration of Conformity was issued in accordance with the IVDD prior to May 26, 2022, and for which the conformity assessment under Regulation 217/746 on IVDs (IVDR) will require the involvement of a notified body. IVDs CE marked in accordance with the IVDR can be placed on the Great Britain market until June 30, 2030.

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

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

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. We currently do not report our environmental emissions and absent a legal requirement to do so we currently do not plan to report our environmental emissions, and lack of reporting could result in certain investors declining to invest in our common stock. As ESG best practices and reporting standards continue to develop, we may incur increasing costs relating to ESG monitoring and reporting and complying with ESG initiatives. For example, California recently enacted Assembly Bill 1305 ("AB 1305"). AB 1305, which became effective on January 1, 2024, creates new annual disclosure requirements regarding substantiation of certain climate-related statements, and, if we report climate related statements in the future, could increase our compliance and reporting costs. Additionally, the SEC adopted rules designed to enhance and standardize climate-related disclosures, which have been stayed pending judicial review. If these rules or other climate-related disclosures rules become effective, they may significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation and/or that harm our stock price. In the event that we communicate certain initiatives or goals regarding ESG matters in the future, we could fail, or be perceived

to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of certain investors and other stakeholders or our initiatives are not executed as planned, our business, financial condition, results of operations, and prospects may be adversely affected.

Intellectual Property Risks

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

Our commercial success will depend, in part, on our avoiding infringement of patents and the infringement, misappropriation, or other violation of proprietary rights of third parties, including, for example, the intellectual property of competitors. There is extensive intellectual property litigation involving the biotechnology and pharmaceutical industries and genetic sequencing technology, including with regard to liquid biopsy assays such as those designed to detect or quantify MRD or recurrence in patients previously diagnosed with cancer. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign patents and pending patent applications exist in the genetic testing market and are owned by third parties. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. For example, we are aware of several third-party issued U.S. patents and pending patent applications with claims relating to genetic sequencing technology and methodology that may be asserted against us and may be construed to encompass our products and services. In order to avoid liability related to an allegation of infringement of these third-party patents, we may find it necessary or prudent to initiate invalidity proceedings against such patents or to obtain licenses from such third-party intellectual property holders. If we are not able to invalidate such patents or obtain or maintain a license on commercially reasonable terms and such third parties assert infringement claims against us, we may be prevented from exploiting our technology and our business, financial condition, results of operations, and prospects may be materially and adversely affected. We may also be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Patent applications in the U.S. and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the U.S. can remain confidential until patents issue. Therefore, patent applications covering our products, services, or technologies could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products, services, technologies, and their use. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent, and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and services. Further, we may incorrectly determine that our technologies, products, or services are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or services.

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

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

pay substantial royalties and other fees; and redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure; or be prohibited from commercializing certain tests, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

In addition, the patent position of companies engaged in the development and commercialization of diagnostic tests is particularly uncertain. Various courts, including the Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or a law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of genetic diagnostic 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 defend or enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, and services are obtained, once the patent life has expired, we may be open to competition from competitive products or services. Our issued patents will expire on dates ranging from 2033 to 2038, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2045. In addition, although upon issuance in the U.S., a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant

during patent prosecution. If we do not have sufficient patent life to protect our technologies, products and services, our competitive position, business, financial condition, results of operations, and prospects will be adversely affected.

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

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

Moreover, the patent position of biotechnology companies can be highly uncertain because it involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the U.S. or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing nucleic acid sequences.

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

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

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

- others will not or may not be able to make, use, offer to sell, or sell tests that are the same as or similar to our products or services but that are not covered by the claims of the patents that we own or license;
- we or our future licensors or collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our future licensors or collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable, and infringed;
- any issued patents that we own or may license will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop or in-license additional proprietary technologies that are patentable;
- pending patent applications that we own or may license will lead to issued patents;

- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products or services for sale in our major commercial markets.

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

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

It is also possible that we fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions. To determine the priority of these inventions, we have participated, and may in the future participate, in interference proceedings, derivation proceedings, *inter partes* review proceedings, or other post-grant proceedings declared by the USPTO or a foreign patent office that have resulted, and could in the future result, in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the U.S. allow for various post-grant opposition proceedings, such as *inter partes* review proceedings, providing additional methods for others to challenge our patents. For example, two of our patents were recently challenged and subsequently invalidated during *inter partes* reviews initiated by Foresight. 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 have in the past been involved in legal proceedings to enforce our intellectual property rights and may in the future become involved in other lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and unsuccessful.

Our intellectual property rights involve complex factual, scientific and legal questions. We operate in an industry characterized by significant intellectual property litigation. Even though we may believe that we have a valid patent on a particular technology, others may infringe our patents or the patents of our licensing partners. For example, in the past we filed complaints against Foresight for infringement of certain of our patents relating to detection of MRD, which complaints we agreed to stipulate to dismiss, pursuant to a settlement agreement with Foresight in June 2024. In addition, our patents or the patents of our licensors may become involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. Further, in such proceedings, the defendant could counterclaim that our asserted patent covering our services or product is invalid or unenforceable, and the court may agree that our asserted patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third

parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, inter partes review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our services or product or the services or products of our competitors. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. An adverse result in any litigation or other proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. For example, two of our patents were recently challenged and subsequently invalidated during *inter partes* reviews initiated by Foresight. 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 have caused and may continue to cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

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

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

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

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

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

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

Although we have policies to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any

such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- actual or anticipated fluctuations in our operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research reports by securities analysts or changed recommendations for our stock;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors relating to significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP, Moderna and Natera, as our largest customers;

- the timing and amount of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business or issues we may face with regulators;
- additions or departures of key management or other personnel;
- inability to obtain additional funding;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments related to our intellectual property or other matters, including litigation;
- health epidemics or pandemics, geopolitical conflicts, inflation, global supply chain issues, regional or national economic slowdowns, recessions, depressions or other economic downturns; and
- other general economic, industry, and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors.

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

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings forecasts that we may provide.

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

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

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

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

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine and the two countries are now at war. In addition, in October 2023, Hamas attacked Israel which provoked a state of war, and there is now a larger regional conflict. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions could continue to affect, and potentially materially adversely affect, global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. As noted above, the FDIC took control of SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank in the first half of 2023. While we did have an account at SVB, we were able to recover all of our deposits when the FDIC stepped in and allowed us to transfer funds held at SVB to another bank without incurring any losses. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Insiders or holders of greater than five percent of our outstanding common stock may exercise significant control over our company and will be able to influence corporate matters.

Our directors, executive officers and their affiliates, and holders of greater than five percent of our outstanding common stock, if they were to act together, would be able to exercise significant influence over our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a third party from acquiring control of our company and could adversely affect the market price of our common stock and may not be in the best interests of our other stockholders. In November 2023, we entered into a Commercialization and Reference Laboratory Agreement ("Tempus Agreement") (see Note 8 to our audited consolidated financial statements included in this Annual Report on Form 10-K for additional information), pursuant to which, Tempus agreed to certain voting commitments that require Tempus to vote the shares it acquired from exercising its warrants for our common stock in accordance with the recommendations of the majority of our board of directors with respect to director nominations for any meeting of our stockholders occurring on or before December 31, 2025, as well as various compensation-related matters. These voting commitments terminate on when the parties' exclusivity obligations expire or terminate under the Tempus Agreement. In addition, in December 2024, we entered into an Investment Agreement with Merck & Co.,

Inc. (“Merck”) (see Note 8 to our audited consolidated financial statements included in this Annual Report on Form 10-K for additional information) pursuant to which Merck agreed to certain voting commitments that require Merck to vote, subject to specified exceptions, any shares of our common stock that Merck owns in accordance with the recommendations of our board of directors. Such voting commitments generally apply to director nominations for any meeting of our stockholders, amendments to our charter to increase the authorized shares of our common stock, various compensation-related matters, and ratification of our auditors. These voting commitments terminate upon the earlier of the second anniversary of the date of the investment agreement with Merck and the first time that Merck and its affiliates no longer own at least 50% of our shares owned by Merck immediately following the date of the investment agreement with Merck.

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

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2024, we had 85,171,146 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 will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. 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 and under our at-the-market facility, 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, 2024, we had federal and state net operating loss carryforwards of approximately $324.1 million and approximately $302.5 million, respectively. Certain of our federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2031. These net operating loss carryforwards could expire unused and be unavailable to offset future taxable income. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, federal net operating losses incurred in tax years beginning in 2018 and thereafter may be carried forward indefinitely, but the deductibility of such federal net operating losses for tax years beginning after 2020 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, as modified by the CARES Act. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (including certain tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. As a result, because of these inherent limitations in our control system, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to file required reports in a timely manner and filing reports containing incorrect information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, damage to our reputation, and harm to our financial condition.

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, personal information, and Personal Health Information ("PHI") (collectively, "Information Systems and Data").

The board of director's audit committee and the internal cybersecurity team help identify, assess and manage the Company's cybersecurity threats and risks, including through the use of our risk register. Our internal cybersecurity team includes our information security function, security management, engineering operations, legal, risk management and third-party service providers. Our cybersecurity team identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and Personalis' risk profile using various methods including, for example: using manual and automated tools, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, conducting threat assessments, employee reporting, encryption of data, penetration testing, and regular reviews and internal and external audits.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident response plan, incident detection and response, disaster recovery and business continuity plans, risk assessments, network security controls, access controls, user management, asset management, hardware and data segregation, system monitoring and regular reviews.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, cybersecurity risk is addressed as a component of our enterprise risk management program and identified in our risk register. Additionally, the cybersecurity team monitors activity on a continual basis and works with security management to prioritize our risk profile and mitigate cybersecurity threats that are more likely to lead to a material impact to our business on a monthly basis; executive management evaluates material risks from cybersecurity threats against our overall business objectives on a periodic basis and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk periodically.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity consultants, threat intelligence service providers, forensic investigators, and professional services firms.

We use third-party service providers to perform a variety of functions throughout our business, including, but not limited to infrastructure support and maintenance, supply chain resources, contracting services and software integrations. These vendors are reviewed as part of our vendor management program, including the management of cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part I, Item1A. Risk Factors in this Annual Report on Form 10-K, including "If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing the Company's cybersecurity risk management processes.

Our cybersecurity risk assessment and management processes are implemented and maintained by our executive leadership team and led by the Vice President of Informatics, who has more than 20 years of experience in information technology and oversees the Informatics department which includes the Company's hardware, software, help desk, and cybersecurity team.

The Vice President of Informatics reports to our Chief Financial Officer and is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. The Vice President of Informatics is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the internal cybersecurity team and others, depending on severity. The cybersecurity team works with our incident response team to help the company mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The board of directors receives periodic updates from certain members of the cybersecurity team concerning the Company's significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee and board also have access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

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

We also lease 31,280 square feet of space in Menlo Park, California, pursuant to a lease that expires in 2027. This facility was previously used for laboratory operations and our former corporate headquarters. We moved all laboratory operations to the Fremont facility during the third quarter of 2023 and are actively marketing the space for sublease.

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

Item 3. Legal Proceedings.

See the disclosure under the heading "Contingencies" in Note 12 to our consolidated financial statements.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

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

Holders

As of February 21, 2025, there were approximately 47 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Item 6. [Reserved]

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

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

Overview

We develop, market, and sell advanced cancer genomic tests and services. Our services are used by pharmaceutical companies for translational research, biomarker discovery, the development of personalized cancer therapies, and for clinical trials. Our tests are used by physicians to detect residual or recurrent cancer in patients, monitor cancer response to therapy, and uncover insights for therapy selection. We also provide whole exome and whole genome sequencing services for other diagnostic companies and population sequencing initiatives.

Today, our products are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples in their clinical trials and drug development programs. Our advanced genomic sequencing and analytics also support the development of personalized neoantigen therapies for cancer and other next-generation cancer immunotherapies. For example, we are providing genomic testing to Moderna, Inc. ("Moderna") in its ongoing clinical trials evaluating a personalized cancer therapy. In addition, we partner with diagnostics companies by providing our advanced tumor profiling and analysis capabilities as an input to their products. More recently, we launched new diagnostic offerings for the clinical setting and, in November 2023, entered into an agreement with Tempus to commercialize our NeXT Personal Dx test. We have also pursued non-cancer related business opportunities, specifically within the population sequencing market, by providing whole genome sequencing ("WGS") services under contract with the U.S. Department of Veterans Affairs Million Veteran Program ("VA MVP").

We are working with a growing number of leading cancer centers and world-class academic research institutions to build and publish the clinical evidence-base to support our products and our key indications, as well as to obtain reimbursement coverage from Medicare and other payors. Because of the ultra-high analytical sensitivity of our technology, we are primarily focusing on three indications: breast cancer, lung cancer, and immunotherapy (IO) monitoring. We have collaborations with Cancer Research UK, University College London, and the Francis Crick Institute (the TRACERx study); Institut Curie; The Royal Marsden; the Vall d'Hebron Institute of Oncology (VHIO); the University of California, San Diego; Duke University; Vanderbilt University and Johns Hopkins University (the PREDICT study); the Dana-Farber Cancer Institute; the University of Texas M.D. Anderson Cancer Center; University Medical Center Hamburg-Eppendorf (also known as UKE); and Criterium and the Academic Breast Cancer Consortium, that will focus on building the evidence-base for our technology and these indications.

Our work in oncology is underpinned by our experience and capacity for next-generation sequencing at scale. We have the capacity to sequence and analyze over 350 trillion bases of DNA per week in our facility. We believe that our capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases. To date, we have sequenced approximately 500,000 human samples, of which approximately 200,000 were whole human genomes.

2024 Highlights

Total revenue of $84.6 million increased 15%, or $11.1 million, during 2024 compared to 2023, primarily driven by higher revenue from pharma tests. Revenue from pharma tests was $50.9 million in 2024 compared to $31.9 million in 2023, an increase of 60%. This increase was partially offset by lower revenue from enterprise sales, which declined $6.4 million, or 20%.

Key business accomplishments and financial updates in 2024 and early 2025 include:

- Received Medicare coverage for NeXT Dx, our comprehensive tumor profiling test and we are currently seeking Medicare coverage for our separate liquid biopsy molecular residual disease ("MRD") test, Next Personal Dx.
- Delivered 3,285 total molecular tests in 2024, compared with 177 tests in the prior year.
- Announced a new publication validating our NeXT Personal test, an ultra-sensitive, tumor-informed circulating tumor DNA (ctDNA) assay for detecting MRD, monitoring therapy response, and detecting recurrence in patients diagnosed with solid tumor cancers.
    - The analytical validation study was published in Oncotarget on March 14, 2024.
    - The test demonstrated a detection threshold of 1.67 parts per million (PPM) of ctDNA with 100% analytical specificity; enabling an ultra-sensitive range leading to early cancer detection.
- Multiple clinical data results demonstrating the clinical performance of NeXT Personal were presented at the American College of Clinical Oncology meeting in Chicago. Key presentations include:

- Compelling early-stage breast cancer detection results presented by Dr. Isaac Garcia-Murillas and team (Institute of Cancer Research, London) and Prof. Nicolas Turner and team (Royal Marsden NHS Foundation Trust UK). In this study, they found:
  - NeXT Personal enabled earlier detection of recurrence, with a ~15-month lead time over imaging.
  - 100% of patients that recurred were detected with NeXT Personal and 100% of patients that were ctDNA negative on longitudinal testing were cancer-free.
- A presentation by Dr. Rodrigo Toledo of the Vall d'Hebron Institute of Oncology (VHIO) highlighted the importance of NeXT Personal's use for immunotherapy monitoring. This data showed:
  - Baseline levels and the changes in levels of ctDNA detected by NeXT Personal predict therapy response and clinical outcomes for late-stage cancer patients receiving immunotherapy.
  - NeXT Personal had an average lead time for detecting cancer progression of 81 days over imaging.

