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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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 No. 001-16537

ORASURE TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**36-4370966**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
220 East First Street **Bethlehem, Pennsylvania**	**18015**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (610) 882-1820
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $0.000001 par value per share	**OSUR**	**The Nasdaq Stock Market LLC**

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 Section 15(d) of the Exchange 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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 ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant's most recently completed second fiscal quarter (June 30, 2023)**:** $368,293,672.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 23, 2024: 73,796,268 shares.

Documents Incorporated by Reference:

Part III of this Annual Report on Form 10-K will be incorporated by reference from certain portions of the Registrant's Definitive Proxy Statement for its 2024 Annual Meeting of Shareholders, or will be included in an amendment hereto, to be filed not later than 120 days after the close of the fiscal year ended December 31, 2023. Except with respect to information specifically incorporated by reference in the Annual Report on Form 10-K, the Definitive Proxy Statement is not deemed to be filed as part hereof.

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Use of Names

References in this Annual Report on Form 10-K for the fiscal year ended December 31, 2023, (the "Annual Report") to "OraSure" mean OraSure Technologies, Inc. References in this Annual Report to “DNAG” mean DNA Genotek, Inc., references to “Diversigen” mean Diversigen, Inc., and references to “Novosanis” mean Novosanis NV. References in this Annual Report to "we", "us", "our", or the "Company" mean OraSure and its consolidated subsidiaries, DNAG, Diversigen, and Novosanis, unless otherwise indicated.

Disclosure Regarding Forward Looking Statements

This Annual Report contains certain “forward-looking statements,” within the meaning of the Federal securities laws. These may include statements about the Company's expected revenues, earnings/losses per share, net income (loss), expenses, cash flow or other financial performance, or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect the Company's future operations, results of operations or financial position. These statements often include words, such as “believes,” “expects,” “anticipates,” “intends,” “plans,” “estimates,” “may,” “will,” “should,” “could,” or similar expressions.

Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to:

- *Market acceptance of, and the Company's ability to market and sell, its products and services, whether through its internal, direct sales force or third parties;*
- *The Company's ability to fulfill its commitments under its contracts with the U.S. government for InteliSwab® COVID-19 Rapid Tests;*
- *Failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for the Company's products;*
- *Significant customer concentrations that exist or may develop in the future;*
- *The Company's ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements;*
- *The Company's ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements;*
- *The Company's ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (or the "FDA”), or other regulators;*
- *Changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements;*
- *The Company's ability to meet increased demand for its products;*
- *The impact of replacing distributors on the Company's business;*
- *Inventory levels at distributors and other customers;*
- *The Company's ability to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales;*
- *The impact of competitors, competing products and technology changes on the Company's business;*
- *Reduction or deferral of public funding available to customers;*
- *Competition from new or better technology or lower cost products;*
- *The Company's ability to develop, commercialize and market new products;*

- *Changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention, (the "CDC") or other agencies; ability to fund research and development and other products and operations;*
- *The Company's ability to obtain and maintain new or existing product distribution channels;*
- *Reliance on sole supply sources for critical products and components;*
- *Availability of related products produced by third parties or products required for use of the Company's products;*
- *The impact of contracting with the U.S. government on the Company's business;*
- *The impact of negative economic conditions on the Company's business;*
- *The Company's ability to maintain sustained profitability;*
- *The Company's ability to increase its gross margins;*
- *The ability to utilize net operating loss carry forwards or other deferred tax assets;*
- *Volatility of the Company's stock price;*
- *Uncertainty relating to patent protection and potential patent infringement claims;*
- *Uncertainty and costs of litigation relating to patents and other intellectual property;*
- *Availability of licenses to patents or other technology;*
- *Ability to enter into international manufacturing agreements;*
- *Obstacles to international marketing and manufacturing of products;*
- *The impact of changes in international funding sources and testing algorithms on international sales;*
- *Adverse movements in foreign currency exchange rates;*
- *Loss or impairment of sources of capital;*
- *The Company's ability to attract and retain qualified personnel;*
- *The Company's exposure to product liability and other types of litigation;*
- *Changes in international, federal or state laws and regulations;*
- *Customer consolidations and inventory practices;*
- *Equipment failures and ability to obtain needed raw materials and components;*
- *The impact of terrorist attacks and civil unrest; and*
- *General political, business and economic conditions, including inflationary pressures.*

These and other factors that could affect the Company's results are discussed more fully under Item 1A, entitled "Risk Factors," and elsewhere in this Annual Report. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements and Risk Factors are made as of the date of this Annual Report and the Company undertakes no duty to update these statements, unless it is required to do so by law. If the Company does update one or more forward-looking statements, no inference should be drawn that it will make updates with respect to other forward-looking statements or that it will make any further updates to those forward-looking statements at any future time.

Investors should also be aware that while the Company does, from time to time, communicate with securities analysts, it is against the Company's policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that the Company agrees with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, the Company has a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

Trademarks, Trade Names and Service Marks

This Annual Report contains certain trademarks, which are protected under applicable intellectual property laws and are the Company's property. Solely for convenience, the Company's trademarks and trade names referred to in this Annual Report may appear without the ® or ™ symbol, but such references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. The Company owns rights to trademarks and service marks that it believes are necessary to conduct its business as currently operated. In the United States, the Company owns a number of trademarks, including the OraSure®, Intercept®, Intercept i2®*he,* Intercept i2*he*®, OraQuick®, OraQuick ADVANCE®, ORASURE QUICKFLU®, SUREQUICK®, Q.E.D.®, InteliSwab®, Oragene®, DNA Genotek®, OMNImet®, ORAcollect®, OMNIgene®, Diversigen®, CoreBiome®, Boostershot®, MetaGene®, Benchmark™, Novosanis®, Colli-Pee®, UCM®, UAS™, THINK OUTSIDE THE CUP®, AUTO-LYTE®, prepIT®, and HEMAgene® trademarks. The Company also owns many of these marks and others in several foreign countries and it is pursuing registration of several other trademarks.

PART I

ITEM 1. Business.

OraSure Technologies transforms health through actionable insight by powering the shift that connects people to healthcare wherever they are.

In February 2023, the Company announced a corporate restructuring to combine the commercial and innovation teams across two segments, being the "Diagnostics" segment and the "Molecular Solutions" segment, into one business unit with sales, marketing, product development and research teams covering multiple product lines. This change is intended to accelerate innovation, enhance customer experience and result in operational synergies. As a result, all products and services reside under one reporting hierarchy. The Company's product portfolio is broadly divided into diagnostics products and sample management solutions.

Products and Services

The Company's business consists of the development, manufacture, marketing and sale of simple, easy to use diagnostic products and specimen collection devices using its proprietary technologies, as well as other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our diagnostic products include tests for diseases including COVID-19, HIV and Hepatitis C that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's COVID-19 and HIV products are also sold in a consumer-friendly format in the over-the-counter ("OTC") market in the U.S. and, in the case of the HIV product, as a self-test to individuals in a number of other countries, including as an oral swab in-home test for HIV-1 and HIV-2 in Europe.

The Company's business also includes molecular sample management solutions and services that are used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers. The revenues from sample management solutions are derived from product sales to commercial customers and sales into the academic and research markets. Customers span the disease risk management, diagnostics, pharmaceutical, biotech, companion animal and environmental market segments. The Company has also developed collection devices for the emerging microbiome market, which focuses on studying microbiomes and their effect on human and animal health. The Company also has a urine collection device which allows for the volumetric collection of first void urine. This product is in its early stages, and initial sales are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets. Additionally, the Company offers laboratory and bioinformatics services for both genomics and microbiome customers. These services are primarily provided to pharmaceutical, biotech companies, and research institutions.

In 2020, the Company expanded its market focus by selling existing collection products for use with COVID-19 tests. Beginning in 2022 and continuing through 2023, demand for COVID-19 PCR testing declined significantly, which was primarily driven by the availability of antigen tests, the reduction in the number of COVID-19 cases, and the wider availability of vaccines that negatively impacted the sales of the collection products.

Business Update Related to InteliSwab® Covid-19 Rapid Tests

In June 2021, the Company received three Emergency Use Authorizations ("EUA") from the FDA for its InteliSwab® COVID-19 Rapid Tests ("InteliSwab®") for non-prescription OTC, professional point-of-care use and prescription home use. The Company began recording revenues on the sales of its InteliSwab® tests during the third quarter of 2021. In January 2022, the Company received FDA authorization for pediatric use of InteliSwab® tests for children ages 2 to 14. In September 2023, the Company received FDA approval for extension of InteliSwab® test shelf-life from 18 months to 24 months. In September 2021, the Defense Logistics Agency ("DLA") awarded the Company a procurement contract for the InteliSwab® tests for OTC use, which the DLA estimated to have a value of $205 million and which would provide InteliSwab® tests to up to 20,000 sites throughout the United States. On November 22, 2022, the DLA awarded the Company a second procurement contract for the InteliSwab® tests for OTC use. In 2023, the Company delivered 18 million tests under the contract, which ran from November 2022 through November 2023. In December 2022, the U.S. Department of Health and Human Services ("HHS") awarded the Company a fully funded firm fixed price contract for a total of 3.2 million InteliSwab® tests which were delivered in February 2023.

In September 2021, the Company entered into an agreement with Biomedical Advanced Research Development Authority ("BARDA"), which is part of the office of the Assistant Secretary for Preparedness and Response at HHS, pursuant to

which BARDA would provide up to $13.6 million in funding to obtain clearance of a premarket notification ("510(k)") and Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) waiver of the InteliSwab® tests. The Company continued development work and analytical testing on this test throughout 2023. However, in early 2024, the Company has communicated to BARDA that it does not intend to pursue further development of this product.

Through 2023, the Company maintained its expanded United States production capacity for InteliSwab® tests to meet capacity targets, set out in its 2021 contract with the U.S. Department of Defense ("DOD") (in coordination with the HHS), of more than 100 million tests annually.

In 2023, the Company announced that the FDA provided approval for a new packaging and labeling configuration for InteliSwab® tests. The Company completed the transition to this new configuration in March 2023, which resulted in lower shipping costs, less packaging and reduced truckloads.

Products

The following is a summary of the Company's principal products for the infectious disease and risk management markets as well as its sample management products:

InteliSwab® COVID-19 Rapid Test

InteliSwab® is the Company's rapid immunoassay product designed to test nasal samples for the presence of antigen from SARS-CoV-2. The device uses an integrated swab to collect a specimen from the lower nostril. After collection, the integrated swab is inserted into a vial containing a pre-measured amount of developer solution to facilitate flow of the sample into the device. The specimen and developer solution flow through the test device and test results are observable in 30 minutes. The InteliSwab® test has received EUA from the FDA for non-prescription, OTC home use in individuals aged two years or older, with symptoms within the first seven (7) days of onset when tested at least twice over a three-day period with at least 48 hours between tests and without symptoms or epidemiological reasons to suspect COVID-19 when tested at least three times over a five-day period with at least 48 hours between tests.

InteliSwab® COVID-19 Rapid Test Pro

The InteliSwab® COVID-19 Rapid Test Pro is a version of InteliSwab® intended for use by healthcare providers at the point of care. The test is performed in the same manner as the OTC version, except that the test is run and interpreted by a healthcare provider. This test has received EUA from the FDA for use by laboratories located in the United States certified under CLIA. The Company has also received a CLIA waiver for use of the test, which enables the test to be used by numerous additional sites in the United States, which are not certified under CLIA, to perform high and moderately complex tests. These additional sites include outreach clinics, community-based organizations and physicians’ offices. This test is also indicated for individuals aged 2 years and older, with and without symptoms of COVID-19.

InteliSwab® COVID-19 Rapid Test Rx

The InteliSwab® COVID-19 Rapid Test Rx is the version of InteliSwab® that has received EUA from the FDA for prescription home use with individuals aged 2 years or older who are suspected of COVID-19 infection by their healthcare provider within the first seven days of symptom onset.

OraQuick® Rapid HIV Test

The OraQuick® Rapid HIV Test is the Company's rapid point-of-care test product designed to test for the presence of HIV-1 and HIV-2 antibodies. This product is sold under the OraQuick ADVANCE® name in North America, Europe and certain other countries, and under the OraQuick® name in other developing countries. The OraQuick ADVANCE® test has received premarket approval (“PMA”) from the FDA for the detection of antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick whole blood, venous whole blood and plasma. The OraQuick® test has received World Health Organization ("WHO") pre-qualification and registration in other countries for the detection of HIV-1 and HIV-2 antibodies in oral fluid, whole blood (fingerstick and venous), serum and plasma. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of developer solution and allowed to develop. When blood-based specimens are to be tested, a loop collection device is used to collect a drop of the specimen and mix it in the developer solution, after which the collection pad is inserted into the solution and the test is allowed to develop. The specimen and developer solution then flow through the testing device

where test results are observable between 20 and 40 minutes. The OraQuick® device is a screening test and requires a confirmation test where an initial positive result is obtained. This test is available for use by laboratories located in the United States certified under CLIA, to perform moderately complex tests. The Company has also received a CLIA waiver for use of the test with oral fluid and finger-stick and venous whole blood. As a result, the test can be used by numerous additional sites in the United States not certified under CLIA to perform moderately complex tests, such as outreach clinics, community-based organizations and physicians' offices.

The OraQuick *ADVANCE*® test is also CE marked for sale in Europe and other countries accepting the CE mark for commercialization. This product is also registered for sale in other countries. The Company has distributors in place for several countries and is seeking to increase awareness and expand its distribution network for this product throughout the world. The Company has also received WHO pre-qualification for its export-only version of this product.

OraQuick® In-Home HIV Test

The OraQuick® In-Home HIV test is an OTC oral-fluid only version of the Company's OraQuick *ADVANCE*® HIV 1/2 Antibody Test. The Company received PMA approval to sell this test in the U.S. OTC market. The In-Home test is performed in the same manner as the OraQuick *ADVANCE*® test, except that it has product labeling and instructions designed for consumers. In addition, the Company has established toll-free, 24/7, 365-day per year customer telephone support to provide additional information and referral services for consumers that use this product.

OraQuick® HIV Self-Test

The OraQuick® HIV Self-Test is sold for use by individuals in certain foreign countries, including under the CE mark in certain European countries, to meet the needs of those markets. This product has received WHO pre-qualification and is eligible for procurement by purchasing entities entitled to access funding and other resources from the Global Fund, UNITAID and other agencies.

OraQuick® HCV Rapid Antibody Test

Another test available on the OraQuick® platform is the OraQuick® HCV rapid antibody test. This product is a qualitative test that can detect antibodies to the hepatitis C virus ("HCV"), in a variety of sample types. The OraQuick® HCV test operates in substantially the same manner as the OraQuick ADVANCE®HIV test.

The Company has received FDA PMA approval and CLIA waiver for use of the test in detecting HCV antibodies in venous whole blood and finger-stick whole blood specimens, making it the first and only rapid HCV test approved by the FDA for use in the United States. The OraQuick® HCV test has received a CE mark for use with oral fluid, venous whole blood, finger-stick whole blood, plasma and serum and is sold in Europe. This CE-marked product is also registered and sold in other foreign countries and has received WHO pre-qualification.

OraQuick® Ebola Rapid Antigen Test

The Company has received De Novo authorization from the FDA for its rapid Ebola test, making it the first and only rapid Ebola test cleared for sale in the U.S. This product utilizes the OraQuick® technology platform for the detection of Ebola antigen and can be used with finger-stick and whole blood samples from live patients and oral fluid samples from recently deceased individuals. The uses for this test are limited to individuals that meet certain criteria indicating they may be infected with the Ebola virus, so the test is not available for general screening of individuals that do not meet this criteria.

In September 2022, the Company entered into an agreement with BARDA, pursuant to which BARDA will provide up to $8.6 million in funding to the Company to develop a 2nd generation Ebola test on the OraQuick® testing platform with the objective of developing increased sensitivity, utilizing sustainable raw materials and increasing shelf life, with new chemistry and higher degrees of automation in the test's manufacturing process. In September 2023, the agreement was modified to add an additional $6.8 million in funding to be used to obtain the appropriate regulatory approvals for the product.

Intercept® Drug Testing System

A collection device that is substantially similar to the OraSure® collection device is sold under the name Intercept®, and is used to collect oral mucosal transudate for oral fluid drug testing. The Company has received FDA 510(k) clearance to use

the Intercept® collection device with laboratory-based EIAs to test for drugs-of-abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 (i.e., tetrahydrocannabinol ("THC" or marijuana), cocaine, opiates, amphetamines/methamphetamines and phencyclidine ("PCP")), and for barbiturates, methadone and benzodiazepines. Each of these EIAs is also FDA 510(k) cleared for use with the Intercept® device. The Intercept® device and oral fluid assays are sold in the U.S. primarily through laboratory distributors.

The Company believes that the Intercept® device has several advantages over competing urine and other drugs-of-abuse testing products, including its lower total testing cost, its non-invasive nature, mobility and accuracy, the ease of maintaining a chain-of-custody, the treatment of test subjects with greater dignity, no requirement for specially-prepared collection facilities and difficulty of sample adulteration. The availability of an oral fluid test is intended to allow the Company's customers to test for drug impairment and eliminate scheduling costs and inconvenience, thereby streamlining the testing process.

The Company has also developed a next-generation collection device, which it is marketing under the trade name "Intercept i2® *he*". This device offers several important advantages over the original Intercept® device, including a sample adequacy indicator that provides a visual prompt when the appropriate volume of oral fluid has been collected, the ability to collect a larger sample required by current laboratory testing protocols and a more optimized chemistry that results in improved recovery of the targeted drug analytes. The Intercept i2®*he* device is currently being sold as a forensic use only device within the criminal justice and drug treatment markets along with a panel of fully-automated high-throughput oral fluid drug assays that the Company distributes under an agreement with Thermo Fisher Scientific.

Immunoassay Tests and Reagents

The Company develops and sell immunoassay tests in formats, known as MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of its customers. The Company also sell fully-automated high-throughput oral fluid drug assays developed under its agreement with Thermo Fisher Scientific.

The Company's MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in oral fluid, urine, serum and sweat specimens. MICRO-PLATE tests are also used as part of the Intercept® product line to detect drugs-of-abuse in oral fluid specimens and the Company is selling a panel of high-throughput assays supplied by Thermo Fisher Scientific to the U.S. forensic market under the agreement described above. AUTO-LYTE® tests are sold in the form of bottles of liquid reagents, are run on commercially available laboratory-based automated analytical instruments, and are typically used in high volume, automated, commercial reference insurance laboratories to detect certain drugs or chemicals in urine.

Genomic Products

The Company sells many genomic products that provide all-in-one systems for the collection, stabilization, transportation, and storage of DNA, RNA, as well as both DNA and RNA together from human and animal biological samples. The Company's lead products are sold under the Oragene® and ORAcollect® brands and are used to collect genetic material from human saliva. These products are currently sold to thousands of academic research and commercial customers in many countries worldwide. The Company has obtained FDA clearance for its ORAcollect® and its Oragene® saliva collection device for general use, including professional and OTC clearances, which allows the Company's commercial partners to use and legally market the device with their assays when used in conjunction with their intended uses.

The Company's genomic products are available in several configurations and contain proprietary chemical solutions optimized for the specific application for which each product is designed. Product physical design is focused on ease-of-use and reliability for self or assisted collection of samples. For example, several of the Oragene® products require users to hold the product close to their mouth and spit into the collection device. When the container is closed, the reagents stored in the container's lid are mixed with the captured saliva and stabilize and preserve the nucleic acids in the sample. This non-invasive collection method yields nucleic acid that remains stable at ambient temperature for extended periods. The stabilizing technology ensures the preservation of high quality and high quantity nucleic acids required for many genetic testing and analysis methods.

The Company believes these products provide significant advantages over competing DNA and RNA collection methods such as blood collection or buccal swabs, particularly in human genetic applications.

Benefits include:

- Reliable high-quality and stable genetic samples.
- Simple, non-invasive collection methods.
- The ability to store and transport collected samples for extended periods at ambient temperatures.
- Compatibility with fully automated laboratory testing systems.

The Company also sells the Colli-Pee® collection device for the volumetric collection of first void urine samples. This product is used in liquid biopsy applications for the prostate and bladder cancer markets and in the sexually transmitted infection screening market. The Colli-Pee® collection device is is registered as a class I urine collection device without a claim for preservative. The Colli-Pee® collection device with preservative solution does not have FDA clearance and is labeled “For Research Use Only” in the U.S.

Microbiome Products

The Company also markets several microbiome collection products designed to collect, stabilize, and transport the microbial profile from multiple sample types. When unstabilized, a microbiome sample can change when exposed to environmental fluctuations, such as temperature changes. The Company's microbiome collection products support collecting and stabilizing metabolites found in fecal samples by capturing and preserving the microbiome after collection until the desired analysis can be performed.

The Company's OMNIgene® • GUT product is an all-in-one system designed to enable an individual to easily self-collect high-quality microbial DNA from feces or stool samples for gut microbiome profiling for use in the clinical laboratory and research settings. The Company's OMNIgene® • GUT DNA and RNA collection device is available to gut microbiome researchers, allowing for self-collection, stabilization, storage and transportation of microbial DNA and RNA at ambient temperature for gut microbiome profiling. Most current methodologies for gut microbiome profiling have distinct shortcomings due to the introduction of bias, leading to a lack of reproducibility in the field. The Company believes its product ensures that the microbial DNA and RNA in the fecal sample are fully stabilized immediately upon collection and maintains an accurate and reliable bacterial profile for weeks at room temperature. In 2023, the Company's OMNIgene® • SALIVA DNA and RNA collection device became available to researchers for self-collection of saliva with stabilization of total nucleic acids. The Company's microbiome products also include devices that apply the principles of sample stabilization to other sample types, including oral, skin, and vaginal samples.

The Company's OMNIgene®•GUT Dx collection device received de novo authorization from the FDA for collection of human fecal samples and the stabilization of DNA from the bacterial community for subsequent assessment of the microbiome profile by an assay validated for use with OMNIgene®·GUT Dx device.

Laboratory and Data Analytical Services

The Company also offers its customers microbiome laboratory testing and analytical services. Its services focus on accelerating microbiome discovery for customers in the pharmaceutical, agriculture, and research communities. The Company's goal is to help customers unleash the translational potential of the microbiome by providing fast and information-rich characterizations of microbial diversity and function paired with expert analytics. The Company also offers comprehensive microbiome and metagenomics services to improve human, animal, and environmental health including its metatranscriptomics sequencing and analysis services for gut microbiome samples. These services generate a microbial community’s gene expression profile to provide information about the interactions between an individual and their microbiome, creating a holistic picture of a sample’s microbial functions and expression levels. Diversigen has obtained the College of American Pathologists (“CAP”) accreditation at its laboratory facilities.

Other Products

In addition to the products described above, the Company offers the following products:

OraSure® Collection Device

The Company's OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and is FDA approved for use in the detection of HIV-1 antibodies. The Company also sells a generic version, which can be used for other analytes. This generic version is a Class I medical device for the detection of cocaine and cotinine in oral fluid specimens for risk assessment testing.

Q.E.D.® Saliva Alcohol Test

The Company's Q.E.D.® saliva alcohol test is a point-of-care test device that is a cost-effective alternative to breath or blood alcohol testing. The test is a quantitative, saliva-based method for the detection of ethanol, has been cleared for sale by the FDA and has received a CLIA waiver. The U.S. Department of Transportation ("DOT") has also approved the test.

COVID Collection Products

Since 2020, the Company has sold its ORAcollect® • RNA and OMNIgene® • ORAL collection devices for use in connection with COVID-19 molecular testing. The Company has actively engaged with several laboratories and researchers to demonstrate the effectiveness of its existing collection products for use with COVID-19 molecular testing.

Products Under Development

Diagnostic Products

The Company's research and development efforts include programs targeted at expanding and enhancing its diagnostics business. These programs typically focus on products related rapid tests for various diseases.

The Company is working to develop a 2nd generation Ebola test on the OraQuick® testing platform with funds obtained under its contract with BARDA.

Sample Management Solutions

In order to intersect evolving customer needs within the academic and commercial markets, the Company's molecular sample management solutions business product development pipeline is focused on extending offerings across different sample types and analytes within both the genomics and microbiome areas. Genomic customers are demonstrating an increasing demand for collection and stabilization of cell-free nucleic acids, exosomes, DNA and RNA. On the microbiome front, the Company continues to focus research and development work on collecting and stabilizing microbial DNA, RNA and metabolites from multiple sample types including gut, skin, vagina and saliva.

The field of microbiome services is fast paced with evolving biological understanding and development of new methodologies. The Company's development efforts are focused on remaining at the forefront of laboratory and informatics technologies, as well as providing new and relevant services to its customers. These include a focus on laboratory and informatics methods to integrate DNA, RNA and metabolites from microbial communities across different sample types.