- Highlighted clinical performance of NeXT Personal at the European Society of Medical Oncology (ESMO) Congress 2024 in Barcelona, Spain:
  - Significant results from the TRACERx study presented by Professor Charles Swanton of University College London and the Francis Crick Institute with an expanded study cohort of non-small cell lung cancer (NSCLC) patients with strong detection rates for residual cancer in the challenging landmark period (first 10 to 120 days immediately after surgery).
  - Compelling data for late-stage cancer patients on immunotherapy presented by Dr. Rodrigo Toledo of the Vall d'Hebron Institute of Oncology that accurately linked significant decreases in ctDNA levels in response to immunotherapy to longer overall survival than patients who did not respond well.
- Commenced NeXT Personal Dx commercialization efforts with Tempus.
- Expanded Tempus collaboration to the biopharma industry, which enables Tempus to market NeXT Personal to Tempus' pharmaceutical and biotech customers who wish to bundle MRD testing with other Tempus offerings in a given study.
- Executed a cross-license agreement with Myriad Genetics, Inc. covering patent estates for tumor-informed approaches to detect MRD.
- Entered into an agreement with Foresight Diagnostics Inc. to settle and dismiss pending claims of intellectual property infringement by licensing our patents. Foresight agreed to pay a low single-digit tiered royalty on sales covered by the patents.
- Raised approximately $35.0 million in net financing proceeds from Tempus, consisting of $18.4 million from Tempus' exercise of all its common stock warrants, at an average price of $2.00 per share, and $16.6 million net of expenses, from Tempus' purchase of common stock at a price of $5.07 per share.
- Raised an additional $30.1 million in net proceeds from selling common stock under our At-The-Market ("ATM") program at a weighted-average price of $4.61 per share.
- Advanced business strategy with investment of $50.0 million from Merck and extended collaboration with Moderna.
- Received a new task order in the amount of $7.5 million from the VA MVP.

Factors Affecting Our Performance

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

- **The continued development of the market for genomic-based tests.** Our performance depends on the willingness of pharmaceutical companies, enterprise customers, and oncologists to continue to seek more comprehensive molecular information to develop more efficacious cancer therapies.
- **The adoption of ultra-sensitive MRD testing.** We are pioneering the ultra-sensitive MRD testing market with the belief that an ultra-sensitive approach will lead to earlier intervention and the ability to better trust that a negative MRD patient is likely cancer-free. There are no assurances that the market will value ultra-sensitive testing over other ways to monitor cancer and look for recurrence and disease.

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

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

- **Obtaining coverage and reimbursement status of our diagnostic tests.** Building our clinical laboratory business is subject to a number or reimbursement challenges and we may not be able to establish the medical necessity of our tests (coverage) or payment rates that cover our costs (reimbursement).

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

- **Investment in product innovation to support growth.** Investment in research and development, including the development of new products and capabilities is critical to establish and maintain our leading position. We have invested significantly in our NeXT platform, introducing new products and additional capabilities. We are also collaborating with KOLs to support the clinical utility of our products. We believe this work is critical to gaining customer adoption and expect our investments in these efforts to continue.

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

Components of Operating Results

Revenue

We derive our revenue primarily from sales of genomic testing services to the following five customer types:

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

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

- **Population sequencing** includes sales of genomic sequencing services and data analytics to support large-scale genetic research programs. All of the revenue in this category is from our partnership with the VA MVP.

- **Clinical diagnostic** includes sales of comprehensive tumor profiling test that is used to help select therapy for a cancer patient and identify potential clinical trials for a patient, and sales of ultra-sensitive, tumor-informed diagnostic tests, ordered by healthcare providers for cancer patients. Revenue in this category is derived from Medicare and private insurance reimbursements.

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

Our ability to increase revenue will depend on our ability to further increase sales to these groups of customers and expand our customer base within each group. To do this, we are developing a growing set of state-of-the-art services and products; advancing our operational infrastructure; building our regulatory credentials; focusing our marketing efforts on large pharmaceutical companies; building and publishing the clinical evidence-base to support our products and services in our key indications, pursuing reimbursement coverage from Medicare and other payors; and seeking additional partnerships. We market to biopharma customers and doctors through a small

direct sales force. In late 2023, we entered into an agreement with Tempus to co-commercialize NeXT Personal Dx in the clinical diagnostics market and will be leveraging Tempus' significantly larger sales force as a key vector to grow our clinical diagnostic business. In late 2024, we expanded our collaboration partnership with Tempus to enable Tempus to market and sell NeXT Personal to Tempus' pharmaceutical and biotech customers who wish to bundle MRD testing with other Tempus offerings in a given study.

We have one reportable segment which is providing advanced cancer genomic tests for precision oncology and personalized testing. Most of our revenue to date has been derived from sales in the United States.

Costs and Expenses

Cost of Revenue

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

Research and Development Expenses

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

We expense our research and development costs in the period in which they are incurred. We expect research and development expenses to remain consistent in the short-term since the completion of our reductions in workforce in 2023.

Selling, General and Administrative Expenses

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

Selling, general and administrative expenses have decreased since the completion of our reductions in workforce in 2023. But we expect them to increase over the medium term as we commercialize our clinical diagnostic offerings.

Lease Impairment

We recognized an impairment loss for operating lease right-of-use assets as a result of the change in use of our Menlo Park facility during the third quarter of 2023.

Restructuring and Other Charges

Restructuring and other charges consists of charges in connection with our reductions in workforce and charges in connection with the closure of our China operations.

Interest Income and Interest Expense

Interest income consists primarily of interest earned on our cash, cash equivalents and short-term investments. Interest expense is the recognition of imputed interest on noninterest bearing loans.

Other Income (Expense), Net

In connection with our November 2023 agreement with Tempus, we issued two warrants to Tempus to purchase, in the aggregate, up to 9,218,800 shares of our common stock (the "Tempus Warrants"). Other income (expense), net consists primarily of a noncash loss related to the remeasurement and settlement of the Tempus Warrants. Other income (expense), net also includes foreign currency exchange gains and losses.

Trend Financial Information

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

	Year Ended December 31,				
	2024	2023	2022	2021	2020
Consolidated Statements of Operations:	(in thousands, except share and per share data)				
Revenue [1]	$ 84,614	$ 73,481	$ 65,047	$ 85,494	$ 78,648
Costs and expenses					
Cost of revenue	57,789	55,273	51,697	53,837	58,534
Research and development	48,905	64,776	64,912	49,312	28,568
Selling, general and administrative [2]	46,187	49,726	63,969	47,698	33,692
Lease impairment	—	5,565	—	—	—
Restructuring and other charges	—	8,077	—	—	—
Total costs and expenses	152,881	183,417	180,578	150,847	120,794
Loss from operations	(68,267)	(109,936)	(115,531)	(65,353)	(42,146)
Interest income	5,510	5,901	2,396	367	949
Interest expense	(24)	(110)	(201)	(184)	(2)
Other income (expense), net [3]	(18,485)	(4,068)	61	(42)	(24)
Loss before income taxes	(81,266)	(108,213)	(113,275)	(65,212)	(41,223)
Provision for income taxes	18	83	40	14	57
Net loss	$ (81,284)	$ (108,296)	$ (113,315)	$ (65,226)	$ (41,280)
Net loss per share, basic and diluted	$ (1.37)	$ (2.25)	$ (2.48)	$ (1.49)	$ (1.20)
Weighted-average shares outstanding, basic and diluted	59,251,013	48,175,201	45,704,805	43,886,730	34,374,903

(1) Includes related party revenue of $2.0 million for the year ended December 31, 2024.
(2) Includes related party sales and marketing expenses of $0.5 million for the year ended December 31, 2024.
(3) Includes related party other expense of $18.3 million in connection with the change in fair value of Tempus Warrants for the year ended December 31, 2024.

	December 31,				
	2024	2023	2022	2021	2020
	(in thousands)				
Cash and cash equivalents, and short-term investments	$ 185,009	$ 114,179	$ 167,658	$ 287,064	$ 203,290
Working capital	171,889	99,510	166,568	286,918	180,083
Total assets	270,268	225,099	292,700	396,528	244,842
Total debt	1,772	2,880	2,596	3,494	—
Long-term obligations	36,185	48,424	41,430	54,914	9,261
Total liabilities	67,311	95,658	74,561	86,227	49,897
Total stockholders' equity	202,957	129,441	218,139	310,301	194,945

Results of Operations

This section discusses 2024 and 2023 items and year-to-year comparisons between 2024 and 2023.

Revenue

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

	Year Ended December 31,			
	2024	2023	Change	
Pharma tests and services [1]	$ 50,939	$ 31,904	$ 19,035	60%
Enterprise sales	25,364	31,729	(6,365)	(20%)
Population sequencing	7,430	9,412	(1,982)	(21%)
Clinical diagnostic	759	38	721	1897%
Other	122	398	(276)	(69%)
Total revenue	$ 84,614	$ 73,481	$ 11,133	15%

(1) Includes related party revenue of $2.0 million for the year ended December 31, 2024.

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

	Year Ended December 31,	
	2024	2023
Natera, Inc.	30%	43%
VA MVP	*	13%
Moderna, Inc.	28%	*

* Less than 10% of revenue

Pharma tests and services

The primary driver for the increase in pharma tests and services revenue in 2024 was due to increases in revenue from one of our personalized cancer therapy customers that ramped up clinical trial patient enrollments. Revenue from this customer increased $20.0 million in 2024 compared with the prior year. Revenue from this customer is expected to decline over the next few quarters until this customer is ready to commercialize its personalized cancer therapy program, or until other projects increase in size.

Enterprise sales

Revenue from enterprise sales decreased in 2024 due to lower average selling prices. The number of samples we processed for Natera increased by over 7%, but such increase was offset by lower selling prices.

We launched a reduced-cost version of our exome product offering for Natera near the end of the first quarter of 2024 to support their requirement for an overall reduction in price. Our agreement with Natera included minimum volume commitments through the end of 2024. We amended our agreement with Natera during the fourth quarter of 2024 to extend minimum volume commitments through the second quarter of 2025.

Population sequencing

Revenue recognized each period from population sequencing is impacted by timing of our fulfillment of samples under each annual task order. The decrease in revenue in 2024 was due to a decrease in the number of samples we processed in addition to a small decline in selling prices. Our annual task orders received in 2024 and 2023 were $7.5 million and $7.5 million, respectively. Our contract with the VA MVP does not include specific testing turnaround times. Therefore, we may modulate the volume of samples processed from the VA MVP to accommodate sample volumes from other customers, which can vary from period to period. We anticipate fulfilling the new task order received in September 2024 during the first three quarters of 2025.

Clinical diagnostic

Clinical diagnostic revenue is generated from Medicare and private insurance payors, In January 2024, we received a Medicare coverage determination for NeXT Dx, our ultra-comprehensive tumor genomic profiling assay. The revenue of $0.8 million in 2024 was mainly due to an increase in NeXT Dx tests reimbursed by Medicare. We delivered a total of 3,285 molecular cancer tests in 2024.

Costs and Expenses

The following table shows costs and expenses (in thousands, except percentages):

	Year Ended December 31,			
	2024	2023	Change	
Cost of revenue	$ 57,789	$ 55,273	$ 2,516	5%
Research and development	48,905	64,776	(15,871)	(25%)
Selling, general and administrative	46,187	49,726	(3,539)	(7%)
Lease impairment	—	5,565	(5,565)	*
Restructuring and other charges	—	8,077	(8,077)	*
Total costs and expenses	$ 152,881	$ 183,417	$ (30,536)	(17%)

* Not meaningful

Cost of revenue

The increase in cost of revenue in 2024 was primarily due to higher revenue levels (revenue increased 15% over the same period). Cost of revenue increased at a lesser rate as compared to the corresponding revenue increases primarily because of lower labor costs resulting from prior workforce reductions and operational efficiencies. Specific components of the increase were a $4.0 million increase in direct material costs due to support higher revenue levels, a $2.1 million increase in allocated facilities and equipment costs (mainly due to moving our laboratory from our Menlo Park facility to our Fremont facility in the third quarter of 2023), partially offset by a

$2.8 million decrease in labor costs and a $0.7 million decrease in shared laboratory costs due to greater usage of our laboratory capacity for R&D projects.

Research and development

The decrease in research and development expenses in 2024 was primarily due to cost savings from our workforce reductions in 2023 and lower sample processing costs for product development, collaborations, and clinical evidence generation.

Specific components of the decrease include a $6.3 million decrease in personnel-related costs driven by our workforce reductions, a $4.7 million decrease in allocated facilities costs (primarily due to a reduction in R&D usage of our facilities relative to other functions, as well as lower facilities costs in general), and a $4.9 million decrease in sample processing costs incurred in our laboratory for product development, collaborations, and clinical evidence generation.

Selling, general and administrative

The decrease in selling, general and administrative expenses was primarily due to lower professional outside services expenses and cost savings from our workforce reductions in 2023.

Specific components of the decrease were a $3.1 million decrease in professional outside services, a $2.9 million decrease in personnel-related costs driven by our workforce reductions, and a $0.5 million decrease in office equipment costs; partially offset by a $1.4 million increase in allocated facilities costs, $1.0 million increase in other outside services and office expenses and a $0.6 million increase in other marketing costs, including trade shows expenses.

Lease impairment

During the third quarter of 2023, we completed the move of our laboratory operations from our Menlo Park facility to our Fremont facility and began actively marketing the Menlo Park space for sublease. Accordingly, we evaluated the ongoing value of the operating lease right-of-use asset associated with the Menlo Park facility. Based on this evaluation, we determined that the right-of-use asset with a carrying amount of $6.7 million was no longer recoverable and was impaired and wrote it down to its estimated fair value of $1.1 million, which resulted in a noncash impairment loss of $5.6 million. Estimated fair value was based on expected future sublease cash flows (with the assistance of a third-party real estate broker), net of brokerage commissions and estimated tenant incentives, discounted at a market rate of return on similar assets. The estimation of fair value also included expected downtime prior to the commencement of a future sublease.

Restructuring and other charges

We reduced our workforce during the first quarter of 2023 and the fourth quarter of 2023 to reduce our cash burn and increase operating efficiencies, which combined affected about 100 employees. We also closed our China operations. The $8.1 million in restructuring and other charges recognized in 2023 is comprised of $7.5 million in one-time employee termination benefits (including costs related to termination of our former China employees) and $0.6 million of other noncash charges (primarily asset disposals and impairments in connection with the closure of our China operations).

Interest Income, Interest Expense and Other Income (Expense), Net

The following table shows interest income and expense, and other income (expense), net (in thousands, except percentages):

	Year Ended December 31,			
	2024	2023	Change	
Interest income	$ 5,510	$ 5,901	$ (391)	(7%)
Interest expense	(24)	(110)	86	(78%)
Other income (expense), net	(18,485)	(4,068)	(14,417)	354%
Total	$ (12,999)	$ 1,723	$ (14,722)	(854%)

Interest income and interest expense

The decrease in interest income was due to lower average investment balances in 2024, partially offset by increased yields on our investments. Interest expense is the recognition of imputed interest on noninterest bearing loans.

Other income (expense), net

In connection with our November 2023 agreement with Tempus, we issued two warrants to purchase, in the aggregate, up to 9,218,800 shares of our common stock ("Tempus Warrants") at an average exercise price of $2.00 per share. If Tempus acquired any shares of common stock directly from us other than by exercising the warrants, then the total number of shares issuable upon exercise of the warrants would have been reduced by such shares. Because the number of shares issuable upon settlement were subject to adjustment, the warrants were classified as liability instruments while outstanding and were subject to remeasurement at each balance

sheet date, with changes in fair value recognized as other income (expense), net. In August 2024, Tempus exercised in full the Tempus Warrants for $18.4 million in cash; as such there will be no further noncash gains or losses associated with the Tempus Warrants going forward.

Prior to the exercise, we recognized noncash losses of $18.3 million as a result of increases in the fair value of the Tempus Warrants in other income (expense), net in the consolidated statements of operations during the year ended December 31, 2024.

The initial fair value at the time of issuance of the warrants of $6.9 million exceeded the total proceeds received from Tempus of $6.0 million, which resulted in a loss of $0.9 million. In addition, we recognized noncash losses of $3.1 million as a result of increases in the fair value of the Tempus Warrants after the issuance date in 2023. The increase in fair value, plus the immediate loss of $0.9 million, resulted in a $4.0 million expense, which was recognized in other income (expense), net in the consolidated statements of operations during the year ended December 31, 2023.

Separately, upon dissolution of our China entity (Personalis (Shanghai) Ltd) during the first quarter of 2024, we reclassified an accumulated foreign currency translation loss of $0.2 million to other income (expense), net.

Liquidity and Capital Resources

The following table presents selected financial information (in thousands):

	December 31,	
	2024	2023
Cash and cash equivalents, and short-term investments	$ 185,009	$ 114,179
Property and equipment, net	48,274	57,366
Contract liabilities	3,100	7,216
Working capital	171,889	99,510

From our inception through December 31, 2024, we have funded our operations primarily from net proceeds from issuance of redeemable convertible preferred stock, IPO, follow-on equity offerings, At-the-Market ("ATM") facility (see Note 2, Summary of Significant Accounting Policies for additional information), Tempus exercising warrants and purchasing additional shares under an investment agreement, and Merck purchasing shares under an investment agreement (see Note 8, "Related Party Transactions" in our consolidated financial statements for additional information), as well as debt financings. As of December 31, 2024, we had cash and cash equivalents of $91.4 million and short-term investments of $93.6 million.

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

We have based these future funding requirements on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our services or other risks described in this Annual Report on Form 10-K, we may seek to sell additional common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing. We filed a sales agreement prospectus supplement in December 2024, pursuant to which we may offer and sell up to $50.0 million of shares of our common stock through our ATM facility. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. Additional capital may not be available on reasonable terms, or at all.

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

Cash Flows

	Year Ended December 31,			
	2024	2023	Change	
Net cash used in operating activities	$ (45,150)	$ (56,258)	$ 11,108	(20%)
Net cash provided by (used in) investing activities	(35,069)	13,099	(48,168)	(368%)
Net cash provided by financing activities	114,672	11,031	103,641	940%

The $11.1 million decrease in cash used in operating activities in 2024 was primarily due to lower operating expenses, particularly lower payroll expenses as a result of our workforce reductions in 2023 and higher gross margin, due to a combination of higher revenue levels and higher gross margin percentage. These increases in operating cash flow were partially offset by changes in working capital. Notably, during the first half of 2023 we received significant customer deposits in connection with our agreement with Moderna to support its ongoing clinical trials project for development of a personalized cancer therapy and the customer deposit did not repeat in 2024. We also paid more in rent in 2024 as compared to 2023 for our Fremont headquarters due to the end of a free rent period plus escalating rent payments. Furthermore, we paid more to vendors in 2024 as compared to 2023 due to timing of vendor shipments and billings.

The $48.2 million decrease in cash provided by investing activities in 2024 was due to increase in investments of our cash into short-term investments by $17.8 million and reduction in maturities of our short-term investments by $40.0 million, partially offset by a $9.3 million reduction in capital expenditures.

The $103.6 million increase in cash provided by financing activities was driven by $50 million from Merck purchasing shares under an investment agreement, $36.2 million from Tempus exercising warrants and purchasing additional shares under an investment agreement, $26.6 million higher net proceeds from sales of common stock under our ATM facility, and $2.1 million lower repayments of loans; partially offset by $1.2 million payments of costs associated with the Tempus and Merck investments, and $0.6 million lower proceeds from our employee incentive plans. In addition, we received $6.0 million in proceeds from the issuance of Tempus Warrants and $3.4 million from loans in 2023, which did not occur in 2024.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist primarily of variable costs of revenue, operating expenditures, capital expenditures, property leases, and other. We plan to fund our material cash requirements with our existing cash and cash equivalents and short-term investments, which amounted to $185.0 million as of December 31, 2024, as well as anticipated cash receipts from customers. To fund our material cash requirements in the short-term and long-term, we may also seek to sell additional common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing.

Variable costs of revenue. From time to time in the ordinary course of business, we enter into agreements with vendors for the purchase of raw materials, laboratory supplies and consumables to be used in the sequencing of customer samples. However, we generally do not have binding and enforceable purchase orders beyond the short term, and the timing and magnitude of purchase orders beyond such period is difficult to accurately project. We currently expect spending in this area to remain similar to the levels in 2024 to support expected higher levels of revenue.

Operating expenditures. Our primary use of cash relates to employee compensation, spend on professional services, spend related to research and development projects, and other costs related to our research and development, selling, general and administrative functions. We currently expect our spending in these areas to remain similar to the levels in 2024. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Capital expenditures. Capital expenditures are expected to increase from 2024 levels as we expect to expand NeXT Personal Dx capacity. Going forward, our capital expenditures are expected to consist primarily of laboratory equipment and computer equipment. We currently expect capital expenditures to be approximately $8.0 million in 2025 and between $7 million to $10 million in each of the years 2026 and 2027.

Property leases. Our noncancelable operating lease payments were $70.5 million as of December 31, 2024. The timing of these future payments, by year, can be found in Part II, Item 8 of this Form 10-K in the Notes to Consolidated Financial Statements in Note 7, “Leases.”

Other. As of December 31, 2024, we have an outstanding noninterest bearing loan that was used to finance the purchase of equipment for our laboratory. We owe a total of $1.8 million, of which the majority is payable in 2025. Further discussion of this loan can be found in Part II, Item 8 of this Form 10-K in the Notes to Consolidated Financial Statements in Note 6, “Loans.”

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

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

We have evaluated the performance obligations contained in contracts with customers to determine whether any of the performance obligations are distinct, such that the customers can benefit from the obligations on their own, and whether the obligations can be separately identifiable from other obligations in the contract. For the significant majority of our contracts to date, the customer orders a specified quantity of sequencing and the delivery of each test to the customer is accounted for as one performance obligation.

Fees for our genomic testing services are predominantly based on a fixed price per sample. The fixed prices identified in the arrangements only change if a pricing amendment is agreed with a customer. In limited cases we provide our customers a discount if samples received above a certain volume are purchased. In such cases, the discount applies prospectively. We have analyzed such discounts if they represent a material right provided to a customer. We have concluded that such discounts generally do not represent a material right provided to a customer since they are not deemed to be incremental to the pricing offered to the customer or are not enforceable options to acquire additional goods. As a result, these discounts do not constitute a material right and do not meet the definition of a separate performance obligation, except in limited instances. We do not offer retrospective discounts or rebates.

Leases

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

In August 2021, we entered into a 13.5-year lease for our corporate headquarters in Fremont, California. We estimated our incremental borrowing rate as the rate implicit in the lease was not readily determinable. To determine the incremental borrowing rate, we estimated our credit rating by comparing certain financial ratios and metrics of the Company to those of other issuers with publicly-available credit ratings from Standard & Poor's (S&P). We then adjusted yields from publicly traded corporate bonds of companies of similar size and credit rating over a term approximating the term of our lease for the nature of the collateral. In September 2022, the lease commencement date for our facility in Fremont, California was delayed from the original intended date due to delays in the completion of the work necessary for us to move into the facility, which resulted in a reassessment of the lease term. Our concluded incremental borrowing rate for this remeasured lease was 10.5%, which resulted in a lease liability and right-of-use asset of $31.8 million.

During the third quarter of 2023, we completed the move of our laboratory operations from our Menlo Park facility to our Fremont facility and began actively marketing the Menlo Park space for sublease. Accordingly, we evaluated the ongoing value of the operating lease right-of-use asset associated with the Menlo Park facility. Based on this evaluation, we determined that the right-of-use asset with a carrying amount of $6.7 million was no longer recoverable and was impaired and wrote it down to its estimated fair value of $1.1 million, which resulted in a noncash impairment loss of $5.6 million. Estimated fair value was based on expected future sublease cash flows (with the assistance of a third-party real estate broker), net of brokerage commissions and estimated tenant incentives, discounted at a market rate of return on similar assets. The estimation of fair value also included expected downtime prior to the commencement of a future sublease.

Common Stock Warrants

In November 2023, we entered into an agreement with Tempus to commercialize NeXT Personal Dx in the clinical diagnostics market. In connection with this agreement, we issued to Tempus two warrants to purchase, in the aggregate, up to 9,218,800 shares of our common stock. In August 2024, Tempus exercised the warrants in full to purchase 9,218,800 shares of Personalis common stock for $18.4 million in cash, at an average exercise price of $2.00 per share.

The Tempus Warrants included a provision under which the total number of shares issuable upon settlement were subject to adjustment. Consequently, prior to the exercise, the Tempus Warrants were classified as liability instruments while outstanding and subject to remeasurement at each balance sheet date, with changes in fair value recognized as other income (expense), net in the consolidated statements of operations. Fair values of the warrants were estimated using the Black-Scholes option-pricing model. Estimating fair value using the Black-Scholes option-pricing model requires a number of assumptions. Changes in the assumptions can materially affect the fair value and ultimately how much other income (or expense) is recognized. The inputs generally require analysis to develop.

- *Expected Term*—The expected term assumption represents the contractual period of each of the two warrants.
- *Expected Volatility*—Expected volatility was based on the Company's actual historical volatility over the expected terms of the warrants.
- *Expected Dividend Yield*—The Black-Scholes option-pricing valuation model calls for a single expected dividend yield as an input. We currently have no history or expectation of paying cash dividends on our common stock.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the warrants.

Recent Accounting Pronouncements

See the sections titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our consolidated financial statements for additional information.

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

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

Item 8. Financial Statements and Supplementary Data.

PERSONALIS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

		Page
Consolidated Balance Sheets		70
Consolidated Statements of Operations		71
Consolidated Statements of Comprehensive Loss		72
Consolidated Statements of Stockholders' Equity		73
Consolidated Statements of Cash Flows		74
Notes to Consolidated Financial Statements		
Note 1.	Company and Nature of Business	75
Note 2.	Summary of Significant Accounting Policies	75
Note 3.	Revenue	81
Note 4.	Balance Sheet Details	82
Note 5.	Fair Value Measurements	83
Note 6.	Loans	84
Note 7.	Leases	85
Note 8.	Related Party Transactions	86
Note 9.	Restructuring and Other Charges	89
Note 10.	Stock-Based Compensation	89
Note 11.	Segment and Geographic Information	93
Note 12.	Commitments and Contingencies	94
Note 13.	Basic and Diluted Net Loss Per Common Share	94
Note 14.	Income Taxes	95
Note 15.	Subsequent Events	97
Report of Independent Registered Public Accounting Firm (BDO USA, P.C., PCAOB ID: 243)		98

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

	December 31,	
	2024	**2023**
Assets		
Current assets		
Cash and cash equivalents	$ 91,415	$ 56,984
Short-term investments	93,594	57,195
Accounts receivable, net [1]	8,140	17,730
Inventory and other deferred costs	5,939	10,474
Prepaid expenses and other current assets	3,927	4,361
Total current assets	203,015	146,744
Property and equipment, net	48,274	57,366
Operating lease right-of-use assets	16,453	17,852
Other long-term assets	2,526	3,137
Total assets	$ 270,268	$ 225,099
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,397	$ 14,920
Accrued and other current liabilities [2]	21,629	23,941
Contract liabilities	3,100	3,288
Short-term warrant liability	—	5,085
Total current liabilities	31,126	47,234
Long-term operating lease liabilities	34,882	38,321
Long-term warrant liability	—	4,942
Other long-term liabilities [3]	1,303	5,161
Total liabilities	67,311	95,658
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, $0.0001 par value — 10,000,000 shares authorized; none issued	—	—
Common stock, $0.0001 par value — 200,000,000 shares authorized; 85,171,146 and 50,480,694 shares issued and outstanding, respectively	9	5
Additional paid-in capital	752,961	598,364
Accumulated other comprehensive loss	(23)	(222)
Accumulated deficit	(549,990)	(468,706)
Total stockholders' equity	202,957	129,441
Total liabilities and stockholders' equity	$ 270,268	$ 225,099

(1) Includes related party accounts receivable of $2.5 million as of December 31, 2024.
(2) Includes related party liabilities of $1.7 million as of December 31, 2024.
(3) Includes related party liabilities of $1.2 million as of December 31, 2024.

See notes to consolidated financial statements.

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

	Year Ended December 31,	
	2024	**2023**
Revenue [1]	$ 84,614	$ 73,481
Costs and expenses		
Cost of revenue	57,789	55,273
Research and development	48,905	64,776
Selling, general and administrative [2]	46,187	49,726
Lease impairment	—	5,565
Restructuring and other charges	—	8,077
Total costs and expenses	152,881	183,417
Loss from operations	(68,267)	(109,936)
Interest income	5,510	5,901
Interest expense	(24)	(110)
Other income (expense), net [3]	(18,485)	(4,068)
Loss before income taxes	(81,266)	(108,213)
Provision for income taxes	18	83
Net loss	$ (81,284)	$ (108,296)
Net loss per share, basic and diluted	$ (1.37)	$ (2.25)
Weighted-average shares outstanding, basic and diluted	59,251,013	48,175,201

(1) Includes related party revenue of $2.0 million for the year ended December 31, 2024.
(2) Includes related party sales and marketing expenses of $0.5 million for the year ended December 31, 2024.
(3) Includes related party other expense of $18.3 million in connection with the change in fair value of Tempus Warrants for the year ended December 31, 2024.

See notes to consolidated financial statements.