Sales and Marketing

The Company markets its products in the United States and internationally. It attempts to reach major target markets through a combination of direct sales, strategic arrangements and independent distributors. The Company's marketing strategy is to create or raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs, distributor promotions, telemarketing and the use of digital and social media in order to stimulate sales in each target market. The Company's revenues by geographic area are described in Note 2 of the notes to the consolidated financial statements included in Item 15 of this Annual Report.

Diagnostics - Professional

The Company's InteliSwab® COVID-19 Rapid Test Pro and Rx products are primarily sold through distributors to U.S. hospitals, physician offices and clinics. These products are also marketed directly to customers in the public health market including clinics and laboratories of state, county and other governmental agencies.

The Company markets the OraQuick *ADVANCE*® HIV-1/2 antibody test directly to customers in the public health market for HIV testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other

governmental agencies, family planning clinics, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market, such as AIDS service organizations and various community-based organizations, that are set up primarily for the purpose of encouraging and enabling HIV testing. The Company sells its OraQuick *ADVANCE*® test to hospitals and physician offices in the U.S. primarily through distributors. In addition, the Company distributes its OraQuick® HIV test in certain foreign countries through distributors.

The OraQuick® HCV test is sold primarily to the same markets where the OraQuick *ADVANCE*® HIV test is sold, including public health organizations, hospitals, physicians and retail clinics. The Company also sells this test in other countries through distributors.

Diagnostics - OTC and Self-Test

The Company sells its InteliSwab® COVID-19 Rapid Test product in the U.S. retail and consumer markets, including for purchase by U.S. customers on Walmart's and Amazon’s online stores. The OTC InteliSwab® test is also sold directly and through distributors into a broad range of business-to-business (B2B) markets including employer testing, colleges and universities, local, state and federal governmental agencies and the U.S. military.

The Company sells its OraQuick® In-Home HIV test in the U.S. retail or consumer market as well as to the same markets as the OraQuick *ADVANCE*® test for use in public health-oriented programs. The product is also available for purchase online through certain retailers and from the Company's website, www.oraquick.com. The Company also sells its OraQuick® HIV Self-Test in certain international markets.

The Company's OraQuick® HIV Self-Test is the only oral fluid HIV test prequalified by the WHO. WHO prequalification helps ensure that diagnostic tests for high burden diseases meet global standards of quality, safety, and efficacy in order to optimize use of health resources and improve health outcomes. WHO prequalification enables governmental organizations implementing HIV Self-Test pilots and programs to access international funding to purchase the Company's test.

Substance Abuse Testing

The Company's substance abuse testing products are marketed to laboratories serving the workplace testing, forensic toxicology, criminal justice and drug rehabilitation markets in the U.S. and certain international markets.

The Company has entered into agreements for the distribution of its Intercept® collection device and associated MICRO-PLATE assays for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors and internationally for workplace, criminal justice and forensic toxicology testing through other distributors. The Company also markets the Intercept® collection device on its own and as a kit in combination with laboratory testing services. To better serve its workplace customers, the Company has contracted with commercial laboratories to provide prepackaged Intercept® test kits, with prepaid laboratory testing and specimen shipping costs included.

The criminal justice market in the United States for the Company's substance abuse testing products consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation offices, police forces, drug courts, prisons, drug treatment programs and community/family service programs. The forensic toxicology market consists of several hundred laboratories including federal, state and county crime laboratories, medical examiner laboratories and reference laboratories.

The Company also sells its next generation Intercept i2® *he* collection device with a panel of fully-automated high-throughput oral fluid assays developed with Thermo Fisher Scientific for the detection of PCP, THC, opiates, cocaine, methamphetamines, amphetamines, barbiturates, benzodiazepines, methadone and oxycodone. These products are currently sold as forensic use only into the criminal justice and drug treatment markets.

The Company distributes its Q.E.D.® saliva alcohol test primarily through various distributors in the United States and internationally. The markets for alcohol testing are relatively small and fragmented with a broad range of legal and procedural barriers to entry. Markets range from law enforcement testing to workplace testing of employees in safety sensitive occupations. Typical usage situations include pre-employment, random, post-accident, reasonable-cause and return-to-duty testing.

Molecular Sample Management Solutions and Molecular Services

The Company's sample management products are sold directly to customers, primarily through its internal sales force in U.S. markets. However, in many international markets, distributors are used.

Most of the Company's revenues from sample management products are derived from sales to commercial customers and sales into the academic and research markets. The Company's commercial customers provide consumer genetics and clinical diagnostic services and account for a majority of these revenues. A significant portion of total sales are derived from repeat customers in both markets. The Company also has customers in the livestock, companion animal and pharmaceutical markets.

The Company has expanded the market focus of its sample management products by selling certain existing collection products for use in infectious disease testing, including by developing new collection devices for the emerging microbiome market, which is focused on the study of microbial communities and their effect on human health. The Company's primary product offering in the microbiome market, OMNIgene®•GUT, is focused on the human gut microbiome (microbes living in human stool). The Company is leveraging its existing sales force and global research connections to engage microbiome customers around the world and establish itself as among the leaders in ease-of-collection, stabilization and transport of microbiome communities in a variety of challenging sample types such as stool, skin, vaginal and oral.

The Company's products include the Colli-Pee® device, a product developed and sold by its Novosanis subsidiary, for the volumetric collection of first void urine. This product is in its early stages and initial sales are occurring primarily through distributors and collaborations for use in the liquid biopsy and sexually transmitted disease markets. The Colli-Pee® collection device is is registered as a class 1 urine collection device without a claim for preservative. The Colli-Pee® collection device with preservative solution does not have FDA clearance and is labeled “For Research Use Only” in the U.S.

The Company also offers laboratory and analytical services for both genomics and microbiome customers in order to more fully meet the needs of customers. These services are primarily provided to pharmaceutical and biotech companies and research institutions.

Significant Products and Customers

Several different product lines have contributed significantly to the Company's financial performance, accounting for 10% or more of its total revenues during the past three years. The table below shows a breakdown of those product lines (dollars in thousands):

	For the Years Ended December 31,		
	2023	2022	2021
InteliSwab®	$ 257,493	$ 233,666	$ 22,405
Genomics	47,005	54,335	63,350
OraQuick® HIV	60,823	38,812	42,144
COVID-19 collection kits	286	9,659	54,167

One customer accounted for approximately 63% of the Company's consolidated net revenues for the year ended December 31, 2023 and 58% for the year ended December 31, 2022. No other individual customers accounted for more than 10% of the Company's consolidated net revenues for the years ended December 31, 2023 and 2022. The Company had no customers that accounted for more than 10% of consolidated net revenues for the year ended December 31, 2021.

Supply and Manufacturing

The Company manufactures its OraQuick *ADVANCE*® Rapid HIV test, OraQuick® In-Home HIV test, OraQuick® HCV test, OraQuick® Ebola test, OraSure®, Intercept® and Intercept i2® *he* collection devices, AUTO-LYTE® and MICRO-PLATE assays and Q.E.D.® saliva alcohol test in its Bethlehem, Pennsylvania facilities. The Company expects to continue to manufacture these products at this location for the foreseeable future.

The Company has contracted with a third party in Thailand for the assembly of the OraQuick® Rapid HIV test and the OraQuick® HIV Self-Test in order to supply certain international markets. The Company believes that other firms would be

able to assemble these OraQuick® tests on terms no less favorable than those set forth in the agreement if the Thailand contractor would be unable or unwilling to continue assembling this product. The Company has long-term agreements in place for the contract manufacturing in Thailand and one of its suppliers, which has been pre-qualified by the WHO, has been manufacturing for the Company for the past 20 years.

The Company can purchase the HIV antigens, the nitrocellulose and certain other critical components, and the HCV and Ebola antigens used in its OraQuick® product lines only from a limited number of sources. If for any reason these suppliers are unwilling or no longer able to supply the Company's antigen or nitrocellulose needs, the Company believes that alternative supplies could be obtained at a competitive cost. However, a change in any of the antigens, the nitrocellulose or other critical components used in the Company's products would require FDA approval and some additional development work. This in turn could require significant time to complete, increase costs and disrupt the Company's ability to manufacture and sell the affected products.

The Company manufactures all of the proprietary chemistry and assay cards for its InteliSwab® COVID-19 Rapid Tests in its Bethlehem, Pennsylvania facilities. The Company significantly scaled up manufacturing capacity in the United States for its InteliSwab® COVID-19 Rapid Tests and has achieved manufacturing capacity targets under its 2021 contract with the U.S. DOD, in coordination with HHS. All milestones under this contract have been achieved and the Company received corresponding milestone payments in 2023. The Company's Opus Way facility was customized to accommodate increased manufacturing capacity. Throughout 2023, the Company made progress on consolidating its manufacturing footprint by using the Opus Way facility for a more significant portion of its manufacturing and distribution needs, including re-shoring of capacity to the United States. One Pennsylvania facility was eliminated from the Company's sites.

The Company's MICRO-PLATE and AUTO-LYTE® assays require the production of highly specific and sensitive antibodies corresponding to the analyte of interest. Substantially all the Company's antibody raw materials are provided by contract suppliers. The Company believes that it has adequate reserves of antibody supplies and that it has access to sufficient raw materials for these products.

The fully-automated high-throughput oral fluid drug assays sold with the Company's new Intercept i2®*he* collection device are manufactured and supplied under a long-term agreement with Thermo Fisher Scientific. There is no other supply source for these products.

DNAG has three long-term contract manufacturing relationships to supply virtually all of its products, including the Oragene® product line. Many of the raw materials and components used in these products are also purchased from third parties, some of which are purchased from a single source supplier. The Company is actively seeking to qualify other suppliers that can manufacture and supply the raw materials and components for the DNAG products. All DNAG products are produced in Canada.

The Company's Colli-Pee® device is currently being manufactured in Canada by its existing contract manufacturers with components supplied by third party vendors.

The Company's genomic, microbiome and metatranscriptomics laboratory testing and analytical services are provided by its subsidiary, Diversigen.

Human Capital Resources

In order to achieve the Company's goals and expectations, it is crucial that it continues to attract and retain top talent. To facilitate talent attraction and retention, the Company strives to be a safe and rewarding workplace with opportunities for its employees to grow and develop in their careers.

As of December 31, 2023, the Company had 638 full-time employees, which compares to 840 employees as of December 31, 2022. The decrease in employees during 2023 was primarily the result of the need to reduce manufacturing capacity for the Company's InteliSwab® COVID-19 Rapid Test. In February 2023, the Company announced an 11% reduction in its non-production workforce. The Company's employees are not currently represented by a U.S. collective bargaining agreement.

The Company believes its employees are among its most important resources and are critical to its continued success. The Company focuses significant attention on attracting and retaining talented and experienced individuals to manage and support its operations, and its management team routinely reviews employee turnover rates at various levels of the

organization. Management also reviews employee engagement and satisfaction surveys to monitor employee morale and receive feedback on a variety of issues.

The health and safety of the Company's workforce is fundamental to the success of its business. The Company safeguards its people, projects and reputation by striving for zero employee injuries and illnesses, while operating and delivering its work responsibly and sustainably. The Company provides its employees upfront and ongoing safety training to ensure that safety policies and procedures are effectively communicated and implemented. Personal protective equipment is provided to those employees where needed for the employee to safely perform their job function.

As part of its compensation philosophy, the Company believes that it must offer and maintain market competitive compensation and benefits programs for its employees in order to attract and retain superior talent. In addition to healthy base wages, additional programs include annual bonus opportunities, a Company matched 401(k) Plan or other savings plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, flexible work schedules, and employee assistance programs.

The OraSure family of companies is committed to creating and fostering an inclusive workplace that reflects and contributes to the global communities in which it does business and the customers and partners it serves. This includes all communities impacted by its corporate presence. The Company's management team and all of its employees are expected to exhibit and promote honest, ethical and respectful conduct in the workplace. All of the Company's employees must adhere to a Code of Business Conduct and Ethics that sets standards for appropriate behavior and includes required annual training on preventing, identifying, reporting and stopping any type of unlawful discrimination. The Company strives to recruit the best people for the job regardless of gender, ethnicity or other protected trait and it is Company policy to fully comply with all laws (domestic and foreign) applicable to discrimination in the workplace. The Company has an active "All Means You" council that strives to drive inclusion and belonging within the workplace. OraSure believes a variety of perspectives are critical to achieving success, and that inclusion and belonging are key drivers to growth-based innovation and profitability. The Company aims to create a culture where all people feel valued, supported, and inspired to be themselves fearlessly, without judgment. The Company believes that when all voices are heard, it honors and exemplifies its core values and best serves its communities.

Competition

The diagnostic industry is a multi-billion dollar international industry and is intensely competitive. Many of the Company's competitors are substantially larger than the Company, and have greater financial, research, manufacturing and marketing resources. The Company has many rapid tests with proprietary features enabling them to compete effectively in select market segments. Broadly, the Company differentiates based on its tests' ease of use, which has enabled it to expand its self-testing offering.

The primary competitive factors for the Company's products include price, quality, performance, ease of use, customer service and reputation. Industry competition is based on these and the following additional factors:

- Scientific and technological capability;
- Proprietary know-how;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other regulatory approvals;
- The ability to manufacture products that meet applicable FDA or other applicable regulatory requirements;
- Commercial execution and strength of distribution;
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented. This enables the Company to serve specific segments where the products provide a unique benefit.

The future market for diagnostic products is expected to be characterized by greater cost consciousness, the development of new technologies, tighter reimbursement policies and consolidation. The purchasers of diagnostic products are expected to place increased emphasis on lowering costs, reducing inventory levels, obtaining better performing products, automation, service and volume discounts.

The Company expects competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render the Company's products impractical, uneconomical or obsolete. There can be no assurance that the Company's competitors will not succeed in developing or marketing technologies and products that are more effective than those it develops or that would render its technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that the Company's competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them, before the Company can do so. These developments could have a material adverse effect on the Company's business, financial condition and results of operations.

Competition in the U.S. market for infectious disease testing in medical settings is intense and is expected to increase. The Company's principal competition for HIV testing in the professional market comes from existing and new professional point-of-care rapid blood tests and automated laboratory-based blood tests. The Company's OraQuick *ADVANCE*® rapid HIV test is the only OTC oral fluid test for HIV in the United States, and as such, enables outreach testing outside of clinics. The Company's OraQuick® rapid HCV test competes against laboratory-based blood tests in the U.S., as there currently are no other rapid HCV testing products approved by the FDA.

The Company's OraQuick® In-Home HIV oral fluid test is the only rapid HIV test approved by the FDA for sale in the U.S. OTC market.

Outside the U.S., the Company's rapid HIV and HCV tests compete against other rapid and laboratory-based tests, which require blood as a sample. The majority of these blood-based tests are priced at or below OraSure's HIV and HCV rapid oral fluid tests. There are no other oral fluid tests for HCV outside the U.S. with WHO Prequalification status and the CE mark. The majority of the Company's sales outside the U.S. are in Africa due to the greater incidence of HIV in that region. The Company's OraQuick® HIV Self-Test is CE marked, which enables it to participate in the European OTC market for HIV.

The United States COVID-19 rapid testing market consists of tests used by medical professionals at the point-of-care as well as OTC tests purchased and used by consumers. There are numerous professional point-of-care tests, OTC Antigen rapid tests and OTC rapid molecular tests authorized under EUA by the FDA. The Company's InteliSwab® test competes in both the professional point-of-care and OTC segments with these products.

In the substance abuse testing market, the Company's Intercept® drug testing system competes with laboratory-based drug testing products using sample matrices such as urine, hair, sweat and oral fluid. The Company expects competition for its products to intensify, particularly from other domestic and international companies that have developed, or may develop, competing oral fluid drug testing products.

The Company's MICRO-PLATE oral fluid drug assays, which are sold for use with the original Intercept® collector and the OraSure® collection device, also continue to come under increasing competitive pressure from “home-brew” assays developed internally by the Company's laboratory customers. The Company's oral fluid MICRO-PLATE assays also compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers.

The Company's MICRO-PLATE drugs-of-abuse reagents sold in the forensic toxicology market are targeted to forensic testing laboratories where sensitivity, automation and “system solutions” are important. The Company competes with both homogeneous and heterogeneous tests manufactured by many companies.

Q.E.D.® competes against other semi-quantitative saliva-based alcohol tests that have received U.S. Department of Transportation approval as well as breath alcohol tests. Although there are lower priced tests on the market that use oral fluid or breath as a test medium, the Company believes that these tests are qualitative tests that are lower in quality and provide fewer benefits than OraSure's Q.E.D.® test.

The Company's Oragene® and ORAcollect® collection systems compete against other types of collection devices used for molecular testing, such as blood collection devices and buccal swabs, which often are sold for prices lower than the prices charged for the Oragene® and ORAcollect® products. Although the Company believes the Oragene® and ORAcollect®

devices offer a number of advantages over these other products, the availability of lower price competitive devices can result in lost sales and degradation in pricing and profit margin. The Company's Oragene® and ORAcollect® products are also facing increasing competition from similarly designed collection systems which are beginning to enter the market.

OMNIgene®•GUT is being sold in the emerging microbiome market and competes with a variety of non-standard in-house solutions developed by various researchers, including simply freezing the sample after collection. The microbiome market is expected to require standardization in the methods used for collection and stabilization in order to derive more accurate and repeatable results. To date, the Company is one of the few vendors to offer a solution that fully meets these requirements.

The Company's genomic, microbiome and metatranscriptomics laboratory service offerings primarily compete against a number of commercial reference laboratories, specialty laboratories and hospital laboratories in the U.S.

Patents and Proprietary Information

The Company seeks patents and other intellectual property rights to protect and preserve its proprietary technology and its right to capitalize on the results of its research and development activities. The Company also relies on trade secrets, know-how, continuing technological innovations and licensing opportunities to provide competitive advantages for its products in its markets and to accelerate new product introductions. The Company regularly searches for third-party patents in fields related to its business to shape its own patent and product commercialization strategies as effectively as possible and to identify licensing opportunities. United States patents generally have a maximum term of 20 years from the date an application is filed.

The Company has patents throughout its product and service lines. Its patent portfolio includes pending applications and issued patents in diagnostics and testing, sampling tools, and services and analysis. The Company's portfolio protects its innovative sampling tools, services and diagnostics that provide access to accurate, essential information that advances global health and well-being.

Diagnostics and testing products include the OraSure® and Intercept® collection devices that are covered by one utility and one design patent in each of the U.S., Canada, Japan, and throughout Europe. The Company has numerous foreign patents for its collection devices and technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluids, and methods to control the volume of oral fluids collected and dispersed. The utility patents will expire in January 2028, and the design patents will expire in 2025.

Sampling tools are the subject of several other patents and pending applications, including U.S. and international utility patent applications directed to a new oral fluid collection device. The international applications entered their national phase in countries throughout the world beginning in October 2023. Patents issuing from these applications will expire in March 2041.

The Company has U.S. and international PCT patent applications that are directed to a new developer solution vial for use with sampling and assay devices. The international application entered its national phase in countries throughout the world in May 2023 and patents issuing from these applications will expire in December 2041. Related design patent applications are pending in the U.S., Canada, and Europe.

The Company has additional pending applications directed to new direct sample collection pads for its InteliSwab® COVID-19 Rapid Test. These applications entered their national phase in countries throughout the world in October 2023, and patents issuing from these applications will expire in December 2042. A related design patent issued in 2022 in the U.S. and corresponding design applications were registered in Canada, China, India, and Europe. These design patents will expire 2035.

The Company has registered design patents for a collection funnel and corresponding plunger device in Europe, China, and India and a corresponding U.S. design patent application is pending.

The Company has pending patent applications throughout its product and service lines directed to assays, methods, devices, and reagents for monitoring adherence to HIV medications, such as nucleoside reverse transcriptase inhibitors used in PrEP regimens.

The Company has two international families of patent applications filed in the United States and in numerous countries worldwide. These applications are directed to novel nucleoside reverse transcriptase inhibitor-specific antibodies for use in assays to detect the presence of nucleoside reverse transcriptase inhibitor drug derivatives, including tenofovir, in fluid samples. Patents issuing from these applications will expire in October 2038 and December 2040.

The Company holds, through its subsidiary, DNAG, thirty granted United States patents and numerous foreign patents issued for compositions, methods and apparatuses for the collection, stabilization, transportation, and storage of nucleic acids (DNA and RNA) from oral fluid and other bodily fluids and tissues. Certain patents expired in June 2023, and others will expire through October 2037.

The Company holds through its subsidiary, Novosanis, one granted United States patent and numerous foreign patents covering a medical device for capturing a predetermined volume of first void urine. This patent expires in September 2033. The Company has also applied for additional patents, in both the United States and certain foreign countries, in novel urine collection devices.

The Company's subsidiary, Diversigen, has licensed one United States patent and several foreign patent applications from the University of Minnesota for analytical standards to detect and/or measure sampling, processing, and/or amplification errors in a biological sample containing polynucleotide molecules. These patents will expire in May 2036. This license also covers certain software and know-how related to laboratory and bioinformatics procedures and processes. Diversigen has also licensed certain know-how and database assets from the Baylor College of Medicine related to laboratory processes for microbiome and metagenomics services.

The Company requires its employees, consultants, outside collaborators and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information developed by or made known to the individual during the course of the individual’s relationship with the Company is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and certain consultants, the agreements also provide that all inventions conceived by the individual during his or her tenure with the Company or the performance by the consultant of services for the Company will be OraSure's exclusive property.

The Company owns rights to trademarks and service marks that it believes are necessary to conduct its business as currently operated. In the United States, the Company owns a number of trademarks, including the OraSure®, Intercept®, Intercept i2®*he,* Intercept i2*he*®, OraQuick®, OraQuick ADVANCE®, ORASURE QUICKFLU®, SUREQUICK®, Q.E.D.®, InteliSwab®, Oragene®, DNA Genotek®, OMNImet®, ORAcollect®, OMNIgene®, Diversigen®, CoreBiome®, Boostershot®, MetaGene®, Benchmark™, Novosanis®, Colli-Pee®, UCM®, UAS™, THINK OUTSIDE THE CUP®, AUTO-LYTE®, prepIT®, and HEMAgene® trademarks. The Company also owns many of these marks and others in several foreign countries and it is pursuing registration of several other trademarks.

Although important, the issuance of a patent or existence of trademark or trade secret protection does not in itself ensure the success of the Company's business. Competitors may be able to produce products competing with the Company's patented products without infringing its patent rights. Issuance of a patent in one country generally does not prevent manufacture or sale of the patented product in other countries. The issuance of a patent is not conclusive as to validity or as to the enforceable scope of the patent. The validity or enforceability of a patent or trademark can be challenged by litigation after its issuance or registration. If the outcome of such litigation is adverse to the owner of the patent, the owner’s rights could be diminished or withdrawn. Trade secret protection does not prevent independent discovery and exploitation of the secret product or technique.

Government Regulation

General

Most of the Company's products are regulated by the FDA, along with other federal, state and local agencies and comparable regulatory bodies in other countries. This regulated environment governs almost all aspects of development, production and marketing, including product design and testing, authorizations to market, labeling, advertising and promotion, manufacturing, distribution, post-market surveillance and reporting, and recordkeeping. The Company believes that its products and procedures are in material compliance with all applicable regulations, but the regulations regarding the manufacture and sale of its products may be unclear and are subject to change. The Company cannot predict the effect, if any, that these changes might have on its business, financial condition or results of operations.

Many of the Company's FDA-regulated products require some form of review and action by the FDA before they can be marketed in the United States. After approval or clearance by the FDA, the Company must continue to comply with other FDA requirements applicable to marketed products and is subject to periodic inspections by the FDA and other regulatory bodies. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties or could disrupt the Company's ability to manufacture and sell these products. In addition, the FDA could refuse permission to obtain certificates needed to export the Company's products if the agency determines that it is not in compliance.

Domestic Regulation

Most of the Company's products are regulated in the United States as in vitro diagnostic and medical devices. In the United States, devices are classified into three groups based on risk: class I (lowest risk), class II (moderate risk), and class III (highest risk). The classification of a device determines the level of regulation applicable to the device: class I devices are subject only to the general controls that are applicable to all regulated devices; class II devices are subject to both general controls and special controls, which are specific to the type of device; and class III devices are subject to general controls and any other controls that are needed to provide reasonable assurance of the safety and effectiveness of the specific device.

The classification of the device also influences the type of premarket submission that is required before the device can be marketed. Some low risk devices (including many class I and some class II devices) may be placed on the market without any premarket submission. Such devices often are referred to as "exempt" or "510(k)-exempt." Most devices, however, require some form of premarket submission prior to marketing. There are several mechanisms by which such devices can be placed on the market in the United States, including 510(k)-clearance, De Novo classification, premarket approval, or EUA.

Many class II devices and some class I devices may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act (the "FDCA"). To obtain this clearance from the FDA, the manufacturer must submit to the FDA a premarket notification that it intends to begin marketing the product, and show that the product is substantially equivalent to another legally marketed predicate device (i.e., a device that has been cleared through the 510(k) process; a device that was legally marketed prior to May 28, 1976; a device that has been reclassified by the FDA; or a device that the FDA previously has determined to be exempt from the 510(k) process). To be substantially equivalent, an applicant must show that when compared to a predicate, the new device has the same intended use and same technology, or if different technology, that the new device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness. In all cases, data from some form of performance testing is required and in some cases, the submission must include data from human clinical studies. An applicant must submit a 510(k) notification at least 90 days before commercial distribution of the product commences. Marketing may only commence when the FDA issues a clearance letter finding that the new device is substantially equivalent to the predicate device. The standards and data requirements necessary for the clearance of a new device may be unclear or may be subject to change. Although FDA clearance usually takes from four to twelve months, in some cases more than a year may be required before clearance is obtained, if at all.

If the device does not qualify for the 510(k) procedure, either because there is no existing predicate device, it is not substantially equivalent to a legally marketed predicate device or because it is classified by the FDA as a class III device, the FDA must approve either a PMA application or for devices that are low to moderate risk, grant a request for De Novo classification before marketing can begin. A De Novo classification is an alternate pathway to classify novel devices of low to moderate risk for which no substantially equivalent predicate device exists into class I or class II. The FDA's goal is to decide a De Novo request in 150 days from the time the request is received, although it can take longer.

PMAs generally are required for class III devices, i.e., high risk devices, and must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness for the intended use(s) of the device. A PMA is typically a complex submission, supported by valid scientific evidence, including the results of preclinical and clinical studies, usability data, detailed information about the manufacturing process for the device, and other data and information. Preparing a PMA is a resource-intensive and time-consuming process. Once a PMA has been submitted, the FDA is required to review the submission within 180 days. However, the FDA's review may be, and often is, much longer, in many cases requiring one to three years or more, and may include requests for additional data, review by an independent panel of experts, and facility inspections before approval is granted, if at all.

If the FDA approves the PMA, it may place restrictions on the device. If the FDA's evaluation of the PMA or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a "not approvable"

letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years or prevent a PMA approval from being obtained.

If the FDA discovers that an applicant has submitted false or misleading information in any application or notification, the FDA may take action against the applicant and its employees or refuse to review submissions until certain requirements are met pursuant to its Application Integrity Policy. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

Another option for marketing a product in the U.S. is through an EUA. The FDA may grant an EUA for a product if the Secretary of Health and Human Services declares that circumstances exist justifying the authorization of emergency use of certain products. Such declaration may be made, amongst other reasons, following a determination by the Secretary of Health and Human Services that there is a public health emergency or a significant potential for a public health emergency, by the Secretary of Homeland Security that there is a domestic emergency, or by the Secretary of Defense that there is a military emergency, or the declaration may be made if a material threat is identified under a particular provision of the Public Health Service Act. Typically, a diagnostic device may receive EUA-authorization on the basis of analytical and clinical studies that do not satisfy the requirements for full clearance or approval. Devices also may be exempt from design controls and other quality requirements. An EUA for a device remains in effect until the Secretary of Health and Human Services, in consultation with the Secretary of Defense, determines that the circumstances justifying emergency use of the device no longer exist, or until the authorized device is approved or cleared.

If there are any modifications made to the Company's marketed devices, a new premarket notification, PMA supplement, or request to change an EUA may be required to be submitted to, and cleared, approved, or authorized by, the FDA, before the modified device may be marketed.

A new PMA or a PMA supplement is required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device’s intended use(s), manufacturing process, manufacturing facility, critical components, labeling and design. Likewise, a new 510(k) clearance is required for any modification that could significantly affect the safety or effectiveness of the device, e.g. a significant change or modification in design, material, chemical composition, energy source, or manufacturing process or a major change or modification in the intended use(s) of the device.

A clinical trial may be required in support of a 510(k) submission and generally is required for a De Novo request or PMA application. These trials generally require an approved application for an Investigational Device Exemption (“IDE”) and compliance with other IDE requirements, unless the proposed study is deemed to be exempt from the IDE requirements. An IDE application must be supported by appropriate data, such as laboratory testing results, protocols for the proposed investigation, and other information demonstrating that the device is appropriate for use with humans in a clinical study. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Submission of an IDE application does not give assurance that the FDA will issue the IDE. If the IDE application is approved, there can be no assurance the FDA will determine that the data derived from the trial(s) support the ultimate approval or clearance of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan in such a way that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial must also comply with the FDA’s regulations, including the requirement that informed consent be obtained from each subject, and with clinical trial reporting regulations that require submission of information on certain clinical trials to a database maintained by the National Institutes of Health. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance to market the product in the United States. If a study meets the requirements for a non-significant risk study, however, it may be eligible for compliance with “abbreviated” IDE requirements, which include a subset of the requirements applicable to significant risk medical device studies. A non-significant risk study also will be considered to have an approved IDE application without such application actually being submitted to FDA.

Some of the Company's products are used for research only or for other nonclinical or non-diagnostic purposes. The Company's molecular sample management solutions are sold to many academic and research institutions for research purposes and the Company's drugs-of-abuse products are sold to laboratories and clinics for forensic or other non-medical uses. The FDA does not currently regulate products used for these purposes, although other state and federal regulatory requirements may apply.

Most devices distributed in the United States must comply with the FDA's Quality System Regulations ("QSRs"), including current good manufacturing practices. These regulations govern the entire life cycle of a medical device, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing as well as complaint handling, corrective and preventative actions, and internal auditing. In complying with the QSRs, manufacturers must continue to expend time, money and effort in the area of production, quality, and post-market surveillance to ensure full compliance.

Companies that market devices are also subject to other post-market and general requirements, including product listing and establishment regulations, which help facilitate FDA inspections and other regulatory action, post-market surveillance requests, restrictions imposed on marketed products, promotional standards and requirements for recordkeeping and reporting of certain adverse reactions and device malfunctions. Device reporting regulations require that manufacturers report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur.

The FDA regularly inspects companies to determine compliance with the QSRs and other post-market requirements. Failure to comply with statutory requirements and the FDA's regulations can result in an FDA Form 483 (which is issued by the FDA at the conclusion of an inspection when an investigator has observed any conditions that may constitute violations), public warning letters, monetary penalties against a company or its officers and employees, suspension or withdrawal of regulatory approvals, operating restrictions, total or partial suspension of production, injunctions, product recalls, product detentions, refusal to provide export certificates, seizure of products and criminal prosecution.

In February 2024, the FDA issued the Quality Management System Regulation ("QMSR") Final Rule to amend the QSR, incorporating by reference the international standard for medical device quality management systems set by the International Organization for Standardization ("ISO"), ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required to comply with the QSR. The Company believes that its facilities and procedures are in material compliance with the FDA's OSR regulations, the European Union's Quality Management Systems requirements, ISO 13485:2016, and other post-market requirements, but the regulations are subject to change or may be unclear, and the Company cannot be sure that FDA investigators will agree with the Company's compliance with the FDA's post-market requirements.

CLIA prohibits any facility that conducts laboratory testing on specimens derived from humans from providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings, unless there is in effect for such facility a certificate issued by the U.S. Department of Health and Human Services or an accredited organization, and such certificate is applicable to the category of examination or procedure performed. Tests may be categorized as "waived," enabling them to be used by laboratories with the lowest level of CLIA oversight if the tests meet certain requirements established under CLIA. The Company considers the applicability of CLIA requirements in the design and development of its products. The Company has obtained a waiver of the CLIA requirements for its OraQuick ADVANCE® rapid HIV-1/2 antibody test, its OraQuick® HCV rapid antibody test and its Q.E.D.® alcohol saliva test and may seek similar waivers for certain other products. In addition, the supplier of the OraSure Quick-Flu® test has obtained a CLIA waiver for that product. The InteliSwab® COVID-19 Rapid Test Pro is authorized for use in patient care settings operating under CLIA Certificate, Certificate of Compliance and Certificate of Accreditation.

The laboratory services provided by the Company's subsidiary, Diversigen, consist of microbiome, metatranscriptomics and metagenomics sequencing, bioinformatics and analysis. Diversigen has elected to obtain a license from CLIA and has received a certificate of accreditation from the College of American Pathologists (CAP).

Certain of the Company's products may also be affected by state regulations in the United States, which can restrict the use and sale of certain diagnostic products.

Advertising and Promotion

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by other federal and state regulatory and enforcement authorities, including the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and various state attorneys general. Although physicians are permitted to exercise medical judgment to use medical devices for indications other than those cleared or approved by the FDA, the Company may not promote its products for such "off-label" uses and can only market its products for cleared or approved uses. Promotional activities for FDA-regulated products of other companies have also been the subject of enforcement actions brought under healthcare reimbursement laws and consumer protection

statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that the Company's promotional materials or training constitute promotion of an uncleared or unapproved use, it could request that the Company modify its training or promotional materials or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a notice of violation, a warning letter, injunction, seizure, civil fine or criminal penalties. Federal Trade Commission enforcement actions often result in consent decrees that constrain future actions. Department of Justice prosecutions can result in significant criminal and civil penalties, including exclusion from the Medicare and Medicaid programs. If an enforcement action is brought by the FDA or Federal Trade Commission, the Company's reputation could be damaged and sales of its products could be impaired.

Import and Export Requirements

Products for export from the United States are subject to foreign countries' import requirements and the exporting requirements of the FDA, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate for Foreign Government ("CFG"). To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with QSR regulations at the time of the last FDA inspection. If the FDA determines that the Company's facilities or procedures do not comply with the QSR regulations, it may refuse to provide such certificates until the Company resolves the issues to the FDA's satisfaction. Failure to obtain a CFG could inhibit the Company's ability to export its products to countries that require such certificates.

International

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval (or pre-qualification or endorsement) from local regulators in such countries or international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. The Company generally pursues approval only in those countries that the Company believes have a significant market opportunity.

The International Organization for Standardization ("ISO") is a worldwide federation of national standards bodies. ISO 13485 certification indicates that the Company's quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution.

The EU Medical Devices Regulation (EU) 2017/745 (the "EU MDR") and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/74 (the "EU IVDR"), which repealed and replaced the Medical Devices Directive 93/42/EEC ("MDD") and the In Vitro Diagnostic Medical Devices Directive 98/79/EC ("IVDD") respectively, govern the regulation of medical devices and in vitro diagnostic devices in the European Union ("EU"). The EU MDR and EU IVDR impose stricter pre-market and post-market requirements for the marketing and sale of medical devices and in vitro diagnostic medical devices than the previous Directives, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The EU IVDR became fully applicable on May 26, 2022. There is a transitional period during which products that have a declaration of conformity issued under the IVDD prior to May 26, 2022 may continue to be placed on the EU market for a certain period before requiring certification under the IVDR (subject to compliance with certain requirements under the IVDR, including in respect of post-market surveillance); however, class A non-sterile products do not benefit from such transitional provisions and have been required to be IVDR compliant since May 26, 2022, class D devices benefit from such transitional provisions until May 26, 2025. On January 23, 2024, the European Commission introduced a legislative proposal to extend such transitional provisions for certain devices. The European Commission has provided the legislative proposal to the European Parliament and the European Council for their review and approval. Once the European Commission's legislative proposal is approved (with or without amendment), it will be adopted into EU law.

In the EU, products that fall under the scope of the MDR and the IVDR may not be placed on the EU market without a valid CE mark. Approval of a regulatory authority is not required to obtain CE certification, but, depending on the class of product, conformity assessment by a notified body may be required. Notified bodies are accredited and supervised by

national regulatory authorities to conduct conformity assessment procedures of medical devices or other products. The conformity assessment procedure for medical devices and in vitro diagnostic devices is to assess whether the device is compliant with the general safety and performance requirements set forth in the EU MDR or EU IVDR (as applicable), and includes an examination of the product's technical dossier and the manufacturer's quality system. ISO certification of the quality system in accordance with the relevant standard for medical devices or in vitro diagnostic devices creates a rebuttable presumption that the product satisfies the applicable requirements of the EU MDR or EU IVDR (as applicable) with respect to the quality management system. Compliance with these general safety and performance requirements allows the Company to complete the applicable conformity assessment procedure, involving a notified body where necessary, and to affix the CE mark to its products, without which they may not be placed on the market in the EU. The Company also notes that from January 1, 2021, the United Kingdom ("UK") has introduced a UK-specific route to market for medical devices. Compliance with these requirements may add further complexities to the Company's international strategy.

The Company must also comply with certain registration and licensing requirements as dictated by Health Canada, prior to commencing sales in Canada. The Company has completed this process for several of its current products and may do so with respect to other products in the future. In addition, Canadian law requires manufacturers of medical devices to have a quality management system that meets various ISO requirements in order to obtain a license to sell their devices in Canada. Health Canada also requires all companies that market Class II, Class III and Class IV products in Canada to be certified as part of the Medical Device Single Audit Program ("MDSAP").

The Company has obtained WHO pre-qualification for its OraQuick® HIV-1/Antibody Test, OraQuick® HIV Self-Test and OraQuick® HCV.

Anti-Kickback and Other Fraud and Abuse Laws

The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for, or to induce:

- The referral of an individual to a person for the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental healthcare programs; or
- The purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable under Medicare, Medicaid, or other governmental healthcare programs.

The Company's products are or may be purchased by customers that will seek or receive reimbursement under Medicare, Medicaid or other governmental healthcare programs. Noncompliance with the Federal Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental healthcare programs, and/or restrictions on the Company's ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on the Company's business and results of operations.

The False Claims Act ("FCA") imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. A violation of the Federal Anti-Kickback Statute is considered a violation of the FCA. Some suits filed under the FCA, known as "qui tam" actions, can be brought by a "whistleblower" or "relator" on behalf of the government, and such individuals may share in any amounts paid by the entity to the government in fines or settlement. Manufacturers can be held liable under false claims laws, even if they do not submit.

The Beneficiary Inducement provisions of the Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil monetary penalties for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Many states have also adopted some form of anti-kickback laws and false claims laws. A determination of liability under such laws could result in fines and penalties, restrictions on the Company's ability to operate in these jurisdictions and significant damage to its reputation.

The Company is also subject to other federal and state laws targeting fraud and abuse in the healthcare industry, including marketing conduct laws, transparency laws, and laws that require the Company to adopt a compliance program. Taken

together, these fraud and abuse laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, such manufacturers can enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs such as Medicare and Medicaid. These laws and regulations are wide ranging and subject to changing interpretation and application. In recent years, there has been greater scrutiny of marketing practices in the medical device industry which has resulted in several government investigations by various government authorities and the introduction and/or passage of federal and state legislation regulating interactions between medical device manufacturers and healthcare professionals and providers and requiring the disclosure by medical device manufacturers of payments to certain healthcare providers. For example, under the Physician Payments Sunshine Act provisions of the Affordable Care Act, device manufacturers are subject to federal reporting and disclosure requirements with regard to payments or other transfers of value made to U.S. physicians, certain other licensed health care practitioners, and teaching hospitals. Reports submitted under the Sunshine Act are placed in a public database. Device manufacturers are required to submit annual reports by March 31 which cover the prior calendar year. To be in compliance with such disclosure laws, the Company has implemented necessary systems to accurately track gifts and other payments.

The Company has implemented a written Policy on Interactions with Health Care Professionals, which is based on the Code of Ethics for Interactions with Health Care Professionals promulgated by the Advanced Medical Technology Association, (the "AdvaMed"), a leading trade association representing medical device manufacturers. The Policy applies to all employees and is intended to comply with applicable state and federal laws, regulations and government guidance. The Policy addresses interactions related to sales and marketing practices, research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. While the Company believes that its practices are in compliance with the Anti-Kickback and other fraud and abuse laws, the standards for compliance with such statutes can be unclear and subject to change.

Foreign Corrupt Practices Act and Other Anti-Corruption Laws

The U.S. Foreign Corrupt Practices Act (“FCPA”), to which the Company is subject, prohibits corporations and individuals from engaging in bribery and corruption when dealing with foreign government officials and foreign political parties. It is illegal to corruptly offer, pay, promise, or authorize the giving of anything of value to any officer or employee of a foreign government or public international organization, political party, political party official, or political candidate, in an attempt to obtain or retain business or to otherwise improperly influence a person working in an official capacity on behalf of a foreign government or public international organization. The Company's present and future business has and will continue to be subject to the FCPA and various other laws, rules and/or regulations applicable to the Company as a result of its international sales. The Company is also subject to the FCPA’s accounting provisions, which require it to keep accurate books and records and to maintain a system of internal accounting controls sufficient to assure management’s control, authority, and responsibility over the Company's assets. The failure to comply with the FCPA and similar laws could result in civil or criminal sanctions or other adverse consequences.

The laws to which the Company is subject as a result of its international sales also includes the U.K. Bribery Act 2010 (the “Bribery Act”), which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

Environmental Regulation

Because of the nature of the Company's current and proposed research, development, and manufacturing processes, the Company is subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge and handling and disposal of solid wastes, hazardous materials and hazardous wastes. Products that the Company sells in Europe are subject to regulation in EU markets under the Directive on the Restriction of the Use of Certain Hazardous Substances (“RoHS”). RoHS prohibits companies from selling electrical and electronic equipment, such as electronic medical devices, that contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in the EU Member States. In addition, the EU’s Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals (“REACH”) imposes severe restrictions and requirements on companies marketing devices in the EU. Among other things, REACH requires companies to obtain prior authorization to use substances of very high concern that are listed for authorization, and imposes bans on the marketing of products that contain specifically listed hazardous substances. Companies marketing

medical devices in the EU may also be subject to expensive waste take back obligations under the EU Directive on Waste Electrical and Electronic Directive, the Packaging and Packaging Waste Directive, and the Batteries Directive.

Future environmental laws, rules, regulations or policies may require the Company to alter its manufacturing processes, thereby increasing its manufacturing costs, or may impose other additional obligations on the Company or its products. The Company believes that its products and manufacturing processes at its facilities comply in all material respects with applicable environmental laws and worker health and safety laws; however, the risk of environmental liabilities cannot be completely eliminated.

The foregoing discussion of the Company's business should be read in conjunction with the consolidated financial statements and accompanying notes included in Item 15 of this Annual Report.

Information Available on the Internet

The Company's filings with the Securities and Exchange Commission, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act are available on the Company's website (www.orasure.com) free of charge as soon as reasonably practicable after the Company electronically files such material with, or furnish it to, the SEC at its website (https://www.sec.gov). The information contained on the Company's website is not a part of this Annual Report.

ITEM 1A. Risk Factors

Summary of Risk Factors

Investing in the Company's securities involves risk. Below is a summary of the principal factors that could adversely affect OraSure's business, operations and financial results. You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report, including the Company's consolidated financial statements and related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, before investing in the Company. This summary does not address all of the risks that the Company faces. Additional discussion of the summarized risks can be found below following this summary.

Risks Relating to Products, Marketing and Sales

- Changes in the genomics market may adversely affect the Company's business.
- The Company's future success depends upon market acceptance of its existing and future products and service offerings.
- The Company may not realize revenue levels from its InteliSwab® COVID-19 Rapid Test consistent with prior years.
- The COVID-19 pandemic continues to cast uncertainty over the Company's consolidated results of operations, financial position and cash flows, while the consequences of COVID-19 and the governmental response to contain the pandemic and pandemic-related macroeconomic impacts could negatively affect the Company's operations and share price.
- Marketing of the Company's COVID-19 tests and collection kits under EUAs from the FDA is subject to certain limitations and it is required to maintain compliance with the terms of the EUA, among other things, and the continuance of the EUAs is subject to government discretion.
- If acceptance and adoption of oral fluid testing and collection products does not continue, the Company's future results may suffer.
- The Company expects to face increasing competition from other providers of diagnostic tests, sample collection products and molecular laboratory services.
- The Company's inability to expand international sales could adversely affect its business and results of operations.
- The Company's international presence may increase its risks and expose its business to regulatory, cultural or other restraints.
- The Company's U.S. government contracts require compliance with numerous laws and increase its risk and liability.
- The Company's inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect its business.
- The Company's business will suffer if it does not effectively manage challenges to its manufacturing processes and it may be unable to successfully scale-up manufacturing of its products in sufficient quality and quantity to meet demand, which would negatively impact revenue expectations.

Risks Relating to the Company's Industry, Business and Strategy

- Consolidation in the healthcare industry could adversely affect the Company's future revenues and operating results.
- The Company's research, development and commercialization efforts may not succeed and its competitors may develop and commercialize more effective or successful offerings.
- Customer concentration creates risk for the Company's business.
- Acquisitions or investments may not generate the expected benefits and could disrupt the Company's ongoing business, distract its management, increase its expenses and adversely affect its business.

Risks Relating to the Company's Reliance on Third Parties

- The use of third party supply sources for critical components of the Company's products could adversely affect its business.
- The Company's failure to maintain existing distribution channels, or develop new distribution channels, may result in lower revenues.

Risks Relating to Intellectual Property

- The Company's success depends on its ability to protect its proprietary technology.
- The Company may become involved in intellectual property disputes, which could increase its costs and limit or eliminate its ability to sell products, provide services or use certain technologies.

Regulatory Risks

- The need to obtain regulatory approvals, clearances, authorizations or certifications could increase the Company's costs and adversely affect its financial performance.
- Failure to comply with FDA or other regulatory requirements may require the Company to suspend production or sale of its products or institute a recall which could result in higher costs and loss of revenues.
- The Company is subject to numerous government regulations in addition to FDA requirements, which could increase its costs and affect its operations.
- Failure to comply with privacy, security and breach notification regulations may increase our costs.
- Failure to comply with data protection requirements or privacy laws could increase our costs.

Risks Relating to the Economy, Company Financial Results, Investments, Credit Facilities and Need for Financing

- The Company has experienced losses in the past and may not be able to again achieve and maintain profitable operations.

Risks Relating to the Company's Common Stock

- The Company's stock price could continue to be volatile.

General Risk Factors

- Cybersecurity incidents and other disruptions could compromise the company's information, expose it to liability and harm its reputation and business.

Risk Factors

You should carefully consider the risks and uncertainties described below. The risks and uncertainties described below are not the only ones facing the Company. Additional risks and uncertainties not disclosed or not presently known to the Company or that it currently deems immaterial may also impair its business operations. The occurrence of any of the following risks could harm the Company's business, financial condition or results of operations.

Risks Relating to Products, Marketing and Sales

Changes in the Genomics Market May Adversely Affect the Company's Business.

The genomics market has been the largest component of the Company's overall molecular sample management solutions business for some time and the major drivers of this market have been the consumer genomics segment, which offers products and services to consumers to provide them with personalized health and genealogical information, and the disease risk management segment which offers genetic testing through physicians for a variety of applications including prenatal testing, risk screening and pharmacogenomics. The ancestry portion of the consumer genomics market may be maturing and the Company's sales to customers with offerings in this market have been volatile. The Company's genomics revenues have also been volatile due to changes in promotional strategies and purchasing patterns by certain customers which serve

the consumer ancestry and genetic testing market and cost cutting and de-stocking efforts at some of the Company's disease risk management customers. These trends in the ancestry testing market may continue and revenues in this market may continue to be volatile.

In an effort to increase the Company's molecular revenues, it has devoted increasing time and attention to expanding sales of its genomics products both domestically and internationally, with both new and existing accounts, including co-clearances and co-promotions with strategic partners. While the Company believes these new markets represent large growth opportunities, there is no assurance that it will be successful in capitalizing on these opportunities or that it will be able to increase the Company's product sales consistent with the Company's expectations. Factors include, but are not limited to, the market acceptance of the Company's products, available funding, cost containment strategies implemented by customers, increasing competition and regulatory constraints could limit sales of the Company's genomics products. To the extent that the Company is unsuccessful or limited in expanding the its business into new markets, the Company's revenues and results of operations could be negatively affected.

Despite these challenges, the Company believes there is significant growth opportunity for its genomics products in the area of research by biotechnology companies, animal genetics, and disease risk management, which includes genetic risk testing, prenatal testing, carrier screening, pharmacogenomics testing and population heath studies.

The Company's Future Success Depends Upon Market Acceptance of its Existing and Future Products and Service Offerings.