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

	Year Ended December 31,	
	2024	2023
Net loss	$ (81,284)	$ (108,296)
Other comprehensive income (loss), net of tax		
Changes in foreign currency translation adjustments:		
Change during period	(35)	19
Reclassification of adjustments to net loss due to dissolution of Personalis (Shanghai) Ltd	199	—
Net changes in foreign currency translation adjustments	164	19
Change in unrealized gain on available-for-sale debt securities	35	671
Comprehensive loss	$ (81,085)	$ (107,606)

See notes to consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2022	46,707,084	$ 5	$ 579,456	$ (912)	$ (360,410)	$ 218,139
Proceeds from sales of common stock under ATM facility, net of commissions	1,935,214	—	3,513	—	—	3,513
Proceeds from exercise of stock options	8	—	—	—	—	—
Proceeds from ESPP	999,194	—	1,344	—	—	1,344
Restricted stock units vested	839,194	—	—	—	—	—
Stock-based compensation	—	—	14,051	—	—	14,051
Foreign currency translation adjustment	—	—	—	19	—	19
Unrealized gain on available-for-sale debt securities	—	—	—	671	—	671
Net loss	—	—	—	—	(108,296)	(108,296)
Balance—December 31, 2023	50,480,694	5	598,364	(222)	(468,706)	129,441
Proceeds from sale of common stock under Merck Investment Agreement, net of issuance costs	14,044,943	2	49,720	—	—	49,722
Exercise of Tempus Warrants	9,218,800	1	46,738	—	—	46,739
Proceeds from sale of common stock under Tempus Investment Agreement, net of issuance costs	3,500,000	—	16,605	—	—	16,605
Proceeds from sales of common stock under ATM facility, net of commissions	6,660,731	1	30,077	—	—	30,078
Proceeds from exercise of stock options	80,998	—	200	—	—	200
Proceeds from ESPP	583,695	—	571	—	—	571
Restricted stock units vested	601,285	—	—	—	—	—
Stock-based compensation	—	—	10,686	—	—	10,686
Foreign currency translation adjustment	—	—	—	164	—	164
Unrealized gain on available-for-sale debt securities	—	—	—	35	—	35
Net loss	—	—	—	—	(81,284)	(81,284)
Balance—December 31, 2024	85,171,146	$ 9	$ 752,961	$ (23)	$ (549,990)	$ 202,957

See notes to consolidated financial statements

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

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (81,284)	$ (108,296)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	10,686	14,051
Depreciation and amortization	10,941	11,296
Noncash operating lease cost	1,399	1,859
Noncash charges related to liability classified Tempus Warrants	18,274	4,027
Amortization of discount on short-term investments	(2,667)	(2,000)
Noncash restructuring and other charges	—	3,605
Noncash lease impairment expense	—	5,565
Other	93	153
Changes in operating assets and liabilities		
Accounts receivable [1]	9,590	(1,088)
Inventory and other deferred costs	4,425	(1,934)
Prepaid expenses and other assets	1,139	3,748
Accounts payable [2]	(8,924)	5,178
Accrued and other current liabilities [2]	(2,401)	742
Contract liabilities	(4,116)	5,952
Operating lease liabilities	(3,505)	894
Other long-term liabilities [2]	1,200	(10)
Net cash used in operating activities	(45,150)	(56,258)
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(121,708)	(103,945)
Proceeds from maturities of available-for-sale debt securities	88,000	127,955
Purchases of property and equipment	(1,603)	(10,911)
Proceeds from sales of property and equipment	242	—
Net cash (used in) provided by investing activities	(35,069)	13,099
Cash flows from financing activities:		
Proceeds from sales of common stock under ATM facility, net of commissions	30,079	3,513
Proceeds from issuance of Tempus Warrants	—	6,000
Proceeds from exercise of Tempus Warrants	18,438	—
Proceeds from sale of common stock under Tempus Investment Agreement	17,745	—
Proceeds from sale of common stock under Merck Investment Agreement	50,000	—
Payment of costs related to Tempus and Merck Investment Agreements	(1,230)	—
Proceeds from loans	—	3,438
Repayments of loans	(1,130)	(3,264)
Proceeds from issuance of common stock under equity incentive plans	770	1,344
Net cash provided by financing activities	114,672	11,031
Effect of exchange rates on cash, cash equivalents and restricted cash	(22)	(16)
Net change in cash, cash equivalents and restricted cash	34,431	(32,144)
Cash, cash equivalents and restricted cash, beginning of period	58,774	90,918
Cash, cash equivalents and restricted cash, end of period	$ 93,205	$ 58,774
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	$ 91,415	$ 56,984
Restricted cash, included in other long-term assets	1,790	1,790
Total cash, cash equivalents and restricted cash	$ 93,205	$ 58,774
Supplemental cash flow information:		
Cash paid for income taxes, net of refunds	$ 38	$ 64
Acquisition of property and equipment included in accounts payable and accrued liabilities	473	104

(1) Includes a change in related party receivable of $2.0 million for the year ended December 31, 2024.

(2) Includes a change in related party payable and accruals of $0.7 million for the year ended December 31, 2024.

See notes to consolidated financial statements.

PERSONALIS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Company and Nature of Business

Personalis, Inc. (the "Company" or "Personalis") develops, markets, and sells advanced cancer genomic tests and services. The services are used by pharmaceutical companies for translational research, biomarker discovery, the development of personalized cancer therapies, and for clinical trials. The tests are used by physicians to detect residual or recurrent cancer in patients, monitor cancer response to therapy, and uncover insights for therapy selection. The Company also provides whole exome and whole genome sequencing services for other diagnostic companies and population sequencing initiatives. The principal markets for the Company's tests and services are in the United States and Europe.

The Company is expanding its business model to offer genomic tests directly to cancer patients in a clinical setting. However, revenue generated from clinical customers was not significant for any periods presented in these consolidated financial statements.

The Company was incorporated in Delaware in February 2011 and began operations in September 2011. The Company formed a wholly owned subsidiary, Personalis (UK) Ltd., in August 2013 and a wholly owned subsidiary, Shanghai Personalis Biotechnology Co., Ltd., which is referred to as "Personalis (Shanghai) Ltd" herein, in October 2020. During the first half of 2023, the Company terminated its operations in China and the Company completed the process of dissolving the Personalis (Shanghai) Ltd entity in February 2024. Refer to Note 9, Restructuring and Other Charges, for further information. The Company operates and manages its business as one reportable operating segment, which is providing advanced cancer genomic tests and services for precision oncology applications, personalized testing, and other tests.

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding annual reporting. The consolidated financial statements include the accounts of Personalis, Inc. and its wholly owned subsidiaries, Personalis (UK) Ltd. and Personalis (Shanghai) Ltd. All intercompany balances and transactions have been eliminated in consolidation. Upon dissolution of Personalis (Shanghai) Ltd during the first quarter of 2024, an accumulated foreign currency translation adjustment of $0.2 million was reclassified from accumulated other comprehensive loss to net loss within other income (expense), net.

Use of Estimates

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

At-the-Market Equity Offerings

In December 2021, the Company entered into an At-the-Market ("ATM") Sales Agreement with BTIG, LLC ("BTIG"), as amended in December 2023 (the "Sales Agreement"), under which it was permitted to offer and sell its common stock from time to time through BTIG as its sales agent. BTIG agreed to use commercially reasonable efforts to sell the Company's common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company agreed to pay BTIG a commission of up to 3% of the gross sales proceeds of any common stock sold through BTIG under the Sales Agreement. The Company was not obligated to make any sales of common stock under the Sales Agreement.

The Company issued and sold 6,660,731 and 1,935,214 shares of its common stock at a weighted-average price of $4.61 and $1.85 per share under the Sales Agreement and received $30.1 million and $3.5 million in proceeds, net of commissions, during 2024 and 2023, respectively.

In December 2024, the Company entered into an Amended and Restated At-the-Market Sales Agreement (the "Amended Sales Agreement") with Piper Sandler & Co. ("Piper") and BTIG. The Amended Sales Agreement amends and restates the Sales Agreement with BTIG, previously entered into in December 2021, as amended in December 2023, to add Piper as a sales agent (Piper and BTIG,

together, the “Sales Agents”), among certain other changes. The Sales Agents have agreed to use commercially reasonable efforts to sell the Company’s common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay the applicable Sales Agent a commission of up to 3% of the gross sales proceeds of any common stock sold through such Sales Agent under the Amended Sales Agreement. The Company is not obligated to make any sales of common stock under the Amended Sales Agreement.

Concentration of Credit Risk and Other Risks and Uncertainties

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

The Company also invests in investment-grade debt instruments and has policy limits for the amount it can invest in any one type of security, except for securities issued or guaranteed by the U.S. government. The goals of the Company’s investment policy are as follows: preservation of principal; liquidity of investments sufficient to meet cash flow requirements; avoidance of inappropriate concentration and credit risk; competitive after-tax rate of returns; and fiduciary control of cash and investments. Under its investment policy, the Company limits the amounts invested in such securities by credit rating, maturity, investment type, and issuer. As a result, management believes that these financial instruments do not expose the Company to any significant concentrations of credit risk.

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

The Company routinely assesses the creditworthiness of its customers and does not require collateral. Historically, the Company has not experienced significant credit losses from accounts receivable. Multiple customers have provided more than 10% of total revenue in the periods presented, or accounted for more than 10% of accounts receivable at each respective balance sheet date, as follows:

	Revenue		Accounts Receivable	
	Year Ended December 31,		December 31,	
	2024	2023	2024	2023
Natera, Inc.	30%	43%	13%	36%
VA MVP	*	13%	*	*
Moderna, Inc.	28%	*	*	*
Merck & Co., Inc.	*	*	31%	*
Pfizer Inc.	*	*	25%	*

* Less than 10% of revenue or accounts receivable

Revenue Recognition

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

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

The genomic testing services are the only distinct services that meet the definition of a performance obligation and are accounted for as one performance obligation. Revenue is recognized at a point in time when test results are transferred to the customer. The Company has elected to exclude all sales and value added taxes from the measurement of the transaction price.

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

Practical Expedients and Exemptions

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

Cost of Revenue

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

Research and Development Expenses

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

Stock-Based Compensation

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

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

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

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

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

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

Foreign Currency Translation

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

Comprehensive Loss

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

Income Taxes

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

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

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

Undistributed earnings of foreign subsidiaries are assumed to be indefinitely reinvested and, accordingly, no U.S. income taxes have been provided thereon.

Cash and Cash Equivalents

Cash equivalents consist of highly liquid investments with original maturities at the time of purchase of three months or less. Cash equivalents include bank demand deposits and money market accounts that invest primarily in cash, U.S. Treasury bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. Government, its agencies or instrumentalities, and repurchase agreements secured by such obligations or cash. Cash equivalents also include commercial paper and U.S. Treasury bills, which are marketable debt securities recorded at fair value and accounted for in the same manner as other marketable debt securities described below.

Restricted Cash

Restricted cash includes cash pledged as collateral for a standby letter of credit related to a property lease. The letter of credit is required to be maintained throughout the term of the lease. If the date of availability or disbursement is less than one year, restricted cash is reported within prepaid expenses and other current assets on the consolidated balance sheets. If the date of availability or disbursement is longer than one year and the balances are maintained under an agreement that legally restricts the use of such funds, restricted cash is reported within other assets on the consolidated balance sheets. As of December 31, 2024, no amount has been drawn under the letter of credit. As of December 31, 2024 and 2023, the Company had restricted cash balances of $1.8 million.

Short-term Investments

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

Any discount or premium arising at purchase is accreted or amortized to interest income or expense. Unrealized gains and losses are included within accumulated other comprehensive income (loss) in the consolidated statements of stockholders' equity. Realized gains and losses are reported within other income (expense), net in the consolidated statements of operations. Accrued interest is excluded from both the fair value and amortized cost basis of debt securities and included in prepaid expenses and other current assets in the consolidated balance sheets. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity is reclassified out of stockholders' equity on a specific-identification basis and recorded in earnings for the period. If an available-for-sale debt security's fair value is less than its amortized cost basis, the Company evaluates whether the decline is the result of a credit loss, in which case an impairment is recorded through an allowance for credit losses.

Fair Value Measurements

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

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

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

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

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

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

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. Certain of the Company's financial instruments, including cash and cash equivalents, accounts payable, accrued expenses and other current liabilities are carried at cost, which approximates their fair value because of their short-term nature.

Accounts Receivable, Net

Trade accounts receivable are recorded at the invoiced amount and are noninterest bearing. The Company maintains an allowance for credit losses, consisting of known specific troubled accounts as well as an amount based on overall estimated potential uncollectible accounts receivable based on historical experience and review of their current credit quality. Expected credit losses are recorded as part of selling, general and administrative expenses in the consolidated statements of operations.

Inventory and Other Deferred Costs

Inventory consists of raw materials and supplies used to fulfill customer contracts and the Company's research and development activities, and is valued at the lower of cost or net realizable value. Cost is determined using actual costs, on a first-in, first-out basis. Other deferred costs relate to materials consumed and work performed on customer orders that have yet to be completed and recognized as revenue and cost of revenue. Other deferred costs are also comprised of direct labor and overhead costs incurred.

Property and Equipment, Net

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

Construction-in-process assets consist primarily of laboratory equipment and computer equipment that have not yet been placed in service. These assets are stated at cost and are not depreciated. Once the assets are placed into service, assets are reclassified to the appropriate asset class based on their nature and depreciated in accordance with the useful lives above. The Company periodically assesses the useful lives of the assets to determine whether events or circumstances may indicate that a revision to the useful life is warranted.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets, including operating lease right-of-use assets, annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such events or circumstances arise, the Company will compare the carrying amount of the asset group comprising the long-lived assets to the estimated future undiscounted cash flows expected to be generated by the asset group. If the estimated aggregate undiscounted cash flows are less than the carrying amount of the asset group, an impairment charge is recorded as the amount by which the carrying amount of the asset group exceeds the fair value of the assets, as based on the expected discounted future cash flows attributable to those assets. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less costs to sell. During the year ended December 31, 2023, the Company recorded a lease impairment charge of $5.6 million related to one of its right-of-use assets. Refer to Note 7, Leases, for more details. There were no impairments of long-lived assets during the years ended December 31, 2024.

Leases

The Company determines if an arrangement includes a lease at inception and categorizes leases with contractual terms longer than 12 months as either operating or finance leases. Finance leases are generally those leases that allow the Company to substantially utilize or pay for the entire asset over its estimated life. All other leases are categorized as operating leases. As of December 31, 2024, the Company had no finance leases.

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

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

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

Warrant Liability

Changes in fair value of liability classified warrants are recognized within other income (expense), net in the consolidated statements of operations. Warrant liabilities are classified as short-term or long-term based on their remaining contractual periods. Cash proceeds in connection with the issuance of warrants for the Company's common stock are presented as financing activities in the consolidated statements of cash flows.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer ("CEO"). The Company has determined that it operates in one operating and reportable segment, as the CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. See Note 11, Segment and Geographic Information, for additional information.

Recent Accounting Pronouncements

New Accounting Pronouncements Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07")*, which requires an enhanced disclosure of significant segment expenses on an annual and interim basis. The Company adopted the new guidance retrospectively in fiscal year 2024.

New Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09")*, which modifies the rules on income tax disclosures to require disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. The Company is currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03")*, which requires the disclosure of additional information related to certain costs and expenses, including amounts of inventory purchases, employee compensation, and depreciation and amortization included in each income statement line item on an interim and annual basis. ASU 2024-03 also requires disclosure of the total amount of selling expenses and the Company's definition of selling expenses. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. Although the new standard requires comparative disclosures for all periods presented, entities will be permitted to begin applying the guidance prospectively. Therefore, comparative disclosures are not required for reporting periods beginning before the effective date. Entities can elect to apply the new standard retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact that adoption of ASU 2024-03 will have on its financial statement disclosures.