The Company's future success will depend, in part, on the market acceptance, and the timing of such acceptance, of products such as InteliSwab®, OraQuick® HIV Self-Test, OraQuick® Ebola test and OMNIgene® • GUT product offerings, and other new products or technologies that may be developed or acquired. In addition, the Company's future revenues will depend on market acceptance of new uses for the Company's saliva collection products, including for COVID-19 testing, and the Company's new service offerings, such as the microbiome laboratory testing and analytical services it provides through Diversigen. To commercially market new uses of the Company's products and to achieve market acceptance, it will likely be required to undertake clinical studies to validate the new uses for its products and spend significant funds to complete product development and clinical studies and then undertake substantial marketing efforts to inform potential customers and the public of the existence and perceived benefits of these products and services. In addition, governmental funding may be needed to help complete development, obtain required regulatory approvals, clearances or EUAs and create market acceptance and expand the use of these products and services.

There may be limited evidence on which to evaluate the market reaction to products and services that may be developed and the Company's marketing efforts for new products and services or products with new uses may not be successful. The market for microbiome products and services is in its early stages and its future development and acceptance by the Company's customers is uncertain. Also, the Company continues to develop and seek 510(k) regulatory clearance for the InteliSwab® tests, and it is uncertain whether it will be successful in the development and validation efforts or whether these products will prove effective, receive applicable regulatory approvals and gain widespread acceptance in the marketplace. As such, there can be no assurance that any products or services will obtain significant market acceptance and fill the market need that is perceived to exist on a timely basis, or at all. It is possible that the Company's expenses to develop and market any such products, including, without limitation the Company's InteliSwab® tests, will exceed any benefit in revenues, which may be short-lived. In addition, other products that compete with the Company's may achieve 510(k) clearance earlier than the Company's do, providing market advantages.

The Company May Not Realize Revenue Levels From its InteliSwab® COVID-19 Rapid Test Consistent With Prior Years.

The Company has experienced significant demand for its InteliSwab® COVID-19 Rapid Test; however, the Company expects a significant decline in revenues from InteliSwab® COVID-19 Rapid Test sales in 2024.

While there are still periods of increased COVID-19 prevalence, the public health emergency declarations related to COVID-19 ended on May 11, 2023. The Company has seen a reduction in the prevalence of COVID-19 since the height of the pandemic, and the Company's revenues relating to the Company's COVID-19 testing products have declined, and it expects they will continue to decline in the future if the prevalence of COVID-19 remains low. Further, if the COVID-19 pandemic becomes a seasonal virus or experiences fluctuations in prevalence, the Company could experience fluctuations in its revenues associated with its InteliSwab® COVID-19 Rapid Tests. While there is still demand for COVID-19 testing products, there is no guarantee that current or anticipated demand will continue, or if demand does continue, that the

Company will be able to produce its InteliSwab® COVID-19 Rapid Test in quantities to meet the demand. A significant decline in demand for the InteliSwab® COVID-19 Rapid Test without a corresponding increase in the Company's other businesses could have a material, adverse effect on the Company's results of operations, cash flow and financial position.

The COVID-19 Pandemic Continues to Cast Uncertainty Over the Company's Consolidated Results of Operations, Financial Position and Cash Flows, While the Consequences of COVID-19 and the Governmental Response to Contain the Pandemic and Pandemic-Related Macroeconomic Impacts Could Negatively Affect the Company's Operations and Share Price.

Although the Company has experienced heavy demand for its InteliSwab® tests and certain specimen collection devices for use in COVID-19 molecular testing as a result of the COVID-19 pandemic, which has had a positive impact on the Company's performance, the duration and level of the demand for COVID-19 testing is highly uncertain. The Company believes the COVID-19 pandemic's continued impact on its consolidated results of operations, financial position and cash flows will be primarily driven by; (i) the severity and duration of the COVID-19 pandemic; (ii) the COVID-19 pandemic's impact on the U.S. healthcare system and the U.S. economy; (iii) the timing, scope and effectiveness of federal, state and local governmental responses to the COVID-19 pandemic, including the development and deployment of vaccine, and (iv) the COVID-19 pandemic's impact on global clinics, research markets and global logistics. Each of these factors are difficult to predict and the nature, length and severity of any adverse consequences as a result of any given factor are uncertain.

Management has closely monitored the impact of the COVID-19 pandemic, with a focus on the health and safety of the Company's employees and business continuity. In response to, or as a result of, the COVID-19 pandemic and emergence of variants, the Company the Company may experience, among other things, voluntary or mandated temporary closures of one or more of its facilities; temporary or long-term labor shortages; temporary or long-term adverse impacts on its supply chain and distribution channels; the potential of increased network vulnerability and risk of data loss resulting from increased use of remote access and removal of data from its facilities; and required reallocation or adjustment of resources, which may impact the its business plans and product offerings. In addition, the direct or indirect impacts of COVID-19 may extend to disrupt the Company's suppliers, partners, manufacturers, customers and other stakeholders, which in turn could materially adversely affect the Company's business, results of operations or financial condition. Any change or disruption in operations could impact and have a material adverse effect on the Company's operations and/or results from operations. In addition, the re-introduction of voluntary or mandated efforts to slow the spread of COVID-19 could impact the Company's operations and sales. If portions or all of the Company's, its partners', or its customer's operations are disrupted or suspended as a result of preventative or reactionary measures in response to the ongoing spread of COVID-19, it could have a material adverse impact on the Company's profitability, results of operations, financial condition and share price. Further, there continue to be significant economic and social impacts of the COVID-19 pandemic, including rising inflation rates, continued levels of higher unemployment, and market volatility, among other impacts; any of which may have an impact on consumer behavior, including use of the Company's products.

Given the uncertainties associated with the COVID-19 pandemic, including the uncertainty surrounding the remaining duration and outcome, COVID-19 variants and vaccine efficacy, the Company is unable to estimate the full impact of the COVID-19 pandemic on its business, financial condition, results of operations, and/or cash flows; however, the impact could be material.

Marketing of the Company's COVID-19 Tests and Collection Kits Under EUAs from the FDA Is Subject To Certain Limitations and the Company Is Required To Maintain Compliance with the Terms of the EUA, Among Other Things, and the Continuance of the EUAs Is Subject To Government Discretion.

On February 4, 2020, the HHS issued a declaration that the threat to public health posed by COVID-19 justifies the emergency use of unapproved in vitro diagnostics for the detection or diagnosis of SARS-CoV-2. Under Section 564 of the FDCA, because HHS has issued this declaration, the FDA Commissioner is authorized to issue EUAs to permit certain developers of SARS-CoV-2 diagnostics to begin offering the tests for detection and diagnosis of COVID-19 without having completed the normally applicable FDA review and clearance or approval process for marketing authorization (with the related standards that would apply to demonstrate safety and effectiveness). The issuance of an EUA reflects an FDA conclusion that based on the totality of scientific evidence available to the FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19, the known potential benefits of the product outweigh the known and potential risks, and there is no adequate, approved, and available alternative to the emergency use of the product.

During 2020, the Company's ORAcollect®·RNA and OMNIgene®·ORAL collection devices were included in EUAs granted by the FDA to certain third parties for use in the detection of SARS-CoV-2, and the Company has separately obtained EUAs for these products. In addition, the Company obtained three EUAs for its new InteliSwab® COVID-19 Rapid Test. Although there are certain regulatory requirements the FDA has waived for the duration of the EUAs, the Company remains subject to specific conditions of the authorization, including ensuring appropriate labeling as approved by FDA specifically for purposes of the EUA, maintaining records of distribution to authorized laboratories, collecting data on occurrences of any false positives or false negatives, and tracking any adverse events. As part of the conditions of authorization, OraSure was required to conduct a clinical study in a pediatric population ages 2-14 and an asymptomatic population in addition to launching an app for consumers to report their test results to public health jurisdictions. OraSure has completed the required conditions of authorization with respect to the pediatric claim and launched the InteliSwab® Connect application for reporting test results to public health jurisdictions. As a result of the National Institutes of Health study (Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study), the FDA has requested modifications to labeling to include serial testing and has removed the requirement for the Company to conduct a study in an asymptomatic population. Labeling has been modified as required for inclusion of serial testing and authorized by FDA.

As with other FDA-regulated products, issues could emerge during the course of the marketing and use of the Company's products under an EUA that could impact the Company's ability to continue the sale and distribution of these products (for example, compliance or product performance issues). The applicable EUAs remain effective only until the HHS declaration is terminated or revoked, and the FDA may also revoke an EUA if it determines the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. If that were to occur, then in order to market the Company's diagnostic products or collection kits for the purpose of detecting COVID-19 the Company would be required to obtain the necessary regulatory clearances or approvals and be subject to the full and usual regulatory obligations for device manufacturers, including the QSR under 21 CFR Part 820. It is possible that the Company may not be able to obtain those clearances or approvals in a timely manner, or at all, and that one or more of OraSure's competitors may obtain the necessary clearances or approvals for their products before it does.

If Acceptance and Adoption of Oral Fluid Testing and Collection Products Does Not Continue, the Company's Future Results May Suffer.

The Company has made significant progress in gaining acceptance of oral fluid testing products, particularly for (i) HIV testing in the public health, hospital, insurance and other markets, and (ii) drugs-of-abuse testing in the workplace and criminal justice markets. Its subsidiary, DNAG, has also made significant progress in gaining acceptance of oral fluid collection products that are used with molecular testing applications including testing for SARS-CoV-2. However, the degree of acceptance for these products is uncertain, and one or more markets may resist the adoption of oral fluid products as a replacement for other testing or collection methods in use today. As a result, there can be no assurance that the Company will be able to expand the use of its oral fluid testing products in these or other markets.

However, clinical reference laboratories and hospital-based laboratories currently provide the majority of diagnostic tests used by physicians and other healthcare providers in the U.S. In certain international markets such as Europe, diagnostic testing is performed primarily by centralized laboratories. The Company's future sales will depend, in part, on the Company's ability to expand market acceptance of rapid point-of-care testing by physicians, other healthcare providers and consumers and successfully compete against laboratory testing methods and products. Even if the Company can demonstrate that its products are more cost effective, save time, or have better performance or other benefits, physicians, other healthcare providers and consumers may resist changing to rapid point-of-care tests and instead may choose to obtain diagnostic results through laboratory tests. The Company's failure to achieve and expand market acceptance of its rapid point-of-care diagnostic tests with customers would have a negative effect on its future sales growth.

The Company Expects to Face Increasing Competition From Other Providers of Diagnostic Tests, Sample Collection Products and Molecular Laboratory Services.

The Company's rapid point-of-care tests compete with other point-of-care products made by the Company's competitors. This competition is particularly evident with respect to the Company's OraQuick *ADVANCE*® HIV-1/2 test and the Company's HIV Self-Test outside of the United States. The Oragene® product line sold by the Company's subsidiary, DNAG, competes against other molecular sample management solutions, such as blood collection kits and buccal swabs and will likely face additional competition from collection devices similar in design and operation to the Company's Oragene® and ORAcollect® products. There are a number of products currently in or expected to enter the market for the

detection of antigen to SARS-CoV-2 that currently or will compete with the Company's InteliSwab® COVID-19 diagnostic test.

The Company's genetic and microbiome laboratory services business is expected to face increasing competition, primarily from large commercial reference laboratories, hospital-based laboratories and specialty laboratories. The Company believes there is significant opportunity in the markets for these services, particularly the microbiome market which is still in the early stages. As these markets evolve and expand, the Company expects competition for genomic and microbiome laboratory services to intensify.

There is significant competition, including from other companies and governmental organizations, who make and distribute rapid tests for COVID-19. Many of these entities have substantially greater resources (including capital and personnel) than OraSure does. Even if the Company is successful in marketing its InteliSwab® tests, there is no guarantee that competitors will not take market share from the Company's offerings through more effective marketing or competitive pricing, higher quality or technological superiority.

A number of the Company's competitors are making investments in competing technologies, products and services, and several may have a competitive advantage because of their greater financial, technical, research and other resources. Some competitors offer broader product lines and service offerings, aggressively discount prices for their products and services and may have greater name recognition than the Company does. The Company also faces competition from certain of its distributors or former customers that have created, or may decide to create, their own products to compete with the Company's. If the Company's competitors take market share from its offerings through more effective marketing or competitive pricing, higher quality or technological superiority, the Company's revenues, margins and operating results could be adversely affected. In addition, the Company's revenues and operating results could be negatively impacted if some of its customers use internally developed or acquired sample collection devices or services in order to reduce costs.

The Company's Product Sales Cycles Can be Lengthy, and May Depend on Public Funding, Which Can Cause Variability and Unpredictability in the Company's Operating Results.

The sales cycles for certain of the Company's products can be lengthy and unpredictable, which makes it more difficult to accurately forecast revenues in a given period and may cause revenues and operating results to vary from period to period. Sales of the Company's products often involve purchasing decisions by large public and private institutions, may require many levels of approval and may be dependent on economic or political conditions and the availability of grants or funding from governmental or public health agencies which can vary from period to period in both amount and timing. For example, in past years the Company's OraQuick *ADVANCE*® HIV-1/2 test has been purchased through bulk procurement or other funding provided by governmental agencies. The Company's OraQuick® HCV test has been purchased by customers who receive government funding, and the Company believes increased funding from the CDC and other agencies will be required to substantially increase the volume of HCV testing, especially in the public health market. There can be no assurance that purchases or funding from these agencies will occur or continue. As a result, the Company may expend considerable resources on unsuccessful sales efforts or it may not be able to complete transactions at all or on a schedule and in an amount consistent with its objectives.

The Company's Inability To Expand International Sales Could Adversely Affect its Business and Results of Operations.

One of the Company's strategic priorities is to substantially expand its product sales internationally. An opportunity to accomplish this objective is with the sale of the Company's OraQuick® HIV Self-Test in support of large self-testing programs in certain African countries and elsewhere. The Company's OraQuick® HIV Self-Test is also currently available in six European countries: United Kingdom, Germany, France, Italy, Spain and Portugal. The Company is also working to expand international sales of its professional HIV and HCV products and its molecular sample management solutions. The Company also believes there is a significant opportunity for international sales of its InteliSwab® COVID-19 Rapid Test once the necessary studies and registrations are complete.

While the Company believes international sales of these and other products represent attractive long-term opportunities with significant growth potential, there is no guarantee that these opportunities will materialize, continue or increase. Among other factors, competition from competitive lower priced products and the uncertainties of available funding could negatively impact the success of these opportunities. If international sales of these products do not occur or increase or if the Company is otherwise unable to expand international sales of its products, the Company's revenues and results of operations could be negatively impacted.

In addition, market conditions in many countries often require that the Company's sell its products at a price below the typical U.S. or European pricing in order to participate in these markets. As a result, sales in certain countries may contribute lower profit margins to the Company's business. To the extent these international sales comprise a large or increasing part of the Company's business, the Company's gross margins will be negatively affected. In addition, the Company may have difficulty selling its products at a sufficiently low price to maintain or increase this business over the long term without funding support from public health entities, government agencies or other sources. If the Company is unable to obtain or continue this funding support at sufficient levels, or at all, its revenues and results of operations could be negatively affected.

The Company's International Presence May Increase Its Risks and Expose Its Business to Regulatory, Cultural or Other Restraints.

The Company seeks to increase revenue derived from international sales of its products. Its international sales accounted for $43.8 million, or 11% of consolidated revenues in 2023, $37.3 million, or 10% of consolidated net revenues in 2022, $45.3 million, or 19%, of consolidated net revenues in 2021. In addition, the Company's subsidiary DNAG, which accounted for $56.2 million or 14% of consolidated net revenues in 2023, is operated in Canada. The Company has previously acquired foreign companies and it may acquire other foreign companies as part of its business development efforts.

A number of factors could adversely affect the performance of the Company's business and/or cause it to incur substantially increased costs because of its international presence and sales, including, but not limited to those set forth below:

- Uncertainty in the application of foreign laws and the interpretation of contracts with foreign parties;
- The potential for inconsistent imposition of legal and regulatory requirements;
- Cultural and political differences that favor local competitors or make it difficult to effectively market, sell and gain acceptance of the Company's products;
- Cultural and language differences that make international operations and business management more difficult;
- Inexperience in international markets and territories and difficulties in staffing and managing foreign operations;
- Exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on international distributors or representatives;
- Regulatory requirements, including compliance with applicable customs regulations and the need to obtain or maintain regulatory approvals, registrations or reimbursement approvals for the Company's products;
- Trade protection measures, additional trade sanctions and import/export licensing requirements;
- The inability to obtain or maintain ISO certification for the Company's or the Company's suppliers’ manufacturing facilities;
- The Company's inability to identify international distributors and negotiate acceptable terms for distribution agreements;
- Diversion to the U.S. of the Company's products that are sold at lower prices into international markets;
- The loss of one or more distributors and difficulties or delays in obtaining new or transferred product registrations or approvals for use by a replacement distributor;
- Differing tax laws across jurisdictions, as well as changes in those laws;
- An increase of withholding and other taxes on remittances and other payments by a foreign subsidiary;
- The creditworthiness of foreign distributors and customers and difficulty in collecting foreign accounts receivable;

- Difficulty of enforcing contractual obligations or recovering damages under foreign legal systems;
- Difficulty collecting amounts owed by foreign governments or other customers;
- Economic conditions, inflation, political instability, the absence of available funding sources, terrorism, civil unrest, war and natural disasters in foreign countries;
- Exposure to infectious disease and epidemics, including the effects of the COVID-19 outbreak on the Company's business operations in geographic locations impacted by the outbreak and on the business operations of the Company's customers and suppliers;
- Long sales cycles in international markets, especially for sales to foreign governments, quasi-governmental agencies and international public health agencies;
- The sale of competing products by foreign competitors at prices at or below the prices offered for the Company's products;
- Restrictions on the Company's ability to repatriate investments and earnings from foreign operations;
- Changes in shipping costs;
- The unavailability of licenses to certain patents in force in a foreign country which cover the Company's products; and
- Reduced protection for, or enforcement of, the Company's patents and other intellectual property rights in foreign countries.

In addition, the Company has contracted with a third party in Thailand for the manufacture of a portion of the Company's OraQuick® HIV tests and all of DNAG's products are produced in Canada. The Company may enter into agreements to manufacture these or other products in additional foreign countries as well. However, economic, cultural and political conditions and foreign regulatory requirements may slow or prevent the manufacture of the Company's products in countries other than the United States. Interruption of the supply of the Company's products could reduce revenues or cause it to incur significant additional expenses in finding an alternative source of supply. Foreign currency fluctuations and economic conditions in foreign countries could also increase the costs of manufacturing the Company's products in foreign countries. In addition, the COVID-19 pandemic previously resulted in, and may in the future result in, increased government-imposed travel restrictions and extended shutdowns of certain businesses in the affected locations as well as logistics delays due to the global logistical crisis from the pandemic. These or any further political or governmental responses to pandemic diseases could result in social, economic and labor instability of foreign countries, which could have a material adverse effect on the Company's business, results of operations and financial condition.

The Company's U.S. Government Contracts Require Compliance With Numerous Laws and Increases Its Risk and Liability.

From time to time, the Company receives funding from the U.S. government and sells some of its products to the federal government. Historically, the Company has sold a number of its products to the government under contracts with the General Services Administration and the Veterans Administration.

In September 2022 the Company entered into an $8.6 million contract with BARDA to develop a second generation Ebola test on the OraQuick® testing platform and the Company was selected to provide its OraQuick® In-Home HIV tests in support of the CDC "Together Take me Home," HIV self-test program. Under the program, the CDC is expected to provide $41.5 million over a five-year period to support community testing. During the third quarter of 2022, the Company entered into a contract with the DLA for the second procurement of the Company's InteliSwab® COVID-19 Rapid Test for OTC use. During the same quarter, the Company entered into a contract with the BARDA to provide it with up to $13.6 million in funding to obtain an FDA 510(k) clearance and CLIA waiver for the Company's InteliSwab® test. The Company continued development work and analytical testing on this test throughout 2023. However, in early 2024, the Company has communicated to BARDA that it does not intend to pursue further development of this product. In September 2021, the Company entered into a contract with the U.S. DOD in coordination with the HHS for $109 million in funding to build additional manufacturing capacity in the United States for the Company's InteliSwab® test.

As a result of the Company's U.S. government funding and product sales to the U.S. government, it must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. U.S. government

contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to the Company as compared to competitors that do not rely on government contracts. For example, the government has the right to terminate one or more of these contracts at its convenience even if the Company has not defaulted in any of its obligations.

As a U.S. government contractor, the Company is subject to increased risks of investigation, criminal prosecution and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact the Company's business and have an adverse effect on its consolidated financial performance.

A violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of the Company's contracts, as well as suspension or debarment. The suspension or debarment in any particular case may be limited to the facility, contract or subsidiary involved in the violation or could be applied to the Company's entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect the Company's ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect the Company's business and results of operations. Fines and penalties could be imposed for failing to follow procurement integrity and bidding rules, employing improper billing practices or otherwise failing to follow rules relating to billing on cost-plus contracts, receiving or paying kickbacks, or filing false claims, among other potential violations. In addition, the Company could suffer serious reputational harm and the value of its common stock could be negatively affected if allegations of impropriety related to such contracts are made against it.

The Company's Inability to Manufacture Products in Accordance with Applicable Specifications, Performance Standards or Quality Requirements Could Adversely Affect Its Business.

The materials and processes used to manufacture the Company's products must meet detailed specifications, performance standards and quality requirements to ensure its products will perform in accordance with their label claims, customers' expectations and applicable regulatory requirements. As a result, the Company's products and the materials used in their manufacture or assembly undergo regular inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in materials or production methods, and other events or conditions could cause the Company's products or the materials used to produce or assemble its products to fail inspections and quality testing or otherwise not perform in accordance with their label claims or the expectations of the Company's customers.

In February 2024, the FDA issued the Quality Management System Regulation (QMSR) Final Rule to amend the QSR, incorporating by reference the international standard for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required to comply with the QSR. We believe that our facilities and procedures are in material compliance with the FDA's OSR regulations, the European Union's Quality Management Systems requirements, ISO 13485:2016, but the regulations are subject to change or may be unclear, and we cannot be sure that FDA investigators will agree with our compliance with the FDA's post-market requirements.

Any failure or delay in the Company's ability to meet the applicable specifications, performance standards, quality requirements or customer expectations could adversely affect its ability to manufacture and sell its products or comply with regulatory requirements. These events could, in turn, adversely affect the Company's revenues and results of operations.

The Company's Business Will Suffer if It Does Not Effectively Manage Challenges to Its Manufacturing Processes and It May be Unable to Successfully Scale-Up Manufacturing of Its Products in Sufficient Quality and Quantity to Meet Demand, Which Would Negatively Impact Revenue Expectations.

In the event of a sudden and significant increase in demand for the Company's products, challenges in the manufacture of products could adversely affect, the Company's operating efficiency and results of operations. Although the Company has expanded its manufacturing capacity, the Company faces risks, including with respect to expanding its overall production capacity, that could increase costs, divert management attention and reduce the Company's operating results, with no guarantee of success.

As the Company increases its manufacturing capacity to meet market demand or begin to manufacture new products at scale, it may face unanticipated manufacturing challenges as production volumes increase, new processes are implemented and new supplies of raw materials used in these products are secured. In addition, the Company could experience delays in

production as it increases manufacturing capacity or begins to manufacture new products that may result in its inability to meet product demand as the products ordered by its customers being on back-order as initial production issues are addressed. If it experiences production delays or inefficiencies, a deterioration in the quality of the Company's products or other complications in managing changes to its manufacturing processes, including those that are designed to increase capacity, enhance efficiencies and reduce costs or that relate to new products or technologies, the Company may not achieve the benefits that it anticipates from these actions when expected, or at all, and the Company's operations could experience disruptions, the Company's manufacturing efficiency could suffer and the Company's business, financial condition and results of operations could be materially and adversely affected. Any such delays could allow the Company's competitors to seize market advantage, which could have a material, adverse effect on the Company's reputation, revenues, results of operations, cash flow and financial position.

The Company's Business Results Depend on Its Ability to Manage Disruptions in Its Domestic and Global Supply Chains and Distribution Channels.

The Company's ability to meet its customers' needs and achieve its financial objectives depends on its ability to maintain key manufacturing, supply and distribution arrangements. The loss or disruption of such manufacturing and supply arrangements could, in the future, interrupt the Company's ability to obtain necessary raw materials and manufacture its products. Such disruptions could result from labor disputes, financial liquidity, natural disasters, extreme weather conditions, public health emergencies and pandemics, supply constraints and general economic and political conditions that could limit the ability of the Company's suppliers to timely provide it with raw materials and components and distribute its products in a timely manner in accordance with applicable quality requirements. Disruptions in the global supply chain could also delay or preclude the ability of the Company's distributors to sell and deliver its products to customers.