Note 3. Revenue

The Company disaggregates revenue by the following five customer types:

- **Pharma tests and services** includes sales of testing services and data analytics for clinical trials and research to pharmaceutical companies in support of their drug development programs. Contracts typically contemplate a single project and involve a range of tests and analytics to fulfill the requirements of each particular project.
- **Enterprise sales** includes sales of tumor profiling and diagnostic tests directly to another business as an input to their products. The Company is typically contracted to deliver specified tests and analytics in high volume over time. Revenue from the Company's partnership with Natera to provide advanced tumor analysis for use in Natera's MRD test makes up substantially all of the revenue in this category.
- **Population sequencing** includes sales of genomic sequencing services and data analytics to support large-scale genetic research programs. The Company is typically contracted to perform whole genome sequencing and provide data that can be used for analysis across a large volume of samples. All of the revenue within this category is from the Company's partnership with the VA MVP.
- **Clinical diagnostic** includes sales of ultra-sensitive, tumor-informed diagnostics tests, ordered by healthcare providers for cancer patients, that can detect cancer recurrence earlier and aids in treatment decision-making. Revenue is derived from Medicare and private insurance reimbursements.
- **Other** includes sales of genomic tests and analytics to universities and non-profits. Other also includes sales of diagnostics tests ordered by healthcare providers for cancer patients, which was insignificant for periods presented.

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

	Year Ended December 31,	
	2024	2023
Pharma tests and services [1]	$ 50,939	$ 31,904
Enterprise sales	25,364	31,729
Population sequencing	7,430	9,412
Clinical diagnostic	759	38
Other	122	398
Total revenue	$ 84,614	$ 73,481

(1) Includes related party revenue of $2.0 million for the year ended December 31, 2024.

Contract Assets and Liabilities

The opening and closing balances of receivables and contract liabilities from contracts with customers are shown below (in thousands). Contract assets were immaterial for all periods presented.

	December 31,	
	2024	2023
Opening balances:		
Accounts receivable, net	$ 17,730	$ 16,642
Short-term contract liabilities	$ 3,288	$ 1,264
Long-term contract liabilities (included in other long-term liabilities)	3,928	—
Total contract liabilities	7,216	1,264
Closing balances:		
Accounts receivable, net	$ 8,140	$ 17,730
Short-term contract liabilities	$ 3,100	$ 3,288
Long-term contract liabilities (included in other long-term liabilities)	—	3,928
Total contract liabilities	3,100	7,216

Remaining Performance Obligations

Amounts collected in advance of services being provided are deferred as contract liabilities in the consolidated balance sheets. The associated revenue is recognized, and the contract liability is reduced, as the services are subsequently performed. Remaining

Performance Obligations ("RPO") are comprised mainly of contract liabilities, and to a lesser extent, unbilled service revenue from non-cancellable contracts for which the Company has not invoiced and has an obligation to perform, and for which revenue has not yet been recognized in the financial statements. As of December 31, 2024, amounts related to unfulfilled services under contracts with an original expected duration of more than one year was $1.3 million. The Company expects to recognize the entire amount of $1.3 million in the next 12 months. Revenue recognized that was included in the contract liability balance at the beginning of each reporting period was $4.7 million and $0.4 million for the years ended December 31, 2024 and 2023, respectively.

Note 4. Balance Sheet Details

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

	December 31,	
	2024	2023
Raw materials	$ 3,976	$ 5,661
Other deferred costs	1,963	4,813
Total inventory and other deferred costs	$ 5,939	$ 10,474

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

	December 31,	
	2024	2023
Machinery and equipment	$ 29,586	$ 27,809
Computer equipment	17,088	17,923
Computer software	2,985	2,961
Furniture and fixtures	2,198	2,045
Construction in progress	899	3,485
Leasehold improvements	41,556	40,811
Total	94,312	95,034
Less: accumulated depreciation and amortization	(46,038)	(37,668)
Property and equipment, net	$ 48,274	$ 57,366

Depreciation and amortization expense for the years ended December 31, 2024 and 2023 was $10.9 million and $11.3 million, respectively.

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

	December 31,	
	2024	2023
Accrued compensation	$ 8,544	$ 12,816
Operating lease liabilities	7,696	7,761
Loans—current portion (Note 6)	1,669	1,646
Market Development Fees received from Tempus (Note 8)	1,400	—
Employee ESPP contributions	301	311
Accrued and other current liabilities	2,019	1,407
Total accrued and other current liabilities	$ 21,629	$ 23,941

Note 5. Fair Value Measurements

The following tables show financial assets and liabilities measured at fair value on a recurring basis and the level of inputs used in such measurements as of December 31, 2024 and 2023 (in thousands):

	December 31, 2024				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 1,152	$ —	$ —	$ 1,152	
Money market funds	44,524	—	—	44,524	Level 1
Commercial paper	39,291	—	(6)	39,285	Level 2
U.S. agency securities	6,453	1	—	6,454	Level 2
Total cash and cash equivalents	91,420	1	(6)	91,415	
Short-term investments:					
Commercial paper	8,697	1	(1)	8,697	Level 2
Corporate debt securities	498	—	—	498	Level 2
U.S. agency securities	2,330	—	—	2,330	Level 2
U.S. government securities	82,042	33	(6)	82,069	Level 2
Total short-term investments	93,567	34	(7)	93,594	
Total assets measured at fair value	$ 184,987	$ 35	$ (13)	$ 185,009	

	December 31, 2023				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 3,649	$ —	$ —	$ 3,649	
Money market funds	14,968	—	—	14,968	Level 1
Commercial paper	34,416	—	(18)	34,398	Level 2
U.S. agency securities	1,985	1	—	1,986	Level 2
U.S. government securities	1,983	—	—	1,983	Level 2
Total cash and cash equivalents	57,001	1	(18)	56,984	
Short-term investments:					
Commercial paper	495	—	—	495	Level 2
U.S. agency securities	1,976	—	—	1,976	Level 2
U.S. government securities	54,720	7	(3)	54,724	Level 2
Total short-term investments	57,191	7	(3)	57,195	
Total assets measured at fair value	$ 114,192	$ 8	$ (21)	$ 114,179	

The amortized costs and fair value of marketable debt securities (excluding cash and money market funds), by contractual maturity, at December 31, 2024 are as follows (in thousands):

	December 31, 2024	
	Amortized Cost	Fair Value
Less than 1 year	$ 127,369	$ 127,392
1 to 5 years	11,942	11,941
Total	$ 139,311	$ 139,333

No security has been in a continuous unrealized loss position for more than 12 months and the Company does not consider any of its marketable debt securities to be impaired.

Tempus Warrants

The Black-Scholes option-pricing model was used to estimate fair value of the warrants issued to Tempus at the date of issuance, November 28, 2023, and at each subsequent balance sheet date prior to their exercises in full in August 2024. Assumptions used are listed below, which are Level 3 fair value inputs. Expected term is equal to the remaining contractual periods of each of the two warrants. Expected volatility was based on the Company's actual historical volatility over the expected terms of the warrants. The risk-free interest

rate was based on the U.S. Treasury yield curve over the expected term of the warrants. Refer to Note 8, Related Party Transactions, for further information about the warrants issued to Tempus.

	As of December 31, 2023
Expected term (in years)	1.00 - 2.00
Volatility	102.6 - 108.5%
Risk-free interest rate	4.23 - 4.79%
Dividend yield	–%
Total fair value of Tempus Warrants (in thousands)	$ 10,027

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

	Year ended December 31,	
Warrant Liabilities	**2024**	**2023**
Beginning balance	$ 10,027	$ —
Initial fair value of warrant liabilities upon issuance	—-	6,942
Change in fair value—recognized as loss within Other income (expense), net in the consolidated statements of operations	18,274	3,085
Derecognition of warrant liabilities due to exercise in full	(28,301)	—
Ending balance	$ —	$ 10,027

Note 6. Loans

Amounts outstanding under loans are as follows (in thousands):

	December 31,	
	2024	**2023**
Principal	$ 1,772	$ 2,904
Less: unamortized discount	—	(24)
Total carrying amount	1,772	2,880
Less: current portion (included in accrued and other current liabilities)	(1,669)	(1,646)
Long-term portion (included in other long-term liabilities)	$ 103	$ 1,234

Equipment and Software Loans

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

The Company entered into two more secured payment agreements in April 2021 and July 2022, with the same financing entity, to finance the purchase of $3.1 million of computer hardware and related hardware maintenance and $1.3 million of internal use software licenses and related ongoing support, respectively. The Company repaid the financed amount in three equal payments of $1.0 million in July 2021, June 2022, and June 2023 for the first agreement, and two equal payments of $0.4 million in September 2022 and September 2023 for the second agreement. The third payment of $0.4 million for the second agreement, which was supposed to be paid in September 2024, was settled in January 2025. As of December 31, 2024, this amount was included in the accrued and other current liabilities in the consolidated balance sheets. The nature of these agreements and resulting accounting treatment are the same as the payment agreement described in the preceding paragraph, except the imputed interest rate was 9% for the July 2022 agreement.

The total initial present value of the payment agreements was $6.4 million and presented as proceeds from loans in the financing activities section of the consolidated statements of cash flows. Such proceeds were used to purchase equipment, software, and related maintenance and are reflected as cash outflows in the investing and operating activities sections. Repayments of $2.2 million, comprised of $0.8 million related to April 2021 internal use software license agreement, $1.0 million related to April 2021 computer hardware agreement, and $0.4 million related to July 2022 internal use software license agreement, were presented as financing cash outflows during the year ended December 31, 2023 in the consolidated statements of cash flows. Imputed noncash interest expense was immaterial and $0.1 million for the year ended December 31, 2024 and 2023, respectively.

Lab Equipment Loan

In November 2023, the Company purchased lab equipment from one of its main vendors for $3.4 million. Extended payment terms were provided to the Company through a financial solutions partner of the vendor. Terms included a 30% down payment and 24 equal monthly payments for the remaining balance, with such monthly payments commencing in January 2024 and the last payment due in January 2026, and no interest or financing charges. Title for the lab equipment transferred immediately upon delivery to the Company. The financial solutions partner retains a security interest until payoff is complete at the end of 2025. The purchase price for the lab equipment was equal to the cash price and thus the impact of imputing interest would have been de minimis.

The total financed amount of $3.4 million was presented as proceeds from loans in the financing activities section of the consolidated statements of cash flows during the year ended December 31, 2023. Such amounts were used to purchase lab equipment and are reflected as purchases of property and equipment in the investing activities section of the consolidated statements of cash flows during the year ended December 31, 2023. Repayments, including both the down payment and future monthly payments, were $1.0 million and $1.1 million during the years ended December 31, 2023 and 2024, respectively, are presented as financing cash outflows in the consolidated statements of cash flows.

Note 7. Leases

In 2021, the Company entered into a noncancelable operating lease for approximately 100,000 square feet in Fremont, California used for laboratory operations and its corporate headquarters. The lease term is 13.5 years and commenced in October 2022. The Company gained early access to the premises for the purpose of constructing and installing tenant improvements, for which the landlord contributed $15.1 million. Such contributions were accounted for as lease incentives and are recognized as reductions to lease expense over the lease term. The lease expires at the end of March 2036 and includes two options to extend the term for a period of five-years per option at market rates. The Company determined the extension options are not reasonably certain to be exercised. The lease includes escalating rent payments.

The Company has a noncancelable operating lease expiring in November 2027 for 31,280 square feet in Menlo Park, California previously used for laboratory operations and its former corporate headquarters. The lease includes escalating rent payments. In 2021, the Company expanded the leased premises by an additional 14,710 square feet of space (the “Expansion Lease”). The Expansion Lease expired at the end of December 2022 and was not extended. The Company moved all laboratory operations to the Fremont facility during the third quarter of 2023 and recorded a $5.6 million impairment loss in its consolidated statements of operations during the year ended December 31, 2023 for operating lease right-of-use assets as a result of the change in use of the Menlo Park office as mentioned below. The Company is actively marketing the vacated Menlo Park space for sublease.

The Company has noncancelable operating leases for data center space expiring between 2025 and 2026. The leases include renewal options that the Company determined are not reasonably certain to be exercised. During 2023, the data center operator agreed to terminate a portion of the lease at no cost. The Company remeasured the remaining lease liability and derecognized $0.6 million of operating lease liabilities and right-of-use assets.

The Company had an operating lease for laboratory space in Shanghai, China that was terminated early upon both parties' approval during 2023. The early termination did not result in any material penalties or charges in the Company's consolidated statements of operations. Separately, the Company also has various other short-term leases.

As of December 31, 2024 and 2023, operating leases had a weighted-average remaining lease term of 9.9 years and 10.4 years, respectively and a weighted-average discount rate of 10.6% and 10.5%, respectively. Discount rates are based on estimates of the Company's incremental borrowing rate, as the discount rates implicit in the leases cannot be readily determined. Future lease payments under operating leases as of December 31, 2024 were as follows (in thousands):

	Amount
2025	$ 8,057
2026	7,230
2027	7,189
2028	5,215
2029	5,371
2030 and thereafter	37,426
Total future minimum lease payments	70,488
Less: imputed interest	(27,910)
Present value of future minimum lease payments	42,578
Less: current portion of operating lease liability (included in accrued and other current liabilities)	(7,696)
Long-term operating lease liabilities	$ 34,882

Cash paid for operating lease liabilities, included in cash flows from operating activities in the consolidated statements of cash flows, for the years ended December 31, 2024 and 2023 was $8.1 million, and $6.0 million, respectively. Right-of-use assets obtained in exchange for new operating lease liabilities during the years ended December 31, 2024 and 2023 were zero and $1.3 million, respectively.

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

	Year Ended December 31,	
	2024	2023
Lease cost		
Operating lease cost	$ 6,028	$ 6,793
Short-term lease cost	199	198
Variable lease cost	2,027	1,828
Total lease cost	$ 8,254	$ 8,819

Lease Impairment

As mentioned above, the Company completed the move of its laboratory operations from its Menlo Park facility to its Fremont facility and began actively marketing the Menlo Park space for sublease during 2023. Accordingly, the Company evaluated the ongoing value of the operating lease right-of-use asset associated with the Menlo Park facility. Based on this evaluation, the Company determined that the right-of-use asset with a carrying amount of $6.7 million was no longer recoverable and was impaired and wrote it down to its estimated fair value of $1.1 million, which resulted in a noncash impairment loss of $5.6 million in its consolidated statements of operations during the year ended December 31, 2023. Estimated fair value was based on expected future sublease cash flows (with the assistance of a third-party real estate broker), net of brokerage commissions and estimated tenant incentives, discounted at a market rate of return on similar assets. The estimation of fair value also included expected downtime prior to the commencement of a future sublease.

Note 8. Related Party Transactions

The Company determined that Tempus and Merck Sharp & Dohme LLC ("Merck") are related parties because they own more than 10% of the Company's common stock.

Tempus

Tempus acquired its ownership stake in August 2024 by exercising the Tempus Warrants and purchasing additional shares under the Investment Agreement (defined below).

Overview of Tempus Agreement

In November 2023, the Company entered into a Commercialization and Reference Laboratory Agreement (the “Tempus Agreement”) with Tempus pursuant to which Tempus markets the Company's NeXT Personal Dx test in the United States. The Company performs tests ordered by patients through Tempus and the Company bills the patients or payors. The Company compensates Tempus for orders obtained and results delivered on a per-test basis. The term of the Tempus Agreement is five years, which may be extended for successive one-year terms. Either party may terminate the Tempus Agreement for convenience upon 30 months' prior written notice.