The availability and price of these materials, parts, products and services are affected by a variety of factors beyond the Company's control, including the willingness of suppliers to sell into the medical device industry, changes in supply and demand, general economic conditions, labor costs, fuel-related transportation costs, liability concerns, climate change (including new and existing laws and regulations to address climate change), competition, import duties, tariffs, currency exchange rates, inflationary pressures and political uncertainty around the world. The Company's suppliers often pass some of their cost increases on to it, and if such increased costs are sustained or increase further, its suppliers may pass further cost increases on to it. In addition, transportation costs have generally increased and may further increase if crude oil prices increase. The Company's transportation and service providers are typically able to pass any significant increases in oil prices on to it. The Company's costs may also be impacted by laws to increase minimum wages, including the potential increase to the federal minimum wage in the United States that has been recently proposed by the current administration.

The Company's ability to recover such increased costs may depend upon its ability to raise prices on its products. Due to the highly competitive nature of the healthcare industry and the cost-containment efforts of the Company's customers and third-party payers, the Company may be unable to pass along cost increases through higher prices. If the Company is unable to fully recover these costs through price increases or offset these increases through cost reductions, or it experiences terminations or interruption of its relationships with its suppliers, it could experience lower margins and profitability, and the Company's results of operations, financial condition and cash flows could be materially harmed.

Recently, the global supply chain has experienced significant disruptions, resulting in shortages of labor and equipment. These conditions, if not mitigated or remedied in a timely manner, could delay or preclude delivery of raw materials needed to manufacture the Company's products or delivery of the Company's products to customers, particularly in international markets. This in turn could have an adverse impact on the Company's business, financial condition, results of operations or cash flows.

Certain of the Company's Products Depend on Components From a Sole-Source Supplier, the Loss of Which Would Cause the Company to be Unable to Deliver Such Products.

The Company currently purchases certain critical components of its products from sole supply sources or other third-party suppliers. For example, the biological antigens and antibodies, nitrocellulose and certain other components required to make the Company's OraQuick® HIV, HCV and Ebola products are currently purchased from sole-source suppliers. The Company's OraSure QuickFlu® test and the fully automated high-throughput drug assays sold with its Intercept i2® device are manufactured and supplied by sole-source suppliers and the conjugates used in its MICROPLATE oral fluid drugs-of-abuse assays are obtained from third-party suppliers. The Company has contracted with third parties in Thailand for parts of the assembly of OraQuick® HIV device and the OraQuick® HIV Self-Test in order to supply certain international

markets. In addition, the Company's subsidiary, DNAG, uses three third-party manufacturers to supply virtually all of its products, including its Oragene® and ORAcollect® lines of collection kits.

Additionally, the Company's Intercept i2®*he* collection device is manufactured and supplied under a long-term agreement with Thermo Fisher, the sole-source supplier for these products. If Thermo Fisher were unable or unwilling to supply the necessary components for the manufacture of the Intercept i2® *he* collection devices, the Company would be unable to produce this product or offer it to customers. Any interruption in, or change in the cost or quality of, the supply of the necessary raw materials, manufacturing services, product and process development, or other materials necessary to manufacture the product could adversely impact the efficacy of the product and negatively affect the Company's reputation with its customers. In addition, many of the raw materials used in the Company's DNAG products, including its Oragene® product line, and components used in these products are also purchased from third parties, some of which are purchased from a sole-source supplier. If the Company's sole-source suppliers were to be acquired by a competitor, they may elect not to provide it with the product, raw materials or other components, as applicable. If the Company's sole-source suppliers were to otherwise cease supplying it, go out of business, or were unable to meet their obligations in a timely fashion or at an acceptable price, or at all, the Company may be forced to incur higher costs to obtain the necessary raw materials elsewhere, if it could even source such materials at all.

Furthermore, the COVID-19 pandemic and the measures taken to contain the spread of the virus, have disrupted, and may in the future disrupt, the normal operations of the Company's third-party suppliers. Additionally, potential future pandemics or other public health emergencies may, in the future, disrupt the normal operations of the Company's third-party suppliers. The Company's third-party suppliers may not have the personnel, raw materials, capacity or capability to manufacture its products according to its schedule and specifications. To the extent any such production and distribution interruption or closures occur and continue for an extended period of time, the impact on the Company's supply chain could have a material adverse effect on its results of operations. If the Company's third-party suppliers are unable or unwilling to supply or manufacture a required component or product or if they make changes to a component, product or manufacturing process or do not supply materials meeting the Company's specifications, it may need to find another source and/or manufacturer. This could require that the Company perform additional development work and it may be difficult to find such an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. The Company may also need to obtain FDA or other regulatory approvals for the use of an alternative component or for changes to its products or manufacturing process. Completing that development and obtaining such approvals could require significant time and expense and such approvals may not occur at all. The availability of critical components and products from sole supply sources or other third parties could also reduce the Company's control over pricing, quality and timely delivery. These events could either disrupt the Company's ability to manufacture and sell certain of its products into one or more markets or completely prevent it from doing so, and could increase the Company's costs. Any such event could have a material adverse effect on the Company's results of operations, cash flow and business.

The Company's U.S. Government Contracts May Affect Its Intellectual Property Rights.

Provisions in the Company's U.S. government contracts may affect its intellectual property rights. Certain of the Company's activities have been funded, and may in the future be funded, by the U.S. government, including its contracts with BARDA. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention. These rights may permit the government to disclose the Company's confidential information to third parties and to exercise “march-in” rights to use and allow third parties to use the Company's patented technology. The government can exercise its march-in rights if it determines that action is necessary because the Company fails to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, government-funded inventions must be reported to the government, government funding must be disclosed in any resulting patent applications, and the Company's rights in such inventions may be subject to certain requirements to manufacture products in the United States. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights that would be voluntary for federal government agencies to follow when deciding whether to exercise march-in rights and which for the first time includes the price of a product as a factor a federal government agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain whether the federal government will actually exercise such march-in rights in connection with medical products or whether any such exercise will be subject to judicial review or challenge.

The Company's U.S. Government Contracts and Related Administrative Processes Are Subject to Audits and Cost Adjustments by the Federal Government.

Federal government agencies can audit and investigate government contracts and the administrative processes and systems of government contractors. These agencies can review the Company's performance on government contracts, pricing practices, cost structure, and compliance with applicable laws, regulations and standards. They can also review the Company's compliance with government regulations and policies and the adequacy of its internal control systems and policies, including its purchasing, accounting, estimating, compensation and management information processes and systems. Any costs found to be improperly allocated to a specific government contract, unallowable or unreasonable will not be reimbursed, and any such costs already reimbursed may be required to be refunded and certain penalties may be imposed. Adjustments arising from government audits and reviews could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

Moreover, if any administrative process or system related to such contracts is found not to comply with governmental requirements, the Company may be subjected to government scrutiny that could delay or otherwise adversely affect its ability to compete for or perform government contracts or collect its revenue in a timely manner. An unfavorable outcome of an audit of the Company's government contracts could adversely affect its results of operations.

Risks Relating to the Company's Industry, Business and Strategy

Consolidation in the Healthcare Industry Could Adversely Affect the Company's Future Revenues and Operating Results.

The healthcare industry has experienced a significant amount of consolidation. As a result of this consolidation, competition to provide goods and services to customers has increased. In addition, group purchasing organizations and integrated health delivery networks have served to concentrate purchasing decisions for some customers, which has also placed pricing pressure on medical device suppliers. The Company may not be able to compete successfully in such a consolidated industry. The Company believes industry consolidation may continue as companies attempt to strengthen or hold their market positions and as more companies are acquired or cease operating. Further consolidation in the industry could exert additional pressure on the prices of the Company's products.

The Company's Research, Development and Commercialization Efforts May Not Succeed and Its Competitors May Develop and Commercialize More Effective or Successful Offerings.

In order to remain competitive, the Company must regularly commit substantial resources to research and development and the commercialization of new or enhanced products and services. The research and development process generally takes a significant amount of time from inception to commercial launch. This process is conducted in various stages. During each stage there is a substantial risk that the Company will not achieve its goals on a timely basis, or at all, and it may have to abandon a new or enhanced product or service in which it has invested substantial time and money.

Successful products and services can require significant development and investment, including testing to demonstrate their performance capabilities, cost-effectiveness or other benefits prior to commercialization. Regulatory approval or clearance must be obtained before most products may be sold and additional development efforts on these products may be required before any regulatory authority will review them. Similarly, regulatory clearances or registrations, such as a CLIA certification, and compliance with industry guidelines, may be required in order to provide competitive laboratory services. As noted above, regulatory authorities may not issue such approvals, clearances or certifications or may substantially delay or condition such action. Even if a product or service is developed and all applicable regulatory approvals, clearance or certifications are obtained, there may be little or no market for the product or service and entry into or development of new markets for the Company's products and services may require an investment of substantial resources, such as new employees, offices and manufacturing facilities. Moreover, the Company may spend a significant amount of money on manufacturing facilities, advertising or other activities and fail to develop a market for the product or service. Other factors that could affect the success of the Company's efforts include its ability to manufacture products or provide laboratory services in a cost-effective manner and whether it can obtain necessary intellectual property rights and protection in the markets where the product or service is sold.

If the Company fails to develop and gain commercial acceptance for its products and services, or if competitors develop more effective products and services or a greater number of successful new products and services, customers may decide not to purchase the Company's products and services or may purchase and use products and services developed by its competitors. This would result in a loss of revenues and adversely affect the Company's results of operations, cash flow and business.

Customer Concentration Creates Risk for the Company's Business.

One of the Company's customers accounted for approximately 63% of its net consolidated revenues for the year ended December 31, 2023. Certain parts of the Company's business may continue to have a high customer concentration and depend disproportionately on a few large customers. To the extent that such a large customers fail to meet their purchase commitments, change their ordering patterns or business strategies, or otherwise reduce their purchases or stop purchasing the Company's products, or if it experiences difficulty in meeting the high demand by these larger customers for its products, the Company's revenues and results of operations could be adversely affected.

Acquisitions or Investments May Not Generate the Expected Benefits and Could Disrupt the Company's Ongoing Business, Distract Its Management, Increase Its Expenses and Adversely Affect Its Business.

Since the beginning of 2019, the Company has acquired or made investments in several companies through which it has gained access to new technologies, products and services which are complementary to its existing business and aligned with its long-term business strategy. For example, in January 2024, the Company announced its investment and entry into wide ranging strategic distribution agreements with KKR Sapphiros, L.P. ("Sapphiors"). The Company will likely continue to pursue strategic acquisitions or investments as a way to expand its business. These activities, and their impact on the Company's business, are subject to many risks, including the following:

- Suitable acquisitions or investments may not be found or consummated on terms or schedules that are satisfactory to the Company or consistent with its objectives;
- The Company may be unsuccessful in competing for acquisitions with other entities, some of which have greater financial resources or may be better able to realize synergies with a potential target;
- The benefits expected to be derived from an acquisition or investment may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, the Company's inexperience with new businesses or markets, general economic conditions and increased competition;
- The Company may be unable to successfully integrate an acquired company’s personnel, assets, management, information technology systems, accounting policies and practices, products, services and/or technology into the Company's business;
- Worse than expected performance of an acquired business may result in the impairment of intangible assets;
- Acquisitions may require substantial expense and management time and could disrupt the Company's business;
- The Company may not be able to accurately forecast the performance or ultimate impact of an acquired business;
- The Company may have difficulties in coordinating geographically separate organizations;
- The Company may fail to successfully manage relationships with customers, distributors and suppliers of an acquired business;
- An acquisition may result in a diversion of resources from the Company's existing products, business and technologies;
- An acquisition and subsequent integration activities may require greater capital and other resources than originally anticipated at the time of acquisition;
- To the extent the Company agrees to pay contingent consideration for an acquisition, if and how much of such consideration it is required to pay may be subject to dispute, resulting in the distraction of the Company's management team and the incurrence of legal costs;
- An acquisition may result in employee anxiety, morale and/or engagement issues;
- An acquisition may result in disparate information technology, internal control, financial reporting and record-keeping systems;
- An acquisition may result in new partners or customers who may operate on terms and programs different than the Company's;

- An acquisition may result in employees not familiar with the Company's operations;
- An acquisition may result in new products and services, including the risk that any underlying intellectual property associated with such products and services may not have been adequately protected or that such products and services may infringe on the proprietary rights of others;
- An acquisition may result in the incurrence of unexpected expenses, stockholder lawsuits, the dilution of the Company's earnings or its existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;
- An acquisition may result in the loss of the Company's or the acquired company's key personnel, customers, distributors or suppliers; and
- An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability or restrictions under foreign laws or regulations, and the Company's inability to successfully assimilate differences in foreign business practices or overcome language or cultural barriers and other inherent risks of operating in unfamiliar legal and regulatory environments.

The occurrence of one or more of the above or other factors may prevent the Company from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect the Company's financial condition, results of operations and ability to grow its business or otherwise achieve its financial and strategic objectives.

The Company's Revenues Could be Affected by Third-Party Reimbursement Policies and Potential Cost Constraints.

The end-users of certain of the Company's products include hospitals, physicians and other healthcare providers. Use of the Company's products could be adversely impacted if these end-users do not receive adequate reimbursement for the cost of its products from their patients' healthcare insurers or payors. The Company's net sales could also be adversely affected by changes in reimbursement policies of governmental or private healthcare payors, including in particular the level of reimbursement for the Company's products.

In the United States, hospitals, physicians and other healthcare providers who purchase diagnostic products generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product and procedure. The overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States in recent years, currently available levels of reimbursement may not continue to be available in the future for the Company's existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for the Company's products or its ability to sell its products on a profitable basis. In addition, the reimbursement approval process may delay the market introduction of the Company's products.

Changes in Healthcare Regulation Could Affect the Company's Revenues, Costs and Financial Condition.

In recent years, there have been numerous initiatives at the federal and state level for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs. One example is the Patient Protection and Affordable Care Act, the federal healthcare reform law enacted in 2010 (the "Affordable Care Act"). Similar reforms may occur internationally.

Legislative and regulatory bodies are likely to continue to pursue healthcare reform initiatives in many forms and may continue to reduce funding in an effort to lower overall federal healthcare spending. The ultimate content and timing of changes to healthcare reform legislation and the resulting impact on the Company are impossible to predict. If significant reforms continue to be made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase the Company's costs or otherwise have an adverse effect on its financial condition and results of operations.

New or Changed Testing Guidelines Could Affect Sales of the Company's Diagnostic Products.

From time to time, governmental agencies such as the CDC issue diagnostic testing guidelines or recommendations, which can affect the usage of the Company's HIV and HCV tests or other diagnostic products. For example, past sales of domestic professional OraQuick® HIV tests have decreased in part due to customer migration to automated fourth generation HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC. In addition, some states have promulgated, or may in the future promulgate, laws and regulations that affect HIV or HCV testing. The issuance of new laws or guidelines, or changes in existing laws or guidelines, and the manner in which these new or changed laws and guidelines are interpreted and applied by healthcare practitioners, could impact the degree to which the Company's OraQuick® rapid HIV and HCV testing products or other products are used. New or changed laws or guidelines could affect the number of people tested, the frequency of testing and whether testing products such as the Company's OraQuick® HIV and HCV tests are used broadly for screening large populations or in a more limited capacity as a confirmatory test or otherwise. These factors could in turn affect the level of sales of the Company's products and its results of operations.

Reductions in Government Funding and Research Budgets Could Adversely Affect the Company's Business and Financial Results.

The Company sells its OraQuick *ADVANCE*® HIV-1/2 and OraQuick® HCV tests into the U.S. public health market which consists of state, county and other governmental public health agencies, community based organizations, service organizations and similar entities. It also sells these products into the hospital market. Many of these customers depend to a significant degree on grants or funding provided by governmental agencies to run their operations including programs that use the Company's products. In international markets, the Company often sell products such as its OraQuick® HIV Self-Test to or through foreign governmental agencies or parties funded by such agencies.

Many of the Company's molecular sample management solutions are sold to researchers at academic institutions, pharmaceutical and biotechnology companies, government laboratories and private foundations. Many research customers are dependent for their funding on grants from U.S. governmental agencies such as the U.S. National Institutes of Health and agencies in other countries to pay for the products and services they purchase. These research customers also purchase the Company's genomic and microbiome laboratory tests and analytical services.

The level of available government grants or funding in the U.S. and elsewhere is unpredictable and may be affected by various factors including economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Further, government proposals to reduce or eliminate budgetary deficits have sometimes included reduced allocations to government agencies in the U.S. and other countries that fund life sciences research and development activities. Any reduction or delay in government or other funding as a result of legislative or regulatory changes or other factors, could cause the Company's customers to delay, reduce or forego purchases of its products and services.

Risks Relating to the Company's Reliance on Third Parties

The Company's Failure to Maintain Existing Distribution Channels, or Develop New Distribution Channels, May Result in Lower Revenues.

The Company has marketed many of its products by collaborating with laboratories, diagnostic companies and distributors. Its sales depend to a substantial degree on its ability to sell products to these customers and on the marketing and distribution abilities of the companies with which it collaborates.

Relying on distributors or others to market and sell the Company's products could harm its business for various reasons, including:

- The Company may not be able to find suitable distributors to distribute its products on satisfactory terms, or at all;
- The Company's distributors or other customers may not fulfill their contractual obligations to it or otherwise market and distribute its products in the manner or at the levels it expects;
- The Company does not control the incentives provided by its distributors to their sales personnel and the effectiveness of these incentives could affect sales of the Company's products;

- Agreements with distributors may terminate prematurely due to disagreements or may result in litigation between the parties;
- The Company may not be able to renew existing distribution agreements on acceptable terms, or at all;
- The Company's distributors may not devote sufficient resources or priority to the sale of its products;
- The Company's distributors may prioritize their own private label products that compete with its products;
- The Company's existing distributor relationships or contracts may preclude or limit it from entering into arrangements with other distributors; and
- The Company may not be able to negotiate future distribution agreements on acceptable terms, or at all.

Although the Company will try to maintain and expand its business with distributors and customers and require that they fulfill their contractual obligations, there can be no assurance that such companies will do so or that new distribution channels will be available on satisfactory terms. As a result, the Company's revenues and business could be adversely affected.

The Company May Need Strategic Partners to Assist in Developing and Commercializing Some of Its Products.

Although the Company may elect to pursue some product opportunities independently, opportunities that require a technology controlled by a third party, a significant level of investment for development and commercialization or a distribution network beyond its existing sales force may necessitate involving one or more strategic partners. Further, the Company's ability to enter into agreements with additional strategic partners depends in part on convincing them that its products can help achieve and accelerate their goals and efforts. The Company's strategy for development and commercialization of products may entail entering into arrangements with distributors or other corporate parties, universities, research laboratories, government agencies, licensees and others. Relying on collaborative relationships could be risky to the Company's business for a number of reasons, including:

- The Company may be required to transfer material rights to such strategic collaborators, government agencies, licensees and others;
- The Company's collaborators may not devote sufficient resources or attach a sufficiently high priority to the success of its collaboration;
- The Company's collaborators may not obtain regulatory approvals necessary to continue the collaborations in a timely manner;
- The Company has limited access to its collaborator’s confidential corporate information and sudden unexpected changes in ownership or strategy or other material events affecting a collaborator of which the Company is not made aware of in a timely manner, or at all, could adversely impact the Company's relationship;
- The Company's collaborators may be acquired by another company, sell the part of their business related to the Company's collaboration, decide to terminate the Company's collaborative arrangement or become insolvent;
- The Company's collaborators may develop technologies or components competitive with its products;
- The Company's collaborators may fail to deliver technologies or components that satisfy market requirements or such products may fail to perform properly;
- Disagreements with collaborators could result in the termination of the relationship or litigation;
- Collaborators may not have sufficient capital resources; and
- The Company may not be able to negotiate future collaborative arrangements, or renewals of existing collaborative agreements, on acceptable terms or at all.

While the Company generally expects that its collaborative partners will have an economic motivation to succeed in performing their contractual responsibilities, there is no assurance that they will do so, either at the level required or at all, and the amount and timing of resources to be devoted to these activities will be controlled by others. Reliance on strategic agreements can also make it difficult to accurately forecast the Company's future revenues or operating results. There can be no assurance that the expected revenues or profits will be fully derived from such arrangements.

Risks Relating to Intellectual Property

The Company's Success Depends on Its Ability to Protect Its Proprietary Technology.

The Company's industry places considerable importance on obtaining patent, trademark and trade secret protection, as well as other intellectual property rights, for new technologies, products and processes. The Company's success depends, in part, on its ability to develop and maintain a strong intellectual property portfolio or obtain licenses to patents and technologies, both in the United States and in other countries. If the Company cannot continue to develop, obtain and protect intellectual property rights, its revenues and profits could be adversely affected. Moreover, the Company's current and future licenses or other rights to patents and other technologies may not be adequate for the operation of its business.

As appropriate, the Company intends to file patent applications and obtain patent protection for its proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for the Company's products, methods of making those products, methods of using those products and apparatuses relating to the use or manufacture of those products.

The Company also relies on trade secrets, know-how and continuing technological advancements to protect its proprietary technology. The Company has entered, and will continue to enter, into confidentiality agreements with its employees, consultants, advisors and collaborators. The Company's employees and third-party consultants also sign agreements requiring that they assign to it interests in inventions and original expressions and any patents or copyrights arising from their work. However, these parties may not honor these agreements.

The Company cannot guarantee that the process of filing patents, the laws governing trade secrets and proprietary information, or any agreements the Company enters into with employees, consultants, advisors or collaborators will provide adequate protection of its intellectual property rights. For example, the Company's competitors may develop similar products without infringing on any of its intellectual property rights or design around its proprietary technologies. Employees, consultants and others who participate in the development of the Company's products may breach their agreements with it regarding its intellectual property, and the Company may not have adequate remedies for the breach. The Company also may not be able to effectively protect its intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the United States.

For a variety of reasons, the Company may decide not to file for patent, copyright or trademark protection outside of the U.S. The Company's trade secrets could become known through other unforeseen means. Although the Company has licensed certain technology for use in its microbiome laboratory services offerings and it has developed proprietary know-how that it uses in this business, it does not currently hold any patents covering the laboratory processes and analytical methods offered to its customers. The absence of patent protection in this or other parts of the Company's business may make it more difficult to protect its intellectual property. In addition, the Company's competitors may independently develop similar or alternative technologies or products that are equal or superior to its technology.

Moreover, issued patents remain in effect for a fixed period and after expiration will not provide protection of the inventions they cover. Once the Company's patents expire, it may be faced with increased competition, which could reduce its revenues. It may also not be able to successfully protect its rights to unpatented trade secrets and know-how.

Some of the Company's employees, including scientific and management personnel, were previously employed by competing companies. Although the Company encourages and expect all of its employees to abide by any confidentiality agreement with a prior employer, competing companies may allege trade secret violations and similar claims against the Company. In addition, some of these agreements may conflict with, or be subject to, the rights of third parties with whom the Company's employees, consultants or advisers have prior employment or consulting relationships. An adverse determination may limit or restrict the type of work that certain employees involved with such products may perform.

The Company may collaborate with universities and governmental research organizations or receive funding for its products from government agencies. As a result, one or more of these entities may acquire part of the rights to any inventions or technical information derived from the Company's collaboration or funding relationship with them.

To facilitate development and commercialization of a proprietary technology base, the Company may need to obtain licenses to patents or other proprietary rights from other parties. Obtaining and maintaining such licenses may require the payment of substantial amounts. In addition, if the Company is unable to obtain these types of licenses, its product development and commercialization efforts may be delayed or precluded. Moreover, some licenses may be nonexclusive, and therefore the Company's competitors may have access to the same technology also licensed to the Company.

The Company May Become Involved in Intellectual Property Disputes, Which Could Increase Its Costs and Limit or Eliminate Its Ability to Sell Products, Provide Services or Use Certain Technologies.

From time to time, the Company may seek to enforce its patents or other intellectual property rights through litigation. In addition, there are a large number of patents and patent applications in the Company's product and service areas, and additional patents may be issued to third parties relating to its product and service areas. The Company, its customers or its suppliers may be sued for infringement of patents or misappropriation of other intellectual property rights with respect to one or more of its products or services. Litigation in the Company's industry regarding patent and other intellectual property rights is prevalent and is expected to continue. The Company may also have disputes with parties that license patents to it if the Company believes the license is no longer needed for its products or services or the licensed patents are no longer valid or enforceable.

The Company's industry is characterized by a large number of patents, and the claims of these patents appear to overlap in many cases. As a result, there is a significant amount of uncertainty regarding the extent of patent protection and infringement. Companies may have pending patent applications, which are typically confidential for the first eighteen months following filing, that cover technologies the Company incorporates in its products or services. Accordingly, the Company may be subjected to substantial damages for past infringement or be required to modify its products or services or stop selling them if it is ultimately determined that its products or services infringe a third party’s proprietary rights. In addition, governmental agencies could commence investigations or criminal proceedings against the Company's employees or the Company itself relating to claims of misuse or misappropriation of another party’s proprietary rights.