Under the Tempus Agreement, the Company conducted development activities to analytically validate NeXT Personal Dx in three indications: breast cancer, lung cancer and immuno-oncology monitoring. In consideration of the Company performing such development activities, Tempus agreed to pay the Company fees of $12.0 million (the "Market Development Fees"), consisting of an activation fee of $3.0 million, a first milestone fee of $3.0 million (upon achievement of one clinical validation), and a second milestone fee payable in six quarterly installments totaling $6.0 million (upon achievement of the two remaining clinical validations). If the Company does not achieve the second milestone by June 2024, Tempus may withhold installment payments, and Tempus will have the right to terminate the Tempus Agreement or convert it to a non-exclusive arrangement. Upon termination or conversion, the Company will refund to Tempus fees received other than the activation fee, subject to certain reductions. The Company has achieved all three clinical validations, thus both milestones have been met.

Separately, the parties are performing co-promotion activities and the Company is compensating Tempus for promotional and commercialization services through the end of 2026 in an amount up to $9.6 million.

The Tempus Agreement also granted Tempus access to initial and longitudinal genomic data derived from performance of the tests and Tempus will have the right to use such data. If Tempus licenses such data to a third party and Tempus recognizes revenue from such license, Tempus will pay the Company a percentage of its gross revenues attributable to such license that is in the range of 10 to 20 percent. Such revenue share shall be payable during the term of the agreement and for 10 years thereafter.

Pursuant to the Tempus Agreement, the Company will not allow another third party to market the test in such indications and Tempus will not market another tumor-informed molecular residual disease test for use in such indications (whether its own or that of a third party), in each case subject to certain exceptions. These exclusivity obligations terminate on December 31, 2027, to the extent they

do not expire earlier. In addition, each party has the right to convert the Tempus Agreement to a non-exclusive arrangement upon the occurrence of certain specified events.

Additionally, as partial consideration of Tempus' obligations to the Company under the Tempus Agreement, the Company issued warrants to Tempus. See "Tempus Warrants" section below.

Tempus Warrants

In consideration of Tempus' obligations to Personalis under the Tempus Agreement, on November 28, 2023, the Company issued to Tempus (1) a warrant to purchase up to 4,609,400 shares of Personalis common stock at an exercise price per share of $1.50, with an expiration date of December 31, 2024 (the "First Warrant"), and (2) a warrant to purchase up to 4,609,400 shares of Personalis common stock at an exercise price per share of $2.50, with an expiration date of December 31, 2025 (the "Second Warrant" and, together with the First Warrant, the "Tempus Warrants"). The Tempus Warrants were exercisable for cash at any time prior to the applicable expiration date, may be net exercised in certain circumstances, and automatically net exercisable in connection with a change of control of Personalis if the value ascribed to the consideration to be paid for one share of common stock exceeds the applicable exercise price. If Tempus acquires any shares of common stock directly from the Company other than by exercising the Warrants (any such shares, "Non-Warrant Shares"), then the total number of shares issuable upon exercise of the Tempus Warrants will be reduced by the Non-Warrant Shares on a share-for-share basis, proportionally between the First Warrant and the Second Warrant based on how many shares are then underlying the Warrants. Subject to limited exceptions, neither the warrants nor any interest therein may be transferred or assigned without the prior written consent of Personalis.

Since the Tempus Warrants included a provision under which the total number of shares issuable upon settlement were subject to adjustment, the Tempus Warrants were classified as liability instruments while outstanding and subject to remeasurement at each balance sheet date, with changes in fair value recognized as other income (expense), net in the consolidated statements of operations. Fair value of the two warrants were estimated at the date of issuance, November 28, 2023, using the Black-Scholes option-pricing model. Since the initial fair value of $6.9 million exceeded the total proceeds from Tempus of $6.0 million, a loss of $0.9 million was immediately recognized within other income (expense), net. None of the remaining Market Development Fees of $6.0 million were allocated to the warrants as such proceeds are contingent upon the Company achieving additional clinical validation milestones. Fair values of the warrants were estimated using the Black-Scholes option-pricing model. See Note 5, Fair Value Measurements for discussion of inputs used in the measurements of the Tempus Warrants and the resulting noncash losses recognized in the consolidated statements of operations. After the issuance of warrants in November 2023, fair value of the Tempus Warrants increased by $3.1 million as of December 31, 2023. The increase in fair value, plus the immediate loss of $0.9 million recognized upon issuance, resulted in a $4.0 million expense recognized in other income (expense), net in the consolidated statements of operations during the year ended December 31, 2023. Prior to the exercise of Tempus Warrants in August 2024, the Company recognized a charge of $18.3 million due to the increase in fair value of Tempus Warrants, which was recorded in other income (expense), net in the consolidated statements of operations during the year ended December 31, 2024.

In August 2024, concurrently with the execution of the Tempus Investment Agreement (described below), Tempus exercised in full the Tempus Warrants to purchase 9,218,800 shares of Personalis common stock for $18.4 million in cash, at an average exercise price of $2.00 per share, which is presented as financing cash flows in the consolidated statements of cash flows for the year ended December 31, 2024. The fair value of Tempus Warrants at the time of exercise was $28.3 million based on intrinsic value of Company's common stock at a per share price of $3.07, which is the difference between the last reported closing price of the common stock and its average exercise price at the time of exercise.

Investment Agreement with Tempus

In August 2024, the Company entered into an investment agreement (the "Tempus Investment Agreement") with Tempus under which the Company issued and sold 3,500,000 shares of common stock at a price per share of $5.07, representing the last reported closing price of the common stock. The Company received $17.7 million of cash from the sale of the shares and incurred $1.1 million of issuance costs directly related to the sale, which are presented as financing cash flows in the consolidated statements of cash flows for the year ended December 31, 2024.

Impact of Tempus Agreement on the Financial Statements

The Company had achieved the first clinical validation milestone at the time of entering the Tempus Agreement and was therefore entitled to Market Development Fees of $6.0 million, consisting of the first milestone fee of $3.0 million and the activation fee of $3.0 million. These proceeds of $6.0 million were received in 2023 and treated as consideration for the Tempus Warrants. These proceeds were presented as financing cash inflows in the consolidated statements of cash flows during the year ended December 31, 2023.

The remainder of Market Development Fees—$6.0 million, payable in six quarterly installments—are recorded as a liability when received and offset against promotional fees as they are paid by the Company to Tempus. As of December 31, 2024, $3.0 million of such $6.0 million Market Development Fees have been received.

Amounts of transactions with Tempus during each income statement period presented, along with amounts due from or to Tempus as of the balance sheet date, follows (in thousands):

	Income Statement Year Ended December 31, 2024
Orders and results delivery fees and net promotional fees—Selling, general and administrative expenses	$ 498
Noncash loss from remeasurement of Tempus Warrants—Other income (expense), net	(18,274)

	Balance Sheet December 31, 2024
Accrued and other current liabilities:	
Unamortized Market Development Fees	$ 1,400
Accrued payable to Tempus	345
Total accrued and other current liabilities	$ 1,745
Other long-term liabilities:	
Unamortized Market Development Fees	$ 1,200
Total other long-term liabilities	$ 1,200

Merck Sharp & Dohme LLC

Investment Agreement with Merck

On December 19, 2024, the Company entered into an investment agreement (the "Merck Investment Agreement") with Merck under which the Company issued and sold 14,044,943 shares of common stock at a price per share of $3.56, representing the last reported closing price of the common stock. The Company received $50.0 million of cash from the sale of the shares and incurred $0.3 million of issuance costs directly related to the sale, which are presented as financing cash flows in the consolidated statements of cash flows for the year ended December 31, 2024. Pursuant to the terms of the Merck Investment Agreement, the Company agreed to reserve $10.0 million of the proceeds to open an ISO-certified laboratory in a region outside of the United States, with such region mutually agreed upon by the Company and Merck. This cash was not legally restricted under the Merck Investment Agreement and therefore included in cash and cash equivalents as of December 31, 2024.

Before Merck became a related party in December 2024, the Company entered into a Master Service Agreement (the “Master Agreement”), in June 2017, as amended from time to time, with Merck for the performance of DNA and RNA sequencing analysis and data interpretation services, as well as synthesis and/or analysis of chemical compounds, genetic material and related samples for preclinical research purposes. In February 2024, the Company entered into an amendment whereby Merck engaged the Company to provide clinical laboratory services in connection with Merck's clinical studies.

After Merck became a related party in December 2024, the Company invoiced $2.0 million for genomic testing services, pursuant to the terms of the Master Agreement and recorded as revenue in its consolidated statement of operations. As of December 31, 2024, $2.5 million was outstanding as a receivable from Merck and included in accounts receivable in the consolidated balance sheets.

Note 9. Restructuring and Other Charges

Costs related to the Company's reductions in workforce and closure of its China operations are included within Restructuring and Other Charges in the consolidated statements of operations. A reconciliation of the beginning and ending related liability balances, included within Accrued and Other Current Liabilities in the consolidated balance sheets, is as follows (in thousands):

	One-time employee termination benefits	Other costs (primarily China asset disposals and impairments)	Total restructuring and other charges
Restructuring liability balance—December 31, 2022	$ —	$ —	$ —
Costs incurred and charged to expense	7,467	610	8,077
Costs paid or otherwise settled	(4,338)	(610)	(4,948)
Restructuring liability balance—December 31, 2023	3,129	—	3,129
Costs paid or otherwise settled	(3,129)	—	(3,129)
Restructuring liability balance—December 31, 2024	$ —	$ —	$ —

Restructuring

In January 2023, the Company initiated a reduction in workforce to reduce operating costs and improve operating efficiency. The workforce reduction affected nearly 100 employees and was substantially completed during the first quarter of 2023. The Company recognized $3.1 million in one-time employee termination benefits in connection with the reduction in workforce in its consolidated statements of operations during the year ended December 31, 2023, comprising separation pay and healthcare benefits payable in cash, all of which were paid by the end of the second quarter of 2023.

In December 2023, the Company initiated a second reduction in workforce to further reduce operating costs and improve operating efficiency. The workforce reduction affected approximately 60 employees and will be completed during the first quarter of 2024. The Company recognized $4.0 million in one-time employee termination benefits in connection with the reduction in workforce in its consolidated statements of operations during the year ended December 31, 2023, comprising separation pay and healthcare benefits payable in cash. The Company paid $3.1 million of such expenses were paid during the first quarter of 2024.

Closure of China Operations

During the first half of 2023, the Company terminated its operations in China with the objective of streamlining international operations and reducing operating costs. The disposal did not qualify for reporting as a discontinued operation because it did not represent a strategic shift that would have a major effect on our operations and financial results. The Company completed the process of dissolving the Personalis (Shanghai) Ltd entity in February 2024.

Expenses of $0.9 million were recognized in connection with closure activities in the Company's consolidated statements of operations during the year ended December 31, 2023, of which $0.3 million was related to one-time employee termination benefits for the Company's 12 former employees located in China and were payable in cash. Substantially all of the terminations were completed during the first quarter of 2023, along with the related cash outlays. The remaining $0.6 million in expenses were comprised primarily of noncash charges, including losses on disposal of fixed assets and impairments of other assets.

Note 10. Stock-Based Compensation

The Company maintains the following equity incentive plans:

2011 Equity Incentive Plan

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

2019 Equity Incentive Plan

The Company’s board of directors adopted and the Company’s stockholders approved the 2019 Equity Incentive Plan (the “2019 Plan”) in May 2019 and June 2019, respectively. The 2019 Plan became effective in June 2019 in connection with the Company’s IPO, and serves as the successor to the 2011 Plan. Pursuant to the 2019 Plan, 7,440,524 shares of common stock were initially reserved for grant, including any shares that were reserved and available for issuance under the 2011 Plan at the time the 2019 Plan became effective, and any shares that become available upon forfeiture or repurchase by the Company under the 2011 Plan, will be reserved for future issuance. No further grants were made under the 2011 Plan after the adoption of 2019 Plan.

The 2019 Plan provides for the grant of ISOs, NSOs, SARs, RSAs, RSUs, PSAs, performance cash awards, and other forms of equity compensation. ISOs may be granted only to the Company's employees and to any of the Company's parent or subsidiary corporation's employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of the Company and any of the Company's affiliates. The exercise price of a stock option generally cannot be less than 100% of the fair market value of the Company's common stock on the date of grant. Options under the 2019 Plan may be granted for periods of up to 10 years. In addition, the number of shares of the Company's common stock available for grant and issuance shall be increased on January 1 of each calendar year during the term of the Plan by the lesser of (i) five percent (5%) of the number of shares of the common stock issued and outstanding on each December 31 immediately prior to the date of increase, or (ii) such number of shares determined by the Board.

2020 Inducement Plan

The Compensation Committee of the Company's board of directors adopted the 2020 Inducement Plan (the "Inducement Plan") in May 2020, which became effective upon adoption. The Inducement Plan was adopted without stockholder approval, as permitted by the Nasdaq Stock Market rules. The Inducement Plan provides for the grant of equity-based awards, including NSOs, SARs, RSAs, RSUs, PSAs, and other forms of equity compensation, and its terms are substantially similar to the stockholder-approved 2019 Plan. In accordance with relevant Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company. These Awards must be approved by either a majority of the Company's independent directors or the Company's compensation committee, provided such committee comprises solely independent directors (the "Independent Compensation Committee") in order to comply with the exemption from the stockholder approval requirement for inducement grants provided under the Nasdaq Marketplace Rules. Pursuant to the Inducement Plan, the aggregate number of shares of Common Stock that may be issued will not exceed 1,000,000 shares.

2019 Employee Stock Purchase Plan

The Company's board of directors adopted and the Company's stockholders approved the 2019 Employee Stock Purchase Plan (the "ESPP") in May 2019 and June 2019, respectively. Pursuant to the ESPP, 250,000 shares of common stock were initially reserved for future issuance. In addition, on each January 1 for the first ten calendar years after the first offering date, the aggregate number of common stock reserved for issuance under the ESPP shall be increased automatically by the number of shares equal to the lesser of (i) one percent (1%) of the total number of outstanding shares of common stock on the immediately preceding December 31, or (ii) 500,000 shares of common stock. Subject to any plan limitations, the ESPP allows eligible employees to contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of the Company's common stock at a discounted price per share. The price at which common stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or last day of the offering period, whichever is lower. The ESPP provides for separate six-month offering periods beginning on May 1 and November 1 of each year.

Shares of common stock available for issuance under the Company's equity incentive plans at December 31, 2024 were as follows:

	December 31, 2024
Outstanding stock awards	9,312,702
Reserved for future award grants	4,827,765
Reserved for future ESPP	61
Total common stock reserved for stock awards	14,140,528

Stock Option Activity

A summary of the Company's stock option activity (excluding performance-based stock option activity summarized further below) for the years ended December 31, 2024 and 2023 is as follows:

	Outstanding Options			
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance—December 31, 2022	5,451,132	$ 9.90	5.31	$ 7
Options granted	2,638,500	2.61		
Options exercised	(8)	2.44		
Options forfeited or expired	(2,284,038)	7.84		
Balance—December 31, 2023	5,805,586	$ 7.40	6.90	$ 64
Options granted	3,612,000	2.19		
Options exercised	(80,998)	2.46		
Options forfeited or expired	(728,870)	9.65		
Balance—December 31, 2024	8,607,718	$ 5.07	7.64	$ 21,949
Options vested and exercisable as of December 31, 2024	4,491,161	$ 7.29	6.45	$ 8,233

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

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $5.78 on December 31, 2024 and the exercise prices of the underlying stock options. Out-of-the money stock options are excluded from aggregate intrinsic value.