Intellectual property litigation is costly. As such, the Company's involvement in litigation or other legal proceedings with respect to patents or other intellectual property and proprietary technology, either as a plaintiff or defendant, could adversely affect its revenues, market share, results of operations and business because:

- It could consume a substantial portion of managerial and financial resources;
- Its outcome would be uncertain and a court may find that the Company's patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by the Company's products or services;
- An adverse outcome could subject the Company to the loss of the protection of its patents or to liability in the form of past royalty payments, penalties, reimbursement of litigation costs and legal fees, special and punitive damages, or future royalty payments, any of which could significantly affect the Company's future earnings;
- Governmental agencies may commence investigations or criminal proceedings against the Company's employees, former employees and the Company itself relating to claims of misappropriation or misuse of another party’s proprietary rights;
- Failure to obtain a necessary license upon an adverse outcome could prevent the Company from selling its current products or services or other products or services it may develop or acquire;
- The Company may be required to alter its product or services, given the proprietary rights of others;
- The pendency of any litigation may in and of itself cause the Company's distributors and customers to reduce or terminate purchases of its products or services; and
- A court could award a preliminary and/or permanent injunction, which would prevent the Company from selling its current or future products or services.

The Company may indemnify some customers and strategic partners under its agreements with such parties if its products, services or activities have actually or allegedly infringed upon, misappropriated or misused another party's proprietary rights. Further, the Company's products or services may contain technology provided to it by other parties, such as universities, contractors, suppliers, customers or collaborators, and it may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. These other parties may also not be required or financially able to indemnify the Company in the event that an infringement or misappropriation claim is asserted against the Company.

The Company may also become involved in other types of disputes regarding intellectual property rights, including state, federal or foreign court litigation, and patent interference, patent reexamination, patent reissue, or trademark opposition proceedings in the United States Patent and Trademark Office. Opposition or revocation proceedings could be instituted in a foreign patent office as well. Under federal law, various forms of post issuance patent review proceedings have been authorized, including an inter-parties review process. These proceedings permit certain persons to challenge the validity of a patent on the grounds that it was known from the prior art. The filing of such proceedings, or the issuance of an adverse decision in such proceedings, could result in the loss of valuable patent rights that could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects. For more information, see Item 3. Legal Proceedings.

Regulatory Risks

The Need to Obtain Regulatory Approvals, Clearances, Authorizations or Certifications Could Increase the Company's Costs and Adversely Affect Its Financial Performance.

Many of the Company's proposed and existing products and services are subject to regulation by the FDA and other governmental or public health agencies. In particular, the Company is subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of its products and the processes and procedure for its laboratory services. The Company's practice is to train its employees on the legal requirements applicable to its business, including the requirements of the FDA and other relevant agencies.

The process of obtaining required approvals, clearances, other premarket authorizations or certifications can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. These approvals, clearances, other premarket authorizations or certifications can require the submission of a large amount of clinical data which can be expensive and may require significant time to obtain. It is also possible that a product will not perform at a level needed to generate the clinical data required to obtain such premarket authorizations or certifications. The submission of an application to the FDA or other regulatory authority does not guarantee that an authorization to market or import the product or a laboratory certification will be received. A regulatory authority may impose requirements as a condition to granting an approval, clearance, premarket authorization or certification that may include significant restrictions or limitations. The regulatory authority may delay or refuse to grant premarket authorization or certification, even though a product has been approved or registered without restrictions or limitations in another country or by another agency. Delays in receipt or failure to receive such approvals, clearances, premarket authorization or certification could have a material adverse effect on the Company's business, financial condition and results of operations.
All in vitro diagnostic products that are to be sold in the EU must bear the CE mark indicating conformance with the requirements of the relevant EU in vitro diagnostic medical devices legislation. The new EU Regulation 2017/746 on in vitro diagnostic medical devices ("IVDR"), became applicable on May 26, 2022 and repealed the previous Directive 98/79/EC, ("IVDD"). There is a transitional period during which products that have a declaration of conformity issued under the IVDD prior to May 26, 2022 may continue to be placed on the EU market for a certain period before requiring certification under the IVDR (subject to compliance with certain requirements under the IVDR, including in respect of post-market surveillance); however, class A non-sterile products do not benefit from such transitional provisions and have been required to be IVDR compliant since May 26, 2022, while Class D devices benefit from such transitional provisions until May 26, 2025. On January 23, 2024, the European Commission introduced a legislative proposal to extend such transitional provisions for certain devices. The European Commission has provided the legislative proposal to the European Parliament and the European Council for their review and approval. Once the European Commission's legislative proposal is approved (with or without amendment), it will be adopted into EU law. The Company has obtained the CE mark for several of its existing products under the IVDD. It also intends to apply for CE marks for certain of its future products and is not aware of any material reason why it would be unable to obtain those marks. However, there can be no assurance that compliance with all provisions of the IVDR will be demonstrated and the CE mark will be obtained or maintained for all products that the Company desires to sell in the EU. The failure to obtain or maintain the CE mark for one or more of the

Company's products could lead to the termination of strategic alliances and agreements for sales of those products in the EU and mean that the Company is unable to sell such products in the EU.

In addition, the Company or its distributors are often required to obtain premarket authorization or product registration with foreign governments or regulatory bodies before it can import and sell its products in foreign countries. The Company may also be required to obtain WHO pre-qualification or endorsement in order to sell certain products in international markets or enable its customers to access interested funding sources for its products. The Company may have difficulty obtaining such authorizations, registrations, pre-qualifications or endorsements and, if obtained, such authorizations, registrations, pre-qualifications or endorsements may contain restrictions that limit the Company's ability to market and sell its products in the relevant country. In addition, any change in the Company's arrangement with a foreign distributor could result in the loss of or delay in transfer of any applicable product registrations, thereby interrupting the Company's ability to sell those products in the affected markets.

Failure to Comply With FDA or Other Regulatory Requirements May Require the Company to Suspend Production or Sale of Its Products or Institute a Recall Which Could Result in Higher Costs and a Loss of Revenues.

Regulation by the FDA and other federal, state and foreign regulatory agencies impacts many aspects of the Company's operations and the operations of its suppliers and distributors, including manufacturing, labeling, packaging, adverse event reporting, recalls, distribution, storage, advertising, promotion and recordkeeping. The Company is subject to routine inspection by the FDA and other agencies to determine compliance with QSR and FDA regulatory requirements in the United States and other applicable regulations worldwide, including but not limited to ISO standards. The Company believes that its facilities and procedures are in material compliance with the FDA requirements and ISO standards, but the regulations may be unclear and are subject to change, and the Company cannot be sure that the FDA or other regulators will agree with its compliance with these requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved or cleared products or impose conditions on any product clearances or approvals that could restrict the distribution or commercial applications of those products. Regulatory agencies may impose restrictions on the Company or its distributors' advertising and promotional activities or preclude these activities altogether if a noncompliance is believed to exist. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product or additional regulatory actions, including withdrawal of the product from the market.

Failure to comply with the applicable requirements of the FDA can result in, among other things, 483 notices, warning letters, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to grant PMA approval for devices, withdrawal of product registrations, marketing clearances or approvals, or criminal prosecution. The ability of the Company's suppliers to supply critical components or materials and of its distributors to sell its products could also be adversely affected if their operations are determined to be out of compliance. Such actions by the FDA and other regulatory bodies could adversely affect the Company's revenues, costs and results of operations.

Some of the Company's products, particularly those sold by DNAG, are sold for research purposes in the U.S. The Company does not promote these products for clinical diagnostic use and they are labeled "For Research Use Only" ("RUO"). If the FDA were to disagree with the Company's RUO designation of a product, the Company could be forced to recall and/or stop selling the product until appropriate regulatory clearance or approval has been obtained.

In the ordinary course of business, the Company must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which the Company has sought to comply with these regulations, it could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of its products. The assessment of any civil and criminal penalties against the Company could severely impair its reputation within the industry and any limitation on its ability to manufacture and market its products could have a material adverse effect on the Company's business.

The Company's Inability to Respond to Changes in Regulatory Requirements Could Adversely Affect Its Business.

The Company believes that its products and procedures are in material compliance with all applicable FDA regulations, ISO requirements, and other applicable regulatory requirements, but the regulations regarding the manufacture and sale of its products, the QSR and ISO requirements, and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to the Company's products, necessitate additional clinical trials or procedures, or make it impractical or impossible for it to market its products for certain uses, in certain markets, or at all.

The FDA and other regulatory authorities also have the ability to change the requirements for obtaining product approval or clearance and/or impose new or additional requirements as part of the approval or clearance process. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and could delay or make it more difficult or complicated to obtain approvals and sell the Company's products. The Company cannot predict the effect, if any, that these changes might have on its business, financial condition or results of operations.

The Company Is Subject to Numerous Government Regulations in Addition to FDA Requirements, Which Could Increase the Company's Costs and Affect Its Operations.

In addition to the FDA and other regulations described previously, laws and regulations in some states may restrict the Company's ability to sell products in those states. While the Company intends to work with state legislators and regulators to remove or modify any applicable restrictions, there is no guarantee it will be successful in these efforts.

The Company must also comply with numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, disposal of hazardous substances, labor or employment practices and the configuration and operation of the websites through which it advertises its products. As a device manufacturer, the Company is required to report annually to the Centers for Medicare & Medicaid Services (“CMS”) any payments or transfers of value it has made to physicians and teaching hospitals and any physician ownership or investment interest in the Company's business. In the U.S., before the Company can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, it generally must first receive either 510(k) clearance or De Novo authorization or approval of a PMA from the FDA. Similarly, most major markets for medical devices outside the U.S. also require clearance, approval, authorization or compliance with certain standards before a product can be commercially marketed. Compliance with these laws or any new or changed laws regulating the Company's business could result in substantial costs. Because of the number and extent of the laws and regulations affecting the Company's industry, and the number of governmental agencies whose actions could affect its operations, it is impossible to reliably predict the full nature and impact of these requirements. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that the Company does not comply, its business and results of operations could be adversely affected.

Failure to Comply With Privacy, Security and Breach Notification Regulations May Increase the Company's Costs.

In the past, the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”) has generally affected the Company indirectly, as the Company is generally neither a Covered Entity nor a Business Associate, as further defined under HIPAA, to Covered Entities. The Company has in place certain administrative, technical and physical safeguards to protect the privacy and security of consumers’ personal information and endeavors to comply with all applicable state and federal laws with respect to the protection of consumers’ personal information. The Company is required to comply with varying state privacy, security and breach reporting laws. If it does not comply with existing or new laws and regulations related to properly transferring data containing consumers’ personal information, it could be subject to monetary fines, civil penalties or criminal sanctions. In addition to other federal and state laws that protect the privacy and security of consumers’ personal information, the Company may be subject to enforcement and interpretations by various governmental authorities and courts resulting in complex compliance issues. Moreover, the potential for enforcement action against the Company is now greater, as the U.S. Department of Health and Human Services (HHS) can take action directly against Business Associates. Thus, while the Company believes it is and will be in compliance with all required HIPAA standards, there is no guarantee that the government will agree. Enforcement actions can be costly and interrupt regular operations of the Company's business. For example, it could incur damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of consumers’ personal information.

Failure to Comply With Data Protection Requirements or Privacy Laws Could Increase the Company's Costs.

The Company is subject to European data protection regulations where it collects and uses personal data related to Europe. This includes the EU General Data Protection Regulation (“GDPR”) as well as other national data protection legislation in force in relevant European Economic Area (“EEA”) member states, which govern the collection, use, storage, disclosure, transfer, or other processing of personal data: (i) regarding individuals in the EEA; and/or (ii) carried out in the context of the activities of the Company's establishment in any EEA member state. Failure to comply with the GDPR, and any supplemental European Economic Area (“EEA”) country’s national data protection laws which may apply by virtue of the location of the individuals whose personal data the Company collects, may result in fines and other administrative

penalties, including fines of up to the greater of 4% of worldwide turnover and €20 million. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR imposes several mandatory requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, legal basis for processing personal data which may include obtaining the consent of the individuals to whom the personal data relates, providing notice to individuals about personal data processing activities, having data processing agreements with third parties who process personal data, notification of personal data breaches to data protection authorities and individuals, and the implementing of safeguards to protect the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to third countries, including the United States in certain circumstances, unless a derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses, or SCCs) have been put in place and a transfer impact assessment carried out. Any inability to transfer personal data from the EEA to the United States in compliance with data protection laws may impede the Company's ability to conduct trials and may adversely affect its business and financial position. Complying with the enhanced obligations imposed by the GDPR imposes additional obligations and risk upon the Company's business, and may result in significant costs to its business and require it to amend certain of its business practices. Further, the Company has no assurances that violations will not occur, particularly given the complexity of the GDPR.

The Company is also subject to the California Consumer Privacy Act of 2018 (“CCPA”), which took effect on January 1, 2020. The CCPA imposes extensive new requirements and protections on the processing of personal data, aimed at giving California consumers more visibility and control over their personal information. Failure to comply with the CCPA or other data processing or security laws, or any changes in these laws, could adversely impact the Company's business and its business plans. In 2020, California residents voted the California Privacy Rights Act (the "CPRA") into law. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. The CPRA also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the CPRA provisions became effective on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have been proposed, and likely will be proposed, in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

FDA Regulation of Laboratory-Developed Tests and Genetic Testing Could Affect Demand For the Company's Products.

The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA has taken the position that it has regulatory authority over laboratory-developed tests ("LDTs"), but has exercised enforcement discretion in not regulating most LDTs performed by high complexity CLIA-certified laboratories. LDTs are tests designed, developed, and performed in-house by a laboratory. Such laboratories are subject to regulation under CLIA but have not been subject to regulation by the FDA under the agency’s medical device requirements. A significant portion of the total volume of genetic or molecular testing is performed with LDTs.

In mid-2010, the FDA announced that it would begin regulating LDTs, including laboratory developed molecular tests, and in October 2014 issued proposed guidance on the regulation of LDTs for public comment. On January 13, 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. The Company cannot predict what policies will be adopted with respect to regulating LDTs. The FDA has been working with regulatory advocacy groups to bring forward legislative approaches specifically for in vitro diagnostic tests including LDTs. For example, in 2021, the Verifying Accurate, Leading-edge, IVCT Development ("VALID") Act was introduced to Congress and provided a framework to change IVDs and LDTs to in vitro clinical tests ("IVCTs"). The proposed regulation would give the FDA oversight of LDTs once it becomes law. In 2022, the VALID Act was incorporated into the Senate user fee bill but was not included in the year-end Consolidated Appropriations Act of 2022. Subsequently, the VALID Act was introduced to Congress again in March 2023.

On October 3, 2023, the FDA published a proposed rule on LDTs, in which the FDA proposes to end enforcement discretion for virtually all LDTs in five stages over a four-year period from the date the FDA publishes a final rule. In Phase 1 (effective one year post-finalization), laboratories would be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements. In Phase 2 (effective two years post-finalization),

laboratories would be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for quality systems and premarket review. In Phase 3 (effective three years post-finalization), laboratories would be required to comply with quality systems requirements. In Phase 4 (effective three and a half years post-finalization, but not before October 1, 2027), laboratories would be required to comply with premarket review requirements for high-risk tests (i.e., tests subject to the PMA requirement). Finally, in Phase 5 (effective four years post-finalization, but not before April 1, 2028), laboratories would be required to comply with premarket review requirements for moderate- and low-risk tests (i.e., tests subject to De Novo or the 510(k) requirement). Unlike previous proposals, the proposed rule does not include provisions that would allow for "grandfathering" of existing tests. The content and timing of any final rule on LDTs is uncertain at this time.

The Company's subsidiary, DNAG, sells its DNA collection systems to certain laboratories and other customers for use with LDTs. The FDA's increased regulation of LDTs could make it more difficult for laboratories and other customers to continue offering LDTs that involve genetic or molecular testing. This, in turn, could increase costs, delay the introduction of new LDTs and reduce demand for DNAG's products and adversely impact the Company's revenues.

In recent years, the Department of Justice indicted a number of telemedicine companies and cancer genetic testing laboratories for allegedly submitting fraudulent insurance claims to Medicare. A number of these companies were customers of DNAG. As a result of these activities, the FDA has issued letters to genetic testing laboratories indicating that it plans to increase oversight of this market which has caused some of these companies to stop providing testing options or to change how they are reporting the information provided by the testing. The activities have negatively affected this market and there is a risk that these enforcement actions will continue to negatively affect this market by forcing laboratories to either stop offering such services or restricting the use of such services. Such a reduction in testing could result in decreased sales of the Company's DNA collection devices.

The Company's International Sales Create Potential Exposure Under Anti-Corruption Laws.

The Company has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the FCPA and similar foreign laws. In 2023, approximately $43.8 million of the Company's consolidated net revenues were generated from sales in a variety of foreign countries. These international activities subject the Company to the FCPA, the U.K. Bribery Act and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by business entities for the purpose of obtaining or retaining business. The Company has operations, enters into agreements with third parties, and makes sales in countries known to experience corruption. Further international expansion, including the acquisition of foreign entities, may create increased exposure to such practices. The Company's activities in these countries creates the risk of unauthorized payments or offers of payments by one of the Company's employees, consultants, sales agents or distributors that could be in violation of various laws, including the FCPA, even though these parties are not always subject to the Company's control. It is the Company's policy to implement safeguards to discourage these practices by its employees and distributors, including employee training, contracts requiring compliance with the FCPA and similar rules, and standard reviews of its distributors. However, the Company's existing safeguards and any future improvements may not prove to be effective, and its employees, consultants, sales agents or distributors may engage in conduct for which the Company might be held responsible. Violations of the FCPA and other laws may result in criminal or civil sanctions, which could be severe and the Company may be subject to other liabilities, which could negatively affect its reputation, business, results of operations and financial condition.

Risks Relating to the Economy, the Company's Financial Results, Investments, Credit Facilities and Need for Financing

The Company Has Experienced Losses in the Past and May Not Be Able To Again Achieve and Maintain Profitable Operations.

The Company has experienced annual net losses during the five years prior to 2015 and between 2020 through 2022. In addition, as of December 31, 2023, the Company had an accumulated deficit of $83.9 million. Even though the Company achieved profitability in 2015 through 2019 and in 2023 there can be no assurance that it will be able to achieve or sustain profitability in the future.

The Company's ability to achieve and continue profitable operations in the future will be dependent upon a number of factors including, without limitation, the following:

- The Company's ability to continue growing sales of its molecular sample management solutions and related genomic and microbiome laboratory services;
- The Company's ability to produce and successfully commercialize its InteliSwab® COVID-19 Rapid Tests and compete with comparable products;
- The Company's ability to grow its OraQuick *ADVANCE*® HIV 1/2 test in the United States and expand sales of its OraQuick® HIV Self-Test internationally;
- Changes in the markets in which the Company operates, including changes in the prevalence of COVID-19;
- Changes in customer buying patterns or a buildup of significant quantities in the Company's distributors' inventories or distribution channels;
- The level of expenditures the Company is required to make in order to develop, obtain regulatory approvals for and successfully commercialize its new products;
- The Company's ability to expand its business through the acquisition of other companies or technologies or through internal development of new or improved products;
- The Company's ability to realize revenues and other anticipated benefits from its distribution relationship with Sapphiros;
- The Company's ability to improve manufacturing efficiencies and reduce cost of goods sold;
- The Company's ability to successfully launch new products after receipt of required regulatory approvals or the acquisition of rights to those products;
- The degree to which the Company's major distributors and customers comply with their contractual obligations, including minimum purchase commitments;
- Whether the Company or entities in which it invests are successful in obtaining and maintaining required regulatory approvals and registrations for its new products;
- The level of competition, including the degree to which competitors sell lower priced products or more attractive offerings to compete with the Company's products;
- Changes in economic conditions in domestic or international markets, such as economic downturns, reduced demand, inflation and currency fluctuations;
- Global economic and political instability and conflicts, such as terrorism, civil unrest, war and natural disasters in foreign countries;
- Failure to achieve the Company's revenue growth targets; and
- The costs and results of patent infringement, product liability and other litigation or claims asserted by or against the Company.

Recent Volatility In Capital Markets and Lower Market Prices For the Company's Securities May Affect Its Ability to Access New Capital Through Sales of Shares of Its Common Stock or Issuance Of Indebtedness, Which May Materially Harm Its Liquidity, Limit Its Ability to Grow Its Business, Pursue Acquisitions or Improve Its Operating Infrastructure and Restrict Its Ability to Compete in Its Markets.

The Company's operations consume substantial amounts of cash, and it intends to continue to make significant investments to support its business growth, respond to business challenges or opportunities, develop new solutions, retain or expand its current levels of personnel, improve its existing solutions, enhance its operating infrastructure, and potentially acquire complementary businesses and technologies. The Company's future capital requirements may be significantly different from its current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance its technological infrastructure and its existing solutions;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, the Company may need to pursue equity or debt financing to meet its capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to the Company or at all. If the Company raises additional funds through further issuances of equity or convertible debt securities, its existing stockholders could suffer significant dilution, and any new equity securities the Company issues could have rights, preferences, and privileges superior to those of holders of its common stock. Any debt financing secured by the Company in the future could involve additional restrictive covenants relating to its capital-raising activities and other financial and operational matters, which may make it more difficult for it to obtain additional capital and to pursue business opportunities, including potential acquisitions. If the Company is unable to obtain adequate financing or financing on terms satisfactory to it, the Company could face significant limitations on its ability to invest in its operations and otherwise suffer harm to its business.

Economic Volatility and Disruption, Including Those Related to the COVID-19 Pandemic, Could Adversely Affect the Company's Business, Financial Performance, Results of Operations, Cash Flow and Financial Condition or Those of Its Customers and Suppliers.

Global and U.S. markets and economies have experienced extreme volatility and disruption following the global outbreak of COVID-19 that has continued throughout 2023. Volatile economic conditions may occur again or continue in the future.

Impacts of the COVID-19 pandemic that the Company has or may experience in the future include, but are not limited to:

- a slowdown or stoppage in the supply chain of the raw materials and components used to manufacture its products;
- interruptions or delays in domestic and/or international shipment of its products to its distributors and customers;
- interruptions in normal operations of certain end-use customers that could result in reductions in demand for its products;
- disruptions to the Company's operations, including a shutdown of its facilities or product lines; restrictions on its operations and sales, marketing and distribution efforts; and interruptions to its research and development, manufacturing, clinical/regulatory and other important business activities;
- shutdown or interruption of the Company's manufacturing facilities due to contamination and costs incurred to clean and disinfect a facility following contamination;
- inefficiencies and increased costs in the Company's production and shipping processes due to premium pay for manufacturing and certain other employees as well as social distancing and personal protective equipment requirements;
- limitations on employee resources and availability, including due to sickness, government restrictions, the desire of employees to avoid contact with large groups of people or mass transit disruptions;
- a fluctuation in foreign currency exchange rates or interest rates could result from market uncertainties;
- an increase in exposure to credit losses for customers adversely affected by the COVID-19 pandemic; and
- an increase in regulatory restrictions or continued market volatility could hinder the Company's ability to execute strategic business activities, including acquisitions.

These conditions could adversely affect the Company's financial performance and condition or those of its customers and suppliers. These circumstances could also adversely affect the Company's access to liquidity needed to conduct or expand its business or conduct future acquisitions or make other discretionary investments. Many of the Company's customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of economic conditions or other factors. These circumstances may adversely impact the Company's customers and suppliers, which, in turn, could adversely affect their ability to purchase and/or distribute the Company's products or supply it with necessary equipment, raw materials or components. Any or all of these effects would have an adverse effect on the Company's operations, business, financial condition and results of operations.

Although there are positive signs that COVID-19 has begun to subside as compared to the height of the pandemic, the duration of the COVID-19 pandemic is still unknown, and it is difficult to predict the full extent of potential impacts the pandemic will have in the future on the Company's business, operations, and financial results, or on its customers, suppliers or logistics providers, or on the global economy as a whole. It is uncertain how materially the COVID-19 pandemic will affect the Company's global operations, particularly if the effects continue or get worse over an extended period of time. Even with the improvement of economic conditions, it may take time for the Company's customers and suppliers to establish new budgets and return to normal purchasing and shipping patterns. The Company cannot predict the re-occurrence of any economic slowdown or the strength or sustainability of an economic recovery.