The weighted-average grant date fair value of options granted was $1.53 and $1.81 per share for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the unrecognized stock-based compensation of unvested options was $6.5 million, which is expected to be recognized over a weighted-average period of 1.9 years.

Valuation of Stock Options

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model. Fair value of stock options is recognized as compensation expense on a straight-line basis over the requisite service periods of the awards. Fair value of stock options was estimated using the following range of assumptions:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	5.50 - 6.08	5.50 - 6.08
Volatility	72.61 - 83.68%	78.47 - 79.31%
Risk-free interest rate	3.48 - 4.65%	3.47 - 4.66%
Dividend yield	–%	–%

Performance-Based Stock Option Activity

During 2020, the Company granted 421,000 PSAs to the Company's then CEO which were vested in the same year due to fulfillment of the performance condition. These PSAs expired at the end of 2023.

During 2024, the Company granted 271,500 PSAs to the executive leadership team. Vesting of the PSAs is based upon attainment of certain Medicare reimbursement coverages by the end of 2025 and subject to continuous service by the executives. Fair value was estimated using the Black-Scholes option-pricing model. Total grant-date fair value of the PSAs was $0.3 million.

A summary of the Company's performance-based stock option activity for the years ended December 31, 2024 and 2023 is as follows:

	Outstanding Performance-Based Options			
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance—December 31, 2022	421,000	$ 5.10	1.00	$ —
Options expired	(421,000)	5.10		
Balance—December 31, 2023	—	$ —	—	$ —
Options granted	271,500	1.61		
Balance—December 31, 2024	271,500	$ 1.61	9.20	$ 1,133
Options vested and exercisable as of December 31, 2024	—	$ —	—	$ —

RSU Activity and Valuation

A summary of the Company's RSU activity for the years ended December 31, 2024 and 2023 is as follows:

	Unvested Restricted Stock Units		
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Fair Value
Balance—December 31, 2022	2,621,482	$ 9.33	$ 5,191
RSUs granted	24,500	2.18	
RSUs vested	(839,194)	9.91	1,520
RSUs forfeited	(552,962)	8.89	
Balance—December 31, 2023	1,253,826	$ 8.99	$ 2,633
RSUs granted	—	—	
RSUs vested	(601,285)	10.46	1,719
RSUs forfeited	(219,057)	10.20	
Balance—December 31, 2024	433,484	$ 6.34	$ 2,506

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

The aggregate fair value of unvested RSUs is calculated using the closing price of the Company's common stock of $5.78 on December 31, 2024. As of December 31, 2024, the unrecognized stock-based compensation cost of unvested RSUs was $2.0 million, which is expected to be recognized over a weighted-average period of 1.3 years.

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

ESPP Activity and Valuation

During the years ended December 31, 2024 and 2023, 583,695 and 999,194 shares of common stock were purchased under the ESPP, respectively. The fair value of stock purchase rights granted under the ESPP was estimated using the following range of assumptions:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	0.5	0.5
Volatility	61.35 - 95.66%	69.23 - 84.88%
Risk-free interest rate	4.42 - 5.43%	5.14 - 5.51%
Dividend yield	–%	–%
Fair value	$0.51 - $2.14	$0.33 - $0.91

Stock-based Compensation Expense

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

	Year Ended December 31,	
	2024	2023
Cost of revenue	$ 658	$ 1,761
Research and development	4,039	4,870
Selling, general and administrative	5,989	7,420
Total stock-based compensation expense	$ 10,686	$ 14,051

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

	Year Ended December 31,	
	2024	2023
Service-based stock options	$ 5,017	$ 5,746
Performance-based stock options	112	—
RSUs	5,251	7,539
ESPP	306	766
Total stock-based compensation expense	$ 10,686	$ 14,051

Note 11. Segment and Geographic Information

The Company operates in one reportable segment, which is providing advanced cancer genomic tests for precision oncology and personalized testing. The Company develops, markets, and sells these tests to pharmaceutical companies, biopharmaceutical companies, diagnostic companies, universities, non-profits, and government entities. It derives revenue primarily in the United States from the sale of genomic testing services and manages its business activities on a consolidated basis. The Company does not have intra-entity sales or transfers. The Company's CODM is its CEO, who reviews consolidated operating results, accompanied by disaggregated information about net revenues by customer types, as presented below, to make decisions about allocating resources and assessing performance for the entire Company.

Consolidated net loss is used to monitor actual performance compared to plans and forecasts. The CODM assesses performance based on revenue growth which is reported on the consolidated statements of operations. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The measure of segment assets is reported on the consolidated balance sheet as total assets. Substantially all of the Company's long-lived assets are located in the United States.

The Company attributes revenues to geographic region based on the billing addresses of customers. The following table presents net revenues by geographic region:

	Year Ended December 31,	
	2024	2023
United States	96%	90%
Others	4%	10%

The following table provides information about reported segment revenue, segment loss, and significant segment expenses (in thousands):

	Year Ended December 31,	
	2024	2023
Revenue	$ 84,614	$ 73,481
Less:		
Payroll and related costs	66,910	86,463
Lab supplies and outside services	12,029	18,841
Facility costs	10,132	16,899
Professional services	9,079	12,448
Repairs and maintenance	8,210	8,479
Lease impairment	—	5,565
Restructuring and other charges	—	8,077
Change in fair value of the Tempus Warrants	18,274	4,027
Depreciation and amortization	10,941	11,770
Other segment items[(a)]	35,833	15,109
Interest income	(5,510)	(5,901)
Segment and consolidated net loss	$ (81,284)	$ (108,296)

(a) Other segment items included in segment net loss include materials cost related to cost of revenue, marketing expenses, office expenses, foreign currency exchange gain and losses, and other overhead expenses.

Note 12. Commitments and Contingencies

Contingencies

In June 2024, the Company and Foresight entered into a Settlement and License Agreement (the "S&L Agreement") to settle litigation related to alleged patent infringement by Foresight. The Company filed complaints against Foresight—one in August 2022 and a second in June 2023—for infringement of certain of the Company's patents relating to detection of MRD. Foresight filed counterclaims and alleged that its solid tumor recurrence test does not infringe the Company's patents and invalidated two of the Company's patents, and sought to invalidate certain of the Company's other patents, through *inter partes* review proceedings with the U.S. Patent Trial and Appeal Board. Pursuant to the S&L Agreement, Foresight and the Company agreed to dismiss the pending claims of infringement and related defenses and counterclaims, and to end the remaining *inter partes* review proceedings.

Under the S&L Agreement, the Company granted Foresight a non-exclusive, worldwide license under certain patents of the Company to develop, manufacture, commercialize and otherwise exploit products and services that use whole genome sequencing and a variable content minimal/molecular residual disease panel that utilizes phased variants in consideration for which Foresight agreed to pay the Company a low single-digit tiered royalty on sales of products and services covered by patents licensed by the Company, subject to customary reductions. The license is perpetual and irrevocable, except in certain limited circumstances, which apply on a patent-by-patent basis. Upon the occurrence of certain specified change of control events with respect to Foresight, the highest percentage of the royalty tiers is subject to a low single-digit increase and Foresight will pay a one-time fee in the low single-digit millions. The term of the S&L Agreement runs through expiration of the patents licensed by the Company to Foresight.

The Company is also subject to claims and assessments from time to time in the ordinary course of business, including claims from customers and vendors, pending and potential legal actions for damages, governmental investigations and other matters. For example, the Company has received, and may in the future continue to receive letters, claims or complaints from others alleging false advertising, intellectual property infringement, and/or violation of employment practices. Accruals for litigation and loss contingencies are reflected in the consolidated financial statements based on management’s assessment, including the advice of legal counsel, of the expected outcome of litigation or other dispute resolution proceedings and/or the expected resolution of contingencies. Liabilities for estimated losses are accrued if the potential losses from any claims or legal proceedings are considered probable and the amounts can be reasonably estimated. Significant judgment is required in both the determination of probability of loss and the determination as to whether the amount can be reasonably estimated. Accruals are based only on information available at the time of the assessment due to the uncertain nature of such matters. As additional information becomes available, management reassesses potential liabilities related to pending claims and litigation and may revise its previous estimates, which could materially affect the Company’s consolidated results of operations in a given period. Except for the matter described in the first two paragraphs of this Note 12, as of December 31, 2024, the Company was not involved in any material legal proceedings.

Indemnification

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

In accordance with the Company's bylaws and/or pursuant to indemnification agreements entered into with directors, officers and certain employees, the Company has indemnification obligations to its directors, officers and employees for claims brought against these persons arising out of certain events or occurrences while they are serving in such a capacity. The Company maintains a director and officer liability insurance coverage to reduce its exposure to such obligations, and payments made under these agreements. To date, there have been no indemnification claims by these directors, officers and employees.

Note 13. Basic and Diluted Net Loss Per Common Share

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

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

	Year Ended December 31,	
	2024	2023
Net loss	$ (81,284)	$ (108,296)
Weighted-average common shares outstanding—basic and diluted	59,251,013	48,175,201
Net loss per common share—basic and diluted	$ (1.37)	$ (2.25)

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

	Year Ended December 31,	
	2024	2023
Tempus Warrants	—	9,218,800
Options to purchase common stock	8,879,218	5,805,586
Unvested RSUs	433,484	1,253,826
ESPP	61	513,881
Total	9,312,763	16,792,093

Note 14. Income Taxes

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

	Year Ended December 31,	
	2024	2023
Domestic	$ (81,312)	$ (106,833)
Foreign	46	(1,380)
Loss before income taxes	$ (81,266)	$ (108,213)

Provision for Income Taxes

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

	Year Ended December 31,	
	2024	2023
Current:		
Federal	$ —	$ (9)
State	4	3
Foreign	15	35
Total current	19	29
Deferred:		
Foreign	(1)	54
Total deferred	(1)	54
Provision for income taxes	$ 18	$ 83

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

	Year Ended December 31,	
	2024	2023
Expected tax (benefit) at federal statutory rate	(21%)	(21%)
Effect of:		
State taxes	(5%)	(7%)
Change in valuation allowance	20%	26%
Stock-based compensation	3%	3%
Research and development credit	(3%)	(3%)
Warrant revaluation	5%	0%
Other	1%	2%
Effective tax rate	–%	–%

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets for federal and state income taxes are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 94,215	$ 83,983
Research and development credits	26,196	22,669
Capitalized research and development	27,088	22,089
Property and equipment	73	—
Deferred revenue	332	362
Accruals and reserves	2,011	2,883
Stock-based compensation	4,084	4,614
Operating lease liabilities	11,828	13,124
Other intangibles	152	209
Other	299	132
Total gross deferred tax assets	166,278	150,065
Less: valuation allowance	(161,698)	(144,861)
Total deferred tax assets	4,580	5,204
Deferred tax liabilities:		
Property and equipment	—	(113)
Operating lease right-of-use assets	(4,571)	(5,084)
Total deferred tax liabilities	(4,571)	(5,197)
Net deferred tax assets	$ 9	$ 7

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Because of the Company's lack of U.S. earnings history, the net U.S. deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $16.8 million and $30.4 million during the years ended December 31, 2024 and 2023, respectively.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2024, the Company had a net operating loss carryforward for federal income tax purposes of $324.1 million, of which $91.9 million is subject to expiration beginning in 2031. The Company had a total state net operating loss carryforward of $302.5 million, which will begin to expire in 2031. Utilization of some of the federal and state net operating loss and credit carryforwards or other tax attributes, such as research tax credits, are subject to annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions. Under Section 382 of the Code, "change in ownership" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. It is possible that an ownership change, or any future ownership change, could have a material effect on the use of our net operating loss carryforwards or other tax attributes, which could adversely affect our operating results.

As of December 31, 2024, the Company has federal credits of $14.2 million, which will begin to expire in 2031 and state research credits of $12.0 million, which have no expiration date. These tax credits are subject to the same limitations discussed above. The Company determined that the ownership changes identified above had no significant impact on federal and state research credits.

Unrecognized Tax Benefits

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

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

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

	December 31,	
	2024	2023
Beginning balance	$ 5,701	$ 4,240
Gross increase—tax position in prior periods	—	162
Gross increase—tax position in current period	882	1,299
Ending balance	$ 6,583	$ 5,701

Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next 12 months due to tax examination changes, settlement activities, expirations of statute of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar activities, the Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months. During the years ended December 31, 2024 and 2023, no interest or penalties were required to be recognized relating to unrecognized tax benefits.

Note 15. Subsequent Events

Equipment and Software Purchases

In January 2025, the Company entered into a $2.9 million non-cancellable purchase agreement to acquire certain equipment and related maintenance services. Under the agreement, the Company is required to make 20% down payment before the equipment is shipped, with the remaining balance due by January 2026.

Additionally, the Company signed a separate purchase agreement with the same vendor for $2.8 million in software services and related support. Under this agreement, the Company is also required to make three equal payments of $1.0 million in January 2026, January 2027 and January 2028 for a 60-month service term beginning from January 2025 to January 2030.

Software Loan

In January 2025, the Company entered into a payment agreement with a financing entity to finance a purchase of $2.8 million of internal-use software licenses and related software support services from a vendor. The financing entity and vendor are not related. The payment agreement is non-interest bearing and the Company is obligated to repay the financed amount in three installments of $0.7 million in February 2025, $1.2 million in February 2026 and $0.9 million in February 2027.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
Personalis, Inc.
Fremont, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Personalis, Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years then, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Transactions

As described in Notes 2 and 3 to the consolidated financial statements, the Company derives revenue from the sale of genomic testing services. The genomic testing services are the only distinct services that meet the definition of a performance obligation and are accounted for as one performance obligation. Revenue is recognized at a point in time when test results are transferred to the customer. The Company's consolidated revenue was $84.6 million for the year ended December 31, 2024.

We identified the auditing of the occurrence of revenue transactions as a critical audit matter. Auditing the occurrence of revenue was especially challenging due to the significant audit effort in performing procedures related to the occurrence of revenue transactions, given the significance of revenue, the large volume of transactions, and the evaluation of the sufficiency of audit evidence.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the occurrence of revenue transactions, on a sample basis, by obtaining and inspecting invoices, customer purchase orders, delivery data from various sources including confirmation of transactions with customers, and cash receipts from customers, where applicable.

/s/ BDO USA, P.C.

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

San Jose, California

February 27, 2025

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer ("CEO") and chief financial officer ("CFO") has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our CEO and CFO have concluded that as of December 31, 2024, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosures.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the 1934 Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

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

Changes in Internal Control

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

Limitations on Controls

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

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except for the principal occupation, business experience, and education of each of our executive officers and directors set forth further below, the information required by this Item is set forth under the headings “Executive Officers,” “Security Ownership of Certain Beneficial Owners and Management,” “Delinquent Section 16(a) Reports,” “Corporate Governance and Board of Directors Matters,” and “Proposal No. 1 Election of Directors—Information About Our Continuing Directors” in the Company’s 2025 Proxy Statement to be filed with the SEC within 120 days after December 31, 2024 in connection with the solicitation of proxies for the Company’s 2025 annual meeting of stockholders, and is incorporated herein by reference.