Rising Inflation Rates Could Negatively Impact the Company's Revenues and Profitability if Increases in the Prices of Its Products or a Decrease in Consumer Spending Results in Lower Sales. In Addition, if the Company's Costs Increase and the Company Is Not Able to Pass Along These Price Increases to Its Customers, Its Net Income Would Be Adversely Affected, and the Adverse Impact May Be Material.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in decreased demand for the Company's products and services, increased operating costs (including the Company's labor costs), reduced liquidity, and limitations on its ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve previously raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. In an inflationary environment, the Company may be unable to raise the sales prices of its products at or above the rate at which its costs increase, which could/would reduce its profit margins and have a material adverse effect on its financial results and net income. The Company may also experience lower than expected sales and potential adverse impacts on its competitive position if there is a decrease in consumer spending or a negative reaction to its pricing. A reduction in the Company's revenue would be detrimental to its profitability and financial condition and could also have an adverse impact on its future growth.

An Impairment of Goodwill and Intangible Assets Could Reduce the Company's Earnings.

At December 31, 2023, the Company's consolidated balance sheet reflected approximately $35.7 million of goodwill and approximately $1.2 million of intangible assets. Goodwill is recorded when the purchase price of a business exceeds the fair value of the tangible and separately measurable intangible net assets. U.S. generally accepted accounting principles (“U.S. GAAP”) require the Company to test goodwill for impairment on an annual basis or when events or circumstances occur indicating that goodwill might be impaired. Long-lived assets, such as intangible assets with finite useful lives, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment review often cannot be done at the level of the individual asset and it must instead be applied to a group of assets. For the purpose of the Company's annual goodwill impairment testing based on the current circumstances of how the Company manages or business, this group of assets is the Company as a whole. If the Company determines that any of its goodwill or intangible assets were impaired, it will be required to take an immediate charge to earnings and its results of operations could be adversely affected. The Company recognized a pre-tax impairment charge of $8.5 million related to intangible assets during the year ended December 31, 2023, which is reported in loss on impairments in the Company's consolidated statement of operations.

Changes in Foreign Currency Exchange Rates Could Negatively Affect the Company's Operating Results.

The Company's financial statements are stated in U.S. dollars and, historically, most of its international sales have also been denominated in U.S. dollars. As a result, in the past the Company's exposure to foreign currency exchange rate risk has not been material. Nonetheless, these sales are subject to currency risks since changes in the values of foreign currencies relative to the value of the U.S. dollar can render the Company's products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of the Company's products, as could changes in the general economic conditions in those markets.

In addition, the revenues and expenses of the Company's subsidiary, DNAG, are recorded in Canadian dollars and the revenues and expenses of its subsidiary Novosanis are recorded in Euros. Revenues and expenses denominated in foreign currencies are translated into U.S. dollars for purposes of reporting consolidated financial results. The Company's expectation is that the businesses of its foreign subsidiaries will continue to grow and its exposure to foreign currency exchange rates may be more significant than in past years.

Exchange rate fluctuations may affect the revenues and expenses of the Company's foreign subsidiaries and the translation of those financial results into U.S. dollars. Favorable movement in exchange rates have benefited the Company in prior periods. However, where there are unfavorable currency exchange rate fluctuations, the Company's consolidated financial statements including its balance sheet, revenues and results of operations, could be negatively affected. In addition, fluctuations in exchange rates could affect year-to-year comparability of operating results. In the past, the Company has not generally entered into hedging instruments to manage its currency exchange rate risk, but it may need to do so in the future. However, the Company's attempts to hedge against these risks may not be successful. If the Company is unable to successfully hedge against unfavorable foreign currency exchange rate movements, its consolidated financial results may be adversely impacted.

Risks Relating to the Company's Common Stock

The Company's Stock Price Could Continue to be Volatile.

The Company's stock price has been volatile, has fluctuated substantially in the past, may be volatile in the future and could experience substantial declines. The following factors, among others, could have a significant impact on the market for the Company's Common Stock:

- The performance of the Company's business, including its efforts to increase sales of OraQuick® HIV, HCV and Molecular sample management solutions and its OraQuick® In-Home HIV test and HIV Self-Test;
- The Company's efforts to expand sales of its genomic and microbiome laboratory service offerings;
- The Company's efforts to produce and commercialize its InteliSwab® Covid-19 Rapid Tests;
- Future announcements concerning the Company and its products or services, including with respect to significant acquisitions, strategic collaborations and joint ventures;
- Ability to achieve the expected benefits, enhanced revenue growth and synergies from strategic acquisitions;
- Clinical results with respect to the Company's products or services or those of its competitors;
- The status of clinical studies and pending submissions for required regulatory approvals;
- The announcement of regulatory or enforcement actions by the FDA or other agencies against the Company, its products or services, or one or more of its customers;
- The gain or loss of significant contracts and availability of funding for the purchase of the Company's products and services;
- Delays in the development, regulatory approval or commercialization of new or enhanced products or services;
- Legislative developments and industry or competitive trends;
- Biological or medical discoveries;
- Disputes or developments with key customers, distributors or suppliers;
- Developments in patent or other proprietary rights;
- Litigation or threatened litigation;
- Complaints or concerns about the performance or safety of the Company's products and publicity about those issues, including publicity expressed through social media or otherwise over the internet;
- Failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about the Company by securities analysts or major stockholders;
- Governmental regulation;
- Changes in the level of competition;

- Loss of or declines in sales to major distributors or customers or changes in the mix of products sold;
- Period-to-period fluctuations in the Company's operating results;
- Additions or departures of key personnel;
- General market and economic conditions; and
- Terrorist attacks, civil unrest, war and national disasters, including pandemics.

In addition, the stock market in general has experienced extreme price and volume fluctuations that have affected the market price of the Company's Common Stock, as well as the stock of many companies in the diagnostics and life sciences industries. Often, price fluctuations are unrelated to the operating performance of the specific companies whose stock is affected.

In the past, following periods of volatility in the market price of a company's stock, securities class action litigation has occurred against the issuing company. If the Company were subject to this type of litigation in the future, it could incur substantial costs and experience a subsequent diversion of management's attention and resources, each of which could have a material adverse effect on the Company's revenue and earnings. Any adverse determination in this type of litigation could also subject the Company to significant liabilities.

Future Sales of the Company's Common Stock by Existing Stockholders, Executive Officers or Directors Could Depress the Market Price of Its Common Stock and Make It More Difficult for the Company to Sell Stock in the Future.

Sales of the Company's Common Stock in the public market, or the perception that such sales may occur, could negatively impact the market price of its Common Stock. The Company is unable to estimate the number of shares of its Common Stock that may actually be resold in the public market since this will depend on the market price for its Common Stock, the individual circumstances of the sellers and other factors.

The Company has a number of institutional stockholders that own significant blocks of its Common Stock. If one or more of these stockholders sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of the Company's Common Stock could be negatively affected. In addition, it is possible that one or more of the Company's executive officers or non-employee members of its Board of Directors could sell shares of its Common Stock during an open trading window or pursuant to a 10b5-1 sales plan under the Company's Insider Trading Policy. These transactions and the perceived reasons for these transactions could have a negative effect on the prevailing market price of the Company's Common Stock.

Because the Company Does Not Intend to Pay Cash Dividends on Its Common Stock, an Investor in the Company's Common Stock Will Benefit Only if the Its Common Stock Appreciates in Value.

The Company currently intends to retain its current earnings and future earnings, if any, to finance the expansion of its business and does not expect to pay any cash dividends on its Common Stock in the foreseeable future. As a result, the success of an investment in the Company's Common Stock will depend entirely upon any future appreciation. There is no guarantee that OraSure's Common Stock will appreciate in value or even maintain the price at which investors purchased their shares.

Certain Provisions in the Company's Certificate of Incorporation and Bylaws and Under Delaware Law Could Make a Third-Party Acquisition of the Company Difficult.

The Company's Certificate of Incorporation and Bylaws contain provisions that could make it more difficult for a third party to acquire it, even if doing so would be beneficial to the Company's stockholders. The Company is also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of it. These provisions could limit the price investors might be willing to pay in the future for shares of the Company's Common Stock.

General Risk Factors

The Company May Face Product Liability Claims for Injuries Resulting From the Use of Its Products.

The Company may be held liable if any of its products, or any product which is made with the use or incorporation of any of its technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. There is no assurance that the Company would be successful in defending any product liability lawsuits brought against it. Moreover, there is no assurance that the Company's products will not be included in unethical, illegal or inappropriate research or applications, which may in turn put the Company at risk of litigation. Regardless of merit or eventual outcome, product liability claims could result in:

- Decreased demand for the Company's products;
- Lost revenues;
- Damage to the Company's image or reputation;
- Costs related to litigation;
- Increased product liability insurance costs;
- Diversion of management time and attention; and
- Incurrence of damages payable to plaintiffs.

The Company is selling the InteliSwab® COVID-19 Rapid Test and the OraQuick® In-Home HIV test in the United States OTC market, and it offers HIV Self-Tests to consumers internationally. The Company believes the sale of products for use by consumers increases its potential exposure to product liability and other claims.

Performance of the Company's Products May Affect Its Revenues, Stock Price and Reputation.

The Company's products are generally sold with labeling that contains performance claims approved or cleared by the FDA or other regulators. However, the Company's products may not perform as expected. For example, a defect in one of the Company's diagnostic or specimen collection products or a failure by a customer to follow proper testing procedures, may cause the product to report inaccurate information such as a false positive result or a false negative result. A false positive or negative result can also occur even when there is no apparent product defect and the customer has apparently used the Company's product properly. Identifying the root cause of a product performance or quality issue can be difficult and time consuming.

If the Company's products fail to perform in accordance with the applicable label claims or otherwise in accordance with the expectations or needs of its customers, customers may switch to a competing product or otherwise stop using the Company's products, and the Company's revenues could be adversely affected. Under such circumstances, the Company may be required to implement shipment holds or product recalls and incur warranty obligations, which would increase its costs. In addition, poor performance by one or more of the Company's products and publicity surrounding such performance could have an adverse effect on the Company's reputation, its continuing ability to sell products and the prevailing market price of its Common Stock.

The Company's Ability to Sell Products Could be Adversely Affected by Competition From New and Existing Products and Services.

The markets the Company serves are highly competitive and rapidly changing and it expects competition to intensify as technological advances are made and become more widely known, and as new products and services reach the market. Many of the Company's principal competitors have considerably greater financial, technical and marketing resources than it does. As new products and services enter the market, the Company's products and services may become obsolete or a competitor’s products and services may be more effective or attractive or more effectively marketed and sold than the Company's. In addition, there can be no assurance that the Company's competitors will not succeed in obtaining regulatory approval for new products and services that would render the Company's technologies, products and services obsolete or otherwise commercially unattractive, or introduce or commercialize such products and services before the Company can do so. If the Company fails to convince its customers of the advantages and economic value of its products and services or otherwise maintain and enhance its competitive position, its customers may decide to use products and services developed by competitors which could result in a loss of revenues. These developments could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company also faces competition from products that are sold at a lower price. Where this occurs, customers may choose to buy lower cost products from third parties or the Company may be forced to sell its products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of its products. The Company may also be required to increase its marketing efforts in order to compete effectively, which would increase its costs.

Failure to Achieve the Company's Financial and Strategic Objectives Could Have a Material Adverse Impact on Its Business Prospects.

As a result of any number of risk factors identified in this Annual Report, no assurance can be given that the Company will be successful in implementing its financial and strategic objectives, including its efforts to increase sales of its products and services or continue growing its business. In addition, the funds for research, clinical development and other projects have in the past come primarily from the Company's business operations. If the Company's business slows and it has less money available to fund research and development and clinical programs, it will have to decide at that time which programs to cut, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, the Company may be required to delay or scale back its business. The Company's operations will be adversely affected if its total revenue and gross profits do not correspondingly increase or if its technology, product, service, clinical and market development efforts are unsuccessful or delayed. Furthermore, the Company's failure to successfully introduce new or enhanced products and services and develop new markets could have a material adverse effect on its business and prospects.

If the Company Fails To Establish and Maintain Proper And Effective Internal Control Over Financial Reporting, Its Operating Results and Its Ability to Operate Its Business Could Be Harmed.

Ensuring that the Company has adequate internal financial and accounting controls and procedures in place so that it can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. The Company is required to comply with the requirements of the Sarbanes-Oxley Act of 2002, or SOX, which requires that it maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, the Company must perform system and process evaluation, document its controls and perform testing of its key controls over financial reporting to allow management and its independent public accounting firm to report on the effectiveness of its internal control over financial reporting, as required by Section 404 of SOX. The Company's testing, or the subsequent testing by its independent public accounting firm, may reveal deficiencies in its internal control over financial reporting that are deemed to be material weaknesses. For instance, management identified a material weakness in the Company's internal control over financial reporting related to customer pricing in the revenue recognition process and concluded that its disclosure controls and procedures were not effective due to the existence of the material weakness as of September 30, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. During the fourth quarter of 2023, the Company implemented controls to validate accurate pricing in customer sales orders. As a result the material weakness was remediated as of December 31, 2023.

If the Company Loses Key Personnel or Is Unable to Attract and Retain Qualified Personnel as Necessary, Its Business Could be Harmed.

The Company's success depends to a large extent upon the contributions of its executive officers, management and sales, marketing, operations and scientific staff. The Company's business may be harmed by the loss of a significant number of its executive officers or senior managers. It may not be able to attract or retain a sufficient number of qualified employees in the future due to the intense competition for qualified personnel among medical products, laboratory services and other life science businesses. The Company's ability to recruit such employees will depend on a number of factors, including compensation, benefits, work location, the prospects of the Company, and the possibility for advancement within the organization. The Company generally does not enter into employment agreements requiring its employees to work for it for any specified period.

If the Company is not able to attract and retain the necessary personnel to accomplish its business objectives, it may experience constraints that will adversely affect its ability to effectively produce, market and sell its products and services, to meet the demands of its strategic partners in a timely fashion, or to support research, development and clinical programs. Although the Company believes it will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other qualified personnel from numerous companies and academic and other research institutions may limit its ability to do so on acceptable terms.

The Company has experienced a number of significant changes in its senior leadership in recent years and faces risks related to losses of key personnel and to any such changes that occur in key senior leadership positions. Although the Company has endeavored to implement any management and director transition in a non-disruptive manner, such transitions might impact its business, and give rise to uncertainty among its customers, investors, vendors, employees and others concerning its future direction and performance, which may materially and adversely affect its business, financial condition, results of operations and cash flows, and its ability to execute its business model. The Company can provide no assurance that it will find suitable successors to key roles as transitions occur or that any identified successor will be successfully integrated into the management team.

In addition, because certain members of the Company's management and board of directors have served in their respective capacities for only limited durations, the Company faces the additional risks that these persons have limited familiarity with the Company's past practices, its business and its industry and lack established track records in managing its business strategy.

Increases in Demand for the Company's Products and Services Could Require It to Expend Considerable Resources or Harm Its Customer Relationships if It Is Unable to Meet That Demand.

If the Company experiences significant or unexpected increases in the demand for its products and services, the Company and its suppliers may not be able to meet that demand without expending additional capital resources. These capital resources could involve the cost of new products, machinery or new manufacturing or laboratory facilities. This would increase the Company's capital costs, which could adversely affect its earnings. The Company's suppliers may be unable or unwilling to expend the necessary capital resources or otherwise expand their capacity. In addition, new manufacturing or laboratory equipment and facilities may require FDA approval or government or industry certification before they can be used to manufacture the Company's products or provide laboratory services. To the extent the Company is unable to obtain or is delayed in obtaining such approvals, its ability to meet the demand for its products and services could be adversely affected.

If the Company is unable to develop necessary manufacturing or laboratory capabilities in a timely manner, its sales could be adversely affected. If the Company fails to increase these capabilities in a cost effective manner or if it experiences lower than anticipated yields or production or performance problems as a result of changes that it makes in its manufacturing or laboratory processes to meet increased demand, it could experience delays or interruptions and increased costs, which could also have a material adverse effect on its revenues and profitability.

Unexpected increases in demand for the Company's products may require it to obtain additional raw materials in order to manufacture products to meet the demand. Some raw materials require significant ordering lead time and some are currently obtained from a sole supplier or a limited group of suppliers. The Company has long-term supply agreements with certain of these suppliers, but these long-term agreements involve risks for the Company, such as its potential inability to obtain an adequate supply of raw materials and components and its reduced control over pricing, quality and timely delivery. It is also possible that one or more of these suppliers may become unwilling or unable to deliver materials to the Company. Any shortfall in the Company's supply of raw materials and components, or its inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on its ability to meet increased demand for its products. This could negatively affect the Company's total revenues or cost of sales and related profits.

The Company's inability to meet customer demand for its products and services could also harm its customer relationships and impair its reputation within the industry. This, in turn, could have a material adverse effect on the Company's business and prospects.

The Company Relies on Information Technology in Its Operations and Any Material Failure, Inadequacy, Interruption or Security Breach of that Technology Could Harm Its Ability to Efficiently Operate Its Business.

The Company relies heavily on enterprise resource planning and other complex information technology systems across its operations and on the internet, including for management of inventory, processing and analyzing laboratory specimens, purchase orders, invoices, shipping, revenue and expense accounting, online business, consumer call support, and various other processes and transactions. The Company's ability to effectively manage its business, coordinate the production, distribution and sale of its products, process and analyze specimens in its laboratories, respond to customer inquiries, and ensure the timely and accurate recording and disclosure of financial information depends significantly on the reliability and capacity of these systems and the internet.

The failure of any of the foregoing systems to operate effectively, problems with transitioning to upgraded or replacement systems, or disruptions in the operation of the internet, could cause delays in product sales or the provision of laboratory services and reduced efficiency of the Company's operations. Significant expenditures could be required to remediate any such problem.

Cybersecurity Incidents and Other Disruptions Could Compromise the Company's Information, Expose It to Liability and Harm Its Reputation and Business.

In the ordinary course of business, the Company collects and stores sensitive and confidential data, including intellectual property, personal information, its proprietary business information and that of its customers, suppliers and business partners, and personally identifiable information of its employees in its data centers and on its networks. Secure maintenance and transmission of this information is critical to the Company's operations business strategy. It generally relies on commercially available systems, software, tools and domestically available monitoring to provide security for processing, transmitting and storing this sensitive and confidential data.

Cyber-attacks and other cybersecurity incidents such as ransomware, phishing, and social engineering attacks could result in unauthorized access to the Company's computer systems or its third-party IT service providers' systems and, if successful, misappropriate personal, sensitive, or confidential information. The Company has in the past and may in the future experience cybersecurity incidents. If successful, these attacks could lead to service interruptions, extortion, theft of confidential, personal or proprietary information, the compromise of data integrity or unauthorized information disclosure. Any technology service interruption or breach of the Company's systems could adversely affect its business operations and/or result in the loss or compromise of personal, sensitive, or confidential information or intellectual property. The Company maintains cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of the Company's systems.

The Company has outsourced significant elements of its IT infrastructure and, as a result, it manages relationships with third-party providers who may or could have access to the Company's sensitive and confidential information. The Company relies on technology developed, supplied and/or maintained by third-parties that may make the Company vulnerable to “supply chain” style cyber-attacks. Further, technology and security vulnerabilities of acquisitions, business partners or third-party providers may not be identified during due diligence or soon enough to mitigate exploitation. The size and complexity of the Company's IT and information security systems, and those of its third-party providers (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security incidents from inadvertent or intentional actions by, but not limited to, Company employees, service providers, business partners, customers or malicious attackers. In addition, a contractor or other third party with whom the Company does business may attempt to circumvent its security measures or obtain such information, and may purposefully or inadvertently cause an incident involving sensitive information. While the Company will continue to evaluate and implement additional protective measures to reduce the risk and detect cybersecurity incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite the Company's cybersecurity measures, its information technology networks and infrastructure may still be vulnerable to damage, disruptions or shutdowns due to cybersecurity incidents, compromises, or malfeasance.

Even the most well protected IT networks, systems and facilities remain potentially vulnerable because the techniques used in attempted cybersecurity incidents are continually evolving and generally are not recognized until launched against a target or, in some cases, are designed not to be detected and, in fact, may not be detected. Any such compromise of the Company's or its third party’s IT service providers’ data security and access, public disclosure, or loss of personal, sensitive, or confidential business information, could result in legal claims and proceedings, liability under laws to protect privacy of personal information, and regulatory penalties, and could disrupt the Company's operations, require significant management attention and resources to remedy any damages that result, and damage the Company's reputation and customers willingness to transact business with it, any of which could adversely affect its business.

As the Company's activities continue to evolve and expand, it may be subject to additional laws which impose further restrictions on the transfer, access, use, and disclosure of health and other personal information which may impact its business either directly or indirectly. The Company's failure to comply with applicable privacy or security laws or significant changes in these laws could significantly impact its business and future business plans.

Federal and State Laws Pertaining to Healthcare Fraud and Abuse Could Adversely Affect the Company's Business, Financial Condition and Results of Operations.

The Company is subject to various federal and state laws targeting fraud and abuse in the healthcare industry, including anti-kickback laws, false claims laws, laws constraining the sales, marketing and promotion of medical devices by limiting the kinds of financial arrangements that manufacturers of these products may enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices, and laws requiring the reporting of certain transactions between manufacturers and healthcare professionals. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs such as Medicare and Medicaid. Many of the existing requirements have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until the Company is in full compliance with these laws, it could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm its business. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require the Company to change its business practices or subject its business practices to legal challenges, which could have a material adverse effect on its business, financial condition and results of operations.

The Company May Experience Fluctuations in Its Financial Results or Fail to Meet Its Financial Projections.

The Company's operating results can fluctuate from quarter to quarter and year to year, which could cause its growth or financial performance to fall below the expectations of investors and securities analysts. The Company's financial projections for future periods are based on a number of assumptions, including estimated demand for its products. However, sales to its distributors and other customers may fall short of expectations because of lower than estimated demand or other factors, including continued volatility and disruption in economic conditions, increasing competition, seasonal fluctuations, changes in ordering patterns or business strategy, reduced governmental funding and other circumstances described elsewhere in this Annual Report. Infrequent, unusual or unexpected changes in revenues or costs could also contribute to the variability of the Company's financial results.

Customers in certain of the markets the Company serves often submit a high percentage of purchase orders in the third month of a calendar quarter. Although this can vary from quarter to quarter, many customers make purchase decisions late in a quarter due to budgetary or financial requirements. In addition, certain governmental customers must fully spend budgeted funds by the end of their fiscal year or risk losing these funds, which can contribute to fluctuations in the Company's sales from year-to-year. This can make it difficult to accurately forecast whether the Company will achieve its quarterly sales forecasts and can cause variability in its operating results.

In addition, the Company's products provide different contributions to its gross margin. Accordingly, its operating results could also fluctuate and be affected by the mix of products sold and the relative prices and gross margin contribution of those products. Failure to achieve operating results consistent with the expectations of investors and securities analysts could adversely affect the Company's reputation and the price of its Common Stock.

The Company May Require Future Additional Capital.

The Company's future liquidity and ability to meet its future capital requirements will depend on numerous factors, including, but not limited to, the following:

- The costs, scope and timing of strategic acquisitions;
- The costs and timing of expansion of sales and marketing activities;
- The timing and success of the commercial launch of new products or services;
- The extent to which the Company gains or expands market acceptance for existing, new or enhanced products and services;
- The costs and timing of the expansion of the Company's manufacturing and laboratory capacity;
- The success of the Company's research and product development efforts;
- The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;
- The magnitude of capital expenditures;

- Changes in existing and potential relationships with distributors and other business partners;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and liability associated with patent infringement or other types of litigation; and
- Competing technological and market developments.

If additional financing is needed, the Company may seek to raise funds through the sale of equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to the Company on satisfactory terms, or at all.

Conditions in the Banking System and Financial Markets, Including the Failure of Banks and Financial Institutions, Could Have an Adverse Effect on the Company's Operations and Financial Results.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10 and March 12, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank, and Signature Bank and Silvergate Capital Corp, respectively, after each bank was unable to continue their operations. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future.

Although the Company does not maintain any deposit accounts, credit agreements or letters of credit with any financial institution currently in receivership, it is unable to predict the extent or nature of the impacts of these evolving circumstances at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, the Company's ability to access its existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that the failure of these financial institutions or the high market volatility and instability of the banking sector could have on economic activity and the Company's business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact the Company's business, financial condition and results of operations

Terrorist Attacks, Natural Disasters, Public Health Crises, Political Unrest or Other Catastrophic Events Outside of the Company's Control May Adversely Affect Its Business.