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

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

Executive Officers

Christopher Hall. Mr. Hall has served as our Chief Executive Officer and President since March 2023 and before that served as our Senior Vice President and Head, Diagnostics Business upon joining our company in October 2022. Mr. Hall has also served as a member of the Board of Directors since March 2023. From October 2020 to July 2022, Mr. Hall served as Chief Executive Officer of Naring Health, Inc., a medical research services company. From February 2010 to July 2019, Mr. Hall served as President, Chief Operating Officer, and Chief Commercial Officer at Veracyte, Inc., a publicly traded global diagnostics company. Mr. Hall holds a B.A. in Political Science and Economics from DePauw University and an M.B.A. from Harvard Business School.

Aaron Tachibana. Mr. Tachibana has served as our Chief Financial Officer since March 2019 and has also served as our Chief Operating Officer since March 2023. From December 2022 to March 2023, Mr. Tachibana served as our interim Chief Executive Officer. From August 2015 to September 2018, Mr. Tachibana served as Chief Financial Officer at Lumentum Holdings Inc., a designer and manufacturer of optical and photonic products. From November 2013 to July 2015, Mr. Tachibana served as Vice President, Finance and Corporate Controller at JDS Uniphase Corp., subsequently renamed Viavi Solutions Inc., a network test, measurement, and assurance technology company. From March 2010 to October 2013, Mr. Tachibana served as Chief Financial Officer at Pericom Semiconductor Corp., a supplier of high-performance connectivity and timing solutions. Mr. Tachibana holds a B.S. in Business Administration and Finance from San Jose State University.

Richard Chen, M.D., M.S. Dr. Chen has served as our Chief Medical Officer since November 2011 (previously designated Chief Scientific Officer). In March 2023, Dr. Chen was promoted to Executive Vice President, R&D, in addition to his role as Chief Medical Officer. Since September 2011, Dr. Chen has served on the clinical faculty at Stanford University School of Medicine. In August 1997, Dr. Chen co-founded Ingenuity Systems, a genomic data software company. Dr. Chen holds a B.S. in Computer Science from Stanford University, an M.S. in Medical Informatics from Stanford University School of Medicine, and an M.D. from Stanford University School of Medicine.

Stephen Moore. Mr. Moore has served as our Vice President and General Counsel since April 2020 and as Corporate Secretary since May 2020. In February 2024, Mr. Moore was promoted to Senior Vice President and Chief Legal Officer. From October 2014 to April 2020, Mr. Moore served as General Counsel and Corporate Secretary at Pacific Biosciences of California, Inc., a publicly traded advanced genomics company. From January 2010 to October 2014, Mr. Moore served in other roles at Pacific Biosciences of California, Inc., including Associate General Counsel and Senior Director of Commercial Legal Affairs, and Vice President, Legal Affairs. From June 2007 to December 2009, Mr. Moore served as General Counsel and Corporate Secretary at Navigenics, Inc., a consumer genomics company. From January 1999 to June 2007, Mr. Moore held various positions at Affymetrix, Inc., a microarray company, including Associate General Counsel. Mr. Moore holds a B.A. in Political Science from San Jose State University and a J.D. from University of California, Davis.

Independent Directors

Olivia K. Bloom. Ms. Bloom has served on our Board of Directors since March 2022. In September 2023, after a 29-year career with Geron Corporation, a publicly traded commercial-stage biopharmaceutical company, Ms. Bloom retired as Executive Vice President, Chief Financial Officer and Treasurer. During that tenure, Ms. Bloom held several financial management positions, including Chief Accounting Officer and Controller, as well as lead several operational functions, including purchasing, information technology and investor relations. Ms. Bloom started her career in public accounting at KPMG International Limited and became a Certified Public Accountant in 1994. Ms. Bloom holds a B.S. in Business Administration from the University of California, Berkeley. Ms. Bloom was selected to serve on our Board of Directors because of her expertise in finance, accounting, and corporate governance and her experience as a senior female executive working for and with publicly-traded life science companies.

A. Blaine Bowman. Mr. Bowman has served on our Board of Directors since May 2019. Beginning in 2006, Mr. Bowman served on the board of directors of Solexa, Inc., a DNA sequencing company, until its sale to Illumina, Inc., a publicly traded biotechnology company and leader in DNA sequencing in January 2007, after which Mr. Bowman continued to serve on the board of directors of Illumina, Inc. until May 2018. From March 1977 to August 2005, Mr. Bowman served in various roles at Dionex Corporation, a publicly traded manufacturer of analytical instruments, including Chairman of the board of directors, President, and Chief Executive Officer, and he served on the board of directors until its sale to Thermo Fisher Scientific Inc. in May 2011. From July 2012 to December 2015, Mr. Bowman served on the board of directors of Altera Corporation, a publicly traded programmable logic devices company. Mr. Bowman holds a B.S. in Physics from Brigham Young University and an M.B.A. from the Stanford Graduate School of Business. Mr. Bowman was selected to serve on our Board of Directors because of his experience in executive roles and his experience serving on the boards of directors of various instrumentation and biotechnology companies.

Karin Eastham. Ms. Eastham has served on our Board of Directors since September 2019. Ms. Eastham has served on the board of Veracyte, Inc., a publicly traded genomic diagnostics company, since December 2012. Ms. Eastham previously served as a member of the board of directors of Nektar Therapeutics, Inc., a publicly traded biopharmaceutical company, from September 2018 to June 2023; Geron Corporation, a publicly traded clinical stage biopharmaceutical company, from March 2009 to May 2023; and Illumina, Inc., a publicly traded biotechnology company and leader in DNA sequencing, from August 2004 to May 2019. From May 2004 to September 2008, Ms. Eastham served as Executive Vice President and Chief Operating Officer, and as a member of the Board of Trustees, of the Burnham Institute for Medical Research, a non-profit corporation engaged in biomedical research. Ms. Eastham holds a B.S. in Accounting and an M.B.A. from Indiana University and is a Certified Public Accountant (inactive). Ms. Eastham was selected to serve on our Board of Directors because of her expertise in financial and operations management and experience serving on the boards of publicly-traded life science companies.

Woodrow A. Myers, Jr., M.D. Dr. Myers has served on our Board of Directors since March 2021. Dr. Myers serves as an Advisor to Lightspeed Venture Partners Inc., to the SCAN Group and to eHealth Inc. From May 2007 to December 2018, Dr. Myers served on the board of directors of Express Scripts Inc., a publicly traded health care company. From January 2018 to February 2019, Dr. Myers served as Chief Medical Officer and Chief Healthcare Strategist for Blue Cross Blue Shield of Arizona. He has also served as the Chief Medical Officer of Wellpoint Health Networks and Director of Healthcare Management for the Ford Motor Company. In the public sector he has served as the Health Commissioner of New York City and the State of Indiana. Since December 2015, Dr. Myers has served as Managing Director of Myers Ventures LLC, a healthcare consulting company. Dr. Myers holds a B.S. in Biology from Stanford University, an M.B.A. from Stanford Graduate School of Business, and an M.D. from Harvard Medical School. Dr. Myers was selected to serve on our Board of Directors because of his extensive experience in the healthcare industry, including in government and health policy roles.

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

Kenneth J. Widder, M.D. Mr. Widder has served on our Board of Directors since June 2023. Dr. Widder currently serves on the boards of QuidelOrtho Corporation and Evoke Pharma, Inc. and has over 40 years of experience working with biomedical companies, having previously served as a founder, director and/or CEO of Sydnexis, Inc., OrphoMed, Inc., Sytera, Inc., NovaCardia, Inc., Santarus, Inc., and Molecular Biosystems Inc., and as a general partner at LVP Life Science Ventures (formerly Latterell Venture Partners) and Windamere Venture Partners. He holds an MD from Northwestern University and trained in pathology at Duke University.

Item 11. Executive Compensation.

The information required by this Item is set forth under the headings “Director Compensation,” “Executive Compensation,” and “Compensation Committee Interlocks and Insider Participation” in the Company’s 2025 Proxy Statement to be filed with the SEC within 120 days after December 31, 2024, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is set forth under the headings “Equity Compensation Plans at December 31, 2024” and “Security Ownership of Certain Beneficial Owners and Management” in the Company’s 2025 Proxy Statement to be filed with the SEC within 120 days after December 31, 2024, and is incorporated herein by reference.

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

The information required by this Item is set forth under the headings “Corporate Governance and Board of Directors Matters” and “Transactions with Related Persons and Indemnification” in the Company’s 2025 Proxy Statement to be filed with the SEC within 120 days after December 31, 2024, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is set forth under the headings “Principal Accountant Fees and Services” and “Pre-Approval Procedures” under the proposal “Ratification of Selection of Independent Registered Public Accounting Firm” in the Company’s 2025 Proxy Statement to be filed with the SEC within 120 days after December 31, 2024, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements and Schedules

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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Consolidated Balance Sheets	70
Consolidated Statements of Operations	71
Consolidated Statements of Comprehensive Loss	72
Consolidated Statements of Stockholders' Equity	73
Consolidated Statements of Cash Flows	74
Notes to Consolidated Financial Statements	75
Report of Independent Registered Public Accounting Firm	98

(b) Exhibits

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38943	3.1	6/24/2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38943	3.1	10/31/2022
4.1	Description of Securities of Personalis, Inc.	10-K	001-38943	4.1	2/25/2021
4.2	Form of Common Stock Certificate of the Registrant.	S-1/A	333-231703	4.1	6/7/2019
4.3	Investment Agreement, dated August 16, 2024, by and between the Registrant and Tempus AI, Inc.	8-K	001-38943	4.1	8/16/2024
4.4	Investment Agreement, dated December 19, 2024, by and between the Registrant and Merck Sharp & Dohme LLC.	8-K	001-38943	4.1	12/19/2024
10.1#	Personalis, Inc. 2011 Equity Incentive Plan, as amended, and forms of agreements thereunder.	S-1	333-231703	10.1	5/23/2019
10.2#	Personalis, Inc. 2019 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-231703	10.2	6/7/2019
10.3#	Personalis, Inc. 2019 Employee Stock Purchase Plan.	S-1/A	333-231703	10.3	6/7/2019
10.4#	Personalis, Inc. 2020 Inducement Plan, as amended.	10-K	001-38943	10.4	2/28/2024
10.5#	Form of RSU Award Agreement under 2020 Inducement Plan.	10-K	001-38943	10.5	2/28/2024
10.6#	Form of Option Agreement under 2020 Inducement Plan.	10-K	001-38943	10.6	2/28/2024
10.7#	Form of Indemnification Agreement entered into by and between the Registrant and each director and executive officer.	S-1/A	333-231703	10.4	6/7/2019
10.8#	Amended and Restated Non-Employee Director Compensation Policy, dated February 27, 2024	10-Q	001-38943	10.1	5/8/2024
10.9#	Amended and Restated Employment Agreement dated March 7, 2023, between the Company and Aaron Tachibana.	8-K	001-38943	10.1	3/8/2023
10.10#	Amended and Restated Offer Letter, dated March 7, 2023, between the Company and Christopher Hall.	8-K	001-38943	10.2	3/8/2023
10.11#	Amended and Restated Employment Agreement dated March 8, 2023, between the Company and Richard Chen.	8-K	001-38943	10.3	3/8/2023
10.12#	Second Amended and Restated Executive Severance Agreement, dated September 25, 2023, between the Company and Christopher Hall.	10-K	001-38943	10.12	2/28/2024
10.13#	Third Amended and Restated Executive Severance Agreement, dated September 25, 2023, between the Company and Aaron Tachibana.	10-K	001-38943	10.13	2/28/2024
10.14#	Third Amended and Restated Executive Severance Agreement, dated September 25, 2023, between the Company and Richard Chen.	10-K	001-38943	10.14	2/28/2024
10.15#	Second Amended and Restated Executive Severance Agreement, dated September 18, 2023, between the Company and Stephen Moore.	10-K	001-38943	10.15	2/28/2024
10.16Ω‡	Commercialization and Reference Laboratory Agreement, between the Registrant and Tempus AI, Inc., dated November 25, 2023.	8-K	001-38943	10.1	11/28/2023

10.17Ω‡	Amendment No. 1 to the Commercialization and Reference Laboratory Agreement, dated August 16, 2024, by and between the Registrant and Tempus AI, Inc.	8-K	001-38943	10.1	8/16/2024
10.18	Amendment No. 2 to the Commercialization and Reference Laboratory Agreement, dated September 20, 2024, by and between the Registrant and Tempus AI, Inc.	10-Q	001-38943	10.2	11/6/2024
10.19Ω*	Amendment No. 3 to the Commercialization and Reference Laboratory Agreement, dated December 13, 2024, by and between the Registrant and Tempus AI, Inc.				
10.20	Lease, by and between MENLO PREHC I, LLC, MENLO PREPI I, LLC, TPI INVESTORS 9, LLC and the Registrant, dated February 2, 2015.	S-1	333-231703	10.9	5/23/2019
10.21	First Amendment to Lease, by and between MENLO PREPI I, LLC and TPI INVESTORS 9, LLC and the Registrant, dated April 8, 2020.	10-Q	001-38943	10.1	8/6/2020
10.22	Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated August 25, 2021.	10-Q	001-38943	10.1	11/4/2021
10.23	Amendment No. 1 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated December 8, 2021.	10-K	001-38943	10.16	2/24/2022
10.24	Amendment No. 2 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated June 9, 2022.	10-Q	001-38943	10.1	8/3/2022
10.25	Amendment No. 3 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated December 19, 2022.	10-K	001-38943	10.19	2/23/2023
10.26‡	Contract No. 36C24E22D0031, by and between the U.S. Department of Veterans Affairs and the Registrant, dated September 30, 2022.	10-Q	001-38943	10.1	11/2/2022
19.1*	Insider Trading Policy.				
21.1	Subsidiaries of the Registrant as of December 31, 2024.				
23.1	Consent of Independent Registered Public Accounting Firm.				
24.1	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K).				
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97#	Incentive Compensation Recoupment Policy.	10-K	001-38943	97	2/28/2024
101*	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.				
104*	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.				

# Indicates management contract or compensatory plan or arrangement.

* Filed herewith.

† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Ω Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted because the Company customarily and actually treats such omitted information as private or confidential and because such omitted information is not material.

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

Table of Contents

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 27, 2025

Personalis, Inc.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher Hall and Aaron Tachibana, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Name and Signature	Title	Date
/s/ Christopher Hall **Christopher Hall**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 27, 2025
/s/ Aaron Tachibana **Aaron Tachibana**	Chief Financial Officer and Chief Operating Officer *(Principal Financial and Accounting Officer)*	February 27, 2025
/s/ Karin Eastham **Karin Eastham**	Director	February 27, 2025
/s/ Olivia Bloom **Olivia K. Bloom**	Director	February 27, 2025
/s/ A. Blaine Bowman **A. Blaine Bowman**	Director	February 27, 2025
/s/ Woodrow A. Myers, Jr. **Woodrow A. Myers, Jr., M.D.**	Director	February 27, 2025
/s/ Lonnie Shoff **Lonnie Shoff**	Director	February 27, 2025
/s/ Kenneth Widder **Kenneth J. Widder, M.D.**	Director	February 27, 2025