Terrorist attacks, natural disasters, including disasters attributable to climate change impacts, public health crises, political unrest or other catastrophic events outside of the Company's control, including pandemics, and subsequent governmental responses to these events, could cause economic instability. These actions could adversely affect economic conditions both within and outside the United States and reduce demand for the Company's products. For example, the COVID-19 outbreak has led to, and for an unknown period of time will continue to lead to, disruptions in local, regional, national and global markets and economies affected thereby, including the United States. This outbreak has resulted in, and until fully resolved is likely to continue to result in, among other things: (i) restrictions on travel, government mandated social distancing measures, and the temporary closure of many corporate offices, retail stores, and manufacturing facilities and factories; (ii) significant disruption to the business of many companies, including the Company's customers and suppliers, as well as layoffs of employees; (iii) reduction or termination by public health and other customers of infectious disease testing programs, including for HIV and HCV, and a reallocation of personnel and monetary resources from these programs to programs intended to address COVID-19; (iv) reduction or termination of clinical and research studies by academic and other entities that use the Company's molecular sample management solutions and molecular laboratory services; and (v) rapidly evolving proposals and actions by state and federal governments to address the problems being experienced by markets, businesses and the economy in general, which may have unintended consequences or may not adequately address such problems. These events have disrupted, and threaten to continue to disrupt, the Company's normal operation, the operations of its customers and suppliers and eliminate, reduce or delay its customers' ability to purchase and use its products and its suppliers' ability to provide raw materials and finished products. Despite the Company's efforts to manage and mitigate the impact of these events on itself, it is impossible to predict the precise nature and consequences of these events, or of any political or policy decisions and regulatory changes occasioned by emerging events or uncertainty under applicable laws or regulations that impact the Company. It is clear that these types of events are impacting and will, for at least some time, continue to impact the Company's product development and operation and in many instances the impact

may be adverse and may be material. Any potential impact to the Company's results of operations will depend to a large extent on future developments and new information that could emerge regarding the duration and severity of the COVID-19 pandemic and the actions taken by authorities and other entities to contain the spread or treat its impact, all of which are beyond the Company's control. These potential impacts, while uncertain, could adversely affect the Company's business and results of operation. In addition, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the United States and China, escalation of tensions between China and Taiwan, or escalation in conflict between Russia and Ukraine or between Israel and the various countries in the surrounding regions, including any resulting sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities in, for example, Russia, also could lead to disruption, instability and volatility in the global markets, which may have an adverse impact on the Company's business or ability to access the capital markets.

Various types of disasters, including earthquakes, fires, floods, riots, acts of terrorism and pandemics, may also affect the Company's manufacturing facilities and computer systems, and increase its cybersecurity risks. Although the Company has business interruption insurance, its facilities, including some pieces of manufacturing equipment and its computer systems, may be difficult to replace and could require substantial replacement lead-time. In the event the Company's existing manufacturing facilities or computer systems are affected by man-made or natural disasters, including pandemics, it may have difficulty operating its business and may be unable to manufacture products for sale or meet customer demands or sales projections. If the Company's manufacturing operations were curtailed or shut down entirely, it would seriously harm its business. Moreover, the Company may incur incremental costs following an unforeseen event which could adversely affect its results of operation.

The Ongoing Conflict Between Russia and Ukraine, and the Israel-Hamas War, and the Related Implications Could Have a Material Adverse Effect on the Company's Business And Results Of Operations.

As a result of the ongoing military conflict between Russia and Ukraine, the United States and other countries have imposed significant sanctions on Russia and could impose even wider sanctions. Such sanctions could damage or disrupt international commerce and the global economy. The Company cannot predict the broader or longer-term consequences of the conflict in Ukraine or Israel, or of the sanctions imposed to date, which could include embargoes, regional instability, geopolitical shifts, exchange rate fluctuations, financial market disruptions and economic recession. Further, the conflict in Ukraine or Israel could exacerbate supply chain challenges, lead to an increase in cyberattacks, affect the global price and availability of key commodities, reduce the Company's sales and earnings or otherwise have an adverse effect on its business and results of operations.

In addition, the conflict between Russia and Ukraine and the Israel-Hamas war may have the effect of heightening other risks disclosed in this Annual Report, any of which could materially and adversely affect the Company's business and results of operations. Such risks include but are not limited to interruptions in the transportation channels for the manufacture and global distribution of the Company's products, heightened inflation, depressed levels of consumer and commercial spending, disruptions to its global technology infrastructure, adverse changes in international trade policies and relations, and the inability to implement and execute its business strategy. The Company is currently unable to predict the extent, nature or duration of any of these occurrences.

Future Sales of Shares of the Company's Common Stock Could Adversely Affect the Trading Price of Its Common Stock and Its Ability to Raise Funds in New Equity Offerings.

Future sales of a substantial number of the Company's shares of Common Stock or equity-related securities in the public market or privately, or the perception that such sales may occur, could adversely affect prevailing trading prices of the Company's Common Stock, and could impair its ability to raise capital through future offerings of equity or equity-related securities. No prediction can be made as to the effect, if any, that future sales of shares of Common Stock or the availability of shares of Common Stock for future sale will have on the trading price of the Company's Common Stock.

ITEM 1B. Unresolved Staff Comments.

None

ITEM IC. Cybersecurity.

Cybersecurity Risk Management and Strategy

Our management recognizes the impact that cybersecurity threats could have on our business operations, our compliance with regulations, and our reputation. We have identified cybersecurity as a critical business risk as part of our overall risk management strategy, which our board of directors oversees.

We have implemented an information security management system in accordance with our risk profile and business that is designed to protect the Company, our employees, and our customers from cybersecurity threats. This system, which is informed by the National Institute of Standards and Technology (NIST) Cybersecurity Framework, includes, among other things, written policies, technical controls, and employee training. We have also developed an incident response policy and procedure designed to facilitate the handling of cybersecurity incidents.

Our cybersecurity risk management program, which is part of our enterprise risk management program, aims to identify risks from cybersecurity threats. Our cybersecurity risk management program includes a number of components, including informal self-assessments, penetration testing, and vulnerability assessments. Our managed security services provider helps us implement additional security controls, including malware protection and network security tools.

We take a risk-based approach to the evaluation of third-party vendors, and apply mitigations and processes based on our evaluation of the sensitivity of the data accessed by the vendor and the maturity of the vendor's programs. We use a third-party tool to assess the degree of risk posed by the vendor, and are in the process of developing a vendor security questionnaire.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party vendors have from time to time experienced threats and cybersecurity incidents that could affect our information or systems. For more information, see Item 1A. Risk Factors.

Governance Related to Cybersecurity Risks

Our vice president of information technology ("VP of IT") is responsible for the strategic leadership and direction of the Company's information security management system. Our VP of IT has 25 years experience managing IT teams, including 10 years managing IT security teams. Led by the VP of IT, along with our Senior Manager of IT Security, the IT leadership team meets at least annually, and more frequently as needed, to review the Company's cybersecurity objectives and take steps to further the suitability and effectiveness of the Company's information security program. The output from these meetings are reviewed periodically with senior management. We are also in the process of establishing a cybersecurity management committee comprised of IT, communications, finance, legal and product personnel.

The board and Audit Committee oversee the management of risks by the Company's executives. The Audit Committee, pursuant to its charter, is responsible for reviewing the Company's cybersecurity program and risks, as identified by Company management, and the steps that Company management has taken to protect against threats to the Company's assets including information systems and data security. The VP of IT provides updates to the Audit Committee approximately annually, which include, as appropriate, a description of risks from cybersecurity threats.

ITEM 2. Properties.

We own a 31,700 square foot facility that houses our primary corporate office, our sales and marketing, research and development, human resources, and regulatory and quality offices, a 48,000 square foot facility and a 33,500 square foot facility which are used for manufacturing activities, and we lease an additional 139,000 square foot manufacturing facility, which is primarily dedicated to the production of our InteliSwab® COVID-19 Rapid Tests. Each of these facilities is located in Bethlehem, Pennsylvania. Our subsidiary, DNAG, also leases a 35,883 square foot facility in Ottawa, Canada, which is used as its primary corporate office and houses sales and marketing, manufacturing, distribution, research and development, and regulatory and quality operations. Our other subsidiaries, Diversigen and Novosanis, also lease facilities for their operations.

The Company believes that the facilities described above are adequate for our current requirements.

ITEM 3. Legal Proceedings.

From time to time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, the outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on our future financial position or results of operations.

In June 2021, the Company filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum filed an answer to the initial complaint, asserting that its device does not infringe the Company's patent and that the Company's patent is invalid. In August 2021, the Company amended its complaint to add a second patent to this litigation. Spectrum responded to the Company's amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation and subsequently filed a request for review of the second patent at the Patent and Trademark Office ("PTO"), which was granted by the PTO. The District Court issued multiple pretrial orders, resolving the infringement, antitrust, and inequitable conduct claims without trial. First, the District Court granted Spectrum's motion for summary judgment of noninfringement, holding that Spectrum's saliva collection devices are not "kits for collecting and preserving a biological sample," among other rulings. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. The appeal is pending, with oral argument expected in the second half of 2024. Second, the Court denied Spectrum's motion to supplement its allegations of alleged antitrust violations, finding that if such an amendment were allowed, Spectrum's claims would not survive a motion for summary judgment. Spectrum thereafter withdrew its antitrust and inequitable conduct counterclaims. Spectrum did not appeal the District Court's denial of its motion to amend. On February 7, 2024, the PTO issued a Final Written Decision regarding the second patent in the litigation, holding that claims 1, 3–8, 11, and 12 of U.S. Patent No. 11,002,646 B2 are unpatentable. The Company is considering its appellate options. On September 15, 2023, Spectrum filed a separate petition for *inter partes* review of a third patent, which DNAG did not assert in the District Court. The Company filed a preliminary patent owner response on December 28, 2023. That petition remains pending.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

The Company's Common Stock is listed for trading on the Global Select Market tier of The Nasdaq Stock Market LLC ("Nasdaq") under the symbol "OSUR". On February 16, 2024, there were 276 holders of record and approximately 24,589 holders in street name of the Company's Common Stock, and the closing price of its Common Stock was $6.75 per share.

Dividends

The Company has never paid any cash dividends and its Board of Directors does not anticipate paying cash dividends in the foreseeable future. The Company intends to retain any future earnings to provide funds for the operation and expansion of its business.

Share Repurchases and Retirements

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs [1, 2]
October 1, 2023 - October 31, 2023	669 [3]	$ 5.66	—	11,984,720
November 1, 2023 - November 30, 2023	4,987 [3]	5.64	—	11,984,720
December 1, 2023 - December 31, 2023	676 [3]	8.01	—	11,984,720
	6,332		—	

(1) On August 5, 2008, the Board of Directors approved a share repurchase program pursuant to which the Company is permitted to acquire up to $25.0 million of outstanding shares. This share repurchase program may be discontinued at any time.

(2) This column represents the amount that remains available under the $25.0 million repurchase plan, as of the period indicated. The Company has made no commitment to purchase any shares under this plan.

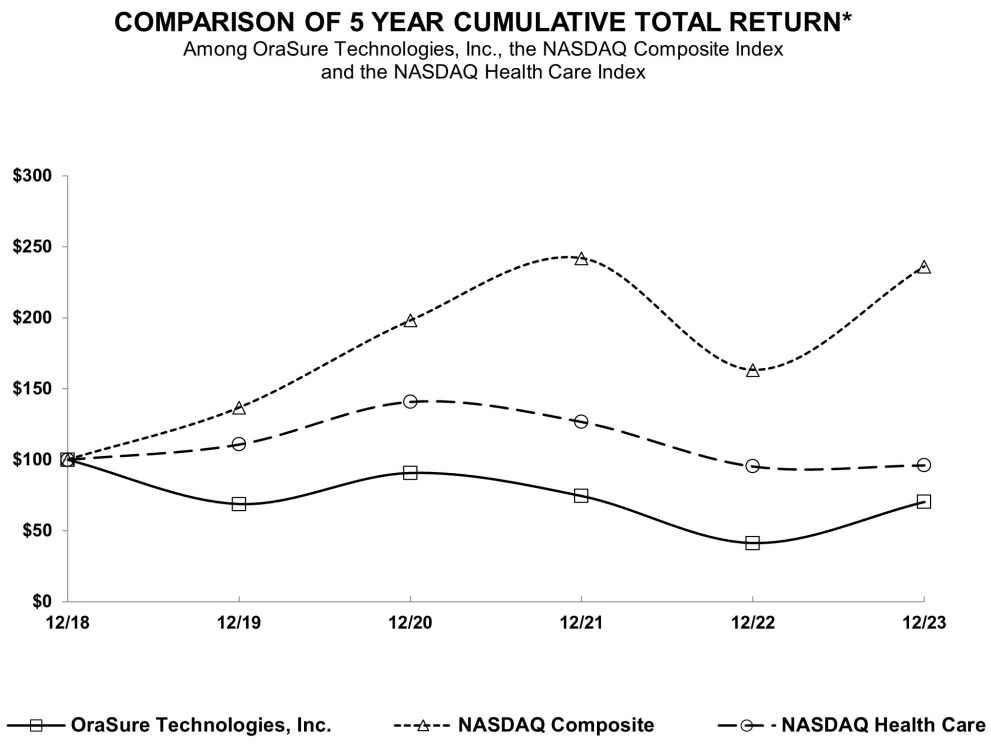
(3) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted and performance shares, these shares were retired to satisfy minimum tax withholdings.

Performance Graph

The performance graph set forth below shall not be deemed "soliciting material" or "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that Section. This graph will not be deemed "incorporated by reference" into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether such filing occurs before or after the date hereof, regardless of any general incorporation language in such filing.

The following graph compares the cumulative total returns to investors in the Company's Common Stock, the Nasdaq Composite Index, and the Nasdaq Health Care Index for the period from December 31, 2018 through December 31, 2023. The graph assumes that $100 was invested on December 31, 2018 in the Company's Common Stock and in each of the above-mentioned indices, and that all dividends, if any, were reinvested.

The Nasdaq Composite Index was chosen because it is a broad index of companies whose equity securities are traded on Nasdaq. The Nasdaq Health Care Index was chosen as it includes companies relevant to the Company's current business, it utilizes this index as a benchmark for compensation decisions, and many healthcare investors look to this index as an appropriate benchmark for stock performance. Stockholders are cautioned that the graph shows the returns to investors only as of the dates noted and may not be representative of the returns for any other past or future period.



*$100 invested on 12/31/18 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	Fiscal year ending December 31,					
	2018	2019	2020	2021	2022	2023
OraSure Technologies, Inc.	**100.00**	**68.75**	**90.63**	**74.40**	**41.27**	**70.21**
NASDAQ Composite	**100.00**	**136.69**	**198.10**	**242.03**	**163.28**	**236.17**
NASDAQ Health Care	**100.00**	**110.75**	**140.85**	**126.71**	**95.29**	**96.06**

Securities Authorized for Issuance Under Equity Compensation Plans

For certain information concerning securities authorized for issuance under the Company's equity compensation plan, see Item 12, “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.”

Item 6. Reserved

Not Applicable

ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

Statements below regarding future events or performance are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect results are discussed more fully under the Item 1A, entitled “Risk Factors,” and elsewhere in this Annual Report. Although forward-looking statements help to

provide complete information about the Company, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The Company undertakes no duty to update any forward-looking statements made herein after the date of this Annual Report.

The following discussion should be read in conjunction with the consolidated financial statements contained herein and the notes thereto, along with the Section entitled “Critical Accounting Policies and Estimates,” set forth below. This section of this Annual Report on Form 10-K for the year ended December 31, 2023 (this "Annual Report") generally discusses 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussion of 2021 items and year-to-year comparisons between 2022 and 2021 that are not included in this Annual Report can be found in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, Item 7 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

Business Overview

The Company's business consists of the development, manufacture, marketing and sale of simple, easy to use diagnostic products and specimen collection devices using the Company's proprietary technologies, as well as other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. These products include tests for diseases including COVID-19, HIV and Hepatitis C that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. The Company's COVID-19 and HIV products are also sold in a consumer-friendly format in the over-the-counter (“OTC”) market in the U.S. and, in the case of the HIV product, as a self-test to individuals in a number of other countries, including as an oral swab in-home test for HIV-1 and HIV-2 in Europe.

The Company's business also includes molecular sample management solutions and services that are used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers. The revenues from sample management solutions are derived from product sales to commercial customers and sales into the academic and research markets. Customers span the disease risk management, diagnostics, pharmaceutical, biotech, companion animal and environmental markets. The Company has also developed collection devices for the emerging microbiome market, which focuses on studying microbiomes and their effect on human and animal health. The Company also has a urine collection device which allows for the volumetric collection of first void urine. This product is in its early stages, and initial sales are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets. Additionally, the Company offers laboratory and bioinformatics services for both genomics and microbiome customers. These services are primarily provided to pharmaceutical, biotech companies, and research institutions.

Recent Developments

In 2022, the Company's business consisted of two segments: the “Diagnostics” segment, and the “Molecular Solutions” segment. In February 2023, the Company announced a corporate restructuring to combine the commercial and innovation teams across two segments, being the "Diagnostics" segment and the "Molecular Solutions" segment, into one business unit with sales, marketing, product development and research teams covering multiple product lines. This change is intended to accelerate innovation, enhance customer experience and result in operational synergies. As a result, all products and services reside under one reporting hierarchy. The Company's product portfolio is broadly divided into diagnostics products and sample management solutions.

In January 2024, the Company announced that it is leading the Series B financing and have entered wide-ranging strategic distribution agreements with KKR Sapphiros L.P. ("Sapphiros"), a privately held consumer diagnostics portfolio company based in Boston, and certain of its related entities. Through this strategic relationship, the Company expects to be able to offer a more comprehensive range of low-cost diagnostic tests and molecular sample management solutions to the Company's customers globally.

The Company has funded approximately $28.3 million for a minority interest in Sapphiros, with an aggregate commitment of up to $30.0 million to be funded by June 2024, contingent on certain terms and conditions being met.

Results of Operations

The Company's consolidated net income for the year ended December 31, 2023 was $53.7 million, or $0.72 per share on a fully diluted basis, compared to a consolidated net loss of $17.1 million, or $0.24 per share on a fully diluted basis, for the year ended December 31, 2022.

Year ended December 31, 2023 compared to December 31, 2022.

CONSOLIDATED NET REVENUES

The table below shows a summary of total consolidated net revenues (dollars in thousands) for the years ended December 31, 2023 and 2022.

	For the Years Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2023	2022	% Change	2023	2022
COVID-19 Diagnostics	$ 257,493	$ 233,666	10 %	64 %	60 %
Diagnostics [1]	73,694	52,181	41	18	14
Molecular Sample Management Solutions [2]	54,274	63,342	(14)	13	16
Other products and services [3]	12,001	11,903	1	3	3
Molecular Services	4,474	7,296	(39)	1	2
COVID-19 Molecular Products	286	9,659	(97)	—	3
Net product and services revenues	402,222	378,047	6	99	98
Non-product and services revenues [4]	3,250	9,432	(66)	1	2
Net revenues	$ 405,472	$ 387,479	5 %	100 %	100 %

[1] Includes HIV and HCV product revenues.
[2] Includes Genomics, Microbiome and Novosanis product revenues.
[3] Includes Risk assessment testing and other product and services revenues.
[4] Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues increased 5% to $405.5 million for the year ended December 31, 2023 from $387.5 million for the year ended December 31, 2022.

COVID-19 Diagnostics revenues increased by 10% to $257.5 million for the year ended December 31, 2023 compared to $233.7 million for the year ended December 31, 2022 due to increased sales of the Company's InteliSwab® tests through its U.S. government procurement contracts. The Company expects a significant decline in COVID-19 revenues during 2024 due to the fulfillment of these contracts and lower overall demand for COVID-19 testing.

Sales of the Company's Diagnostics products increased 41% to $73.7 million for the year ended December 31, 2023 from $52.2 million for the year ended December 31, 2022. This increase in revenues was primarily driven by higher sales of the Company's OraQuick® In-Home HIV tests in support of the CDC's "Together Take Me Home" HIV self-test program which commenced during the first quarter of 2023, and higher sales of the Company's OraQuick® HIV Self-Test in international markets due to increased adoption of the Company's self-test in several new African countries and due to customer ordering patterns.

Molecular Sample Management Solutions revenues decreased 14% to $54.3 million for the year ended December 31, 2023 from $63.3 million for the year ended December 31, 2022. Sales of the Company's Molecular Sample Management Solutions are being impacted by macro-economic factors in the market in which the customers operate such as a decline in discretionary consumer spend. Sample Management Solutions revenues are also impacted by customer ordering patterns.

Other products and services revenues increased 1% to $12.0 million for the year ended December 31, 2023 from $11.9 million for the year ended December 31, 2022.

Molecular Services revenues, which are largely derived from the Company's laboratory services, decreased 39% to $4.5 million for the year ended December 31, 2023 from $7.3 million for the year ended December 31, 2022. The decline in services revenues was largely the result of the loss of two customers in 2022: one customer ceased operations in 2022 and the other deprioritized microbiome studies. These loss of customers is coupled with the completion of certain large clinical trial studies which have not been replaced with new studies.

Sales of the Company's COVID-19 Molecular Products collection kits decreased by 97% to $0.3 million for the year ended December 31, 2023 from $9.7 million for the year ended December 31, 2022 due to decline in demand for COVID-19 PCR testing given the availability of rapid antigen tests.

Non-Product and Services Revenues

Non-product and services revenues decreased 66% to $3.3 million for the year ended December 31, 2023 from $9.4 million for the year ended December 31, 2022 as a result lower funding for research and development activities and lower royalty income.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 42% for the year ended December 31, 2023 from 38% for the year ended December 31, 2022. This increase in margins was driven by the higher InteliSwab® sales which also generated higher margins due to reduced costs associated with manufacturing efficiencies and a packaging change implemented during the first quarter of 2023. Also contributing to improved margins is lower product scrap expense. These improvements in margins were partially offset by $6.9 million of accelerated depreciation associated with the wind-down of InteliSwab® manual assembly in Thailand as the Company on-shores and automates the manufacturing of this product at its Pennsylvania facilities and $0.5 million from the exit from one of its leased warehouse in an effort to consolidate facilities and further lower costs.

Consolidated operating income for the year ended December 31, 2023 was $32.7 million, a $54.8 million improvement from the $22.2 million operating loss reported for the year ended December 31, 2022. Results for the year ended December 31, 2023 were positively impacted by lower operating expenses and lower impairment losses. Results for the year ended December 31, 2023 included $10.8 million of impairment losses compared to $17.1 million for the year ended December 31, 2022. Impairment losses in 2023 were comprised of impairments of intangible assets and idle manufacturing equipment.

Operating expenses for the year ended December 31, 2023, excluding the impairment charges, decreased by $25.4 million to $128.2 million compared to $153.7 million the year ended December 31, 2022, reflecting the impact of the Company's cost saving measures and headcount reductions.

Research and development expenses decreased 7% to $33.7 million for the year ended December 31, 2023 from $36.2 million for the year ended December 31, 2022 largely due a decrease in spend on COVID-19 product development, a decrease in employee costs associated with a reduction in headcount, partially offset by increased engineering consulting spend associated with the Company's $109 million DOD manufacturing expansion contract.

Sales and marketing expenses decreased 26% to $36.3 million for the year ended December 31, 2023 from $49.2 million for the year ended December 31, 2022 due to lower advertising spend, lower employee costs associated with a decrease in headcount, a decrease in the Company's provision for uncollectible accounts, lower commissions, and lower sales meeting and consulting spend.

General and administrative expenses decreased 15% to $58.2 million for the year ended December 31, 2023 from $68.2 million for the year ended December 31, 2022 largely due a decrease in consulting fees, lower employee costs associated with lower headcount and severance, lower project management fees associated with the $109 million DOD manufacturing expansion contract, and lower sales tax penalties, board of directors fees, legal fees, and recruitment fees. In 2022, the Company incurred high severance expense associated with the Company's former CEO's and general counsel's employment agreements and higher recruitment expense associated with the new CEO search.

All of the above contributed to the Company's operating income of $32.7 million for the year ended December 31, 2023, which included non-cash impairment charges of $10.8 million, non-cash charges of $20.9 million for depreciation and amortization, and $10.7 million for stock-based compensation. The Company's operating loss of $22.2 million for the year ended December 31, 2022 included a non-cash impairment charge of $17.1 million, non-cash charges of $15.3 million for depreciation and amortization, and $11.6 million for stock-based compensation.

CONSOLIDATED OTHER INCOME

Other income for the year ended December 31, 2023 was $23.6 million compared to $6.5 million for the year ended December 31, 2022. This increase is largely due to $12.8 million of additional profit earned above the guaranteed profit earned under the $109 million DOD manufacturing expansion contract that completed in the fourth quarter. This additional profit resulted from lower spend under the fixed firm contract than originally budgeted. Also contributing to the higher other income is higher interest income offset by lower foreign currency gains.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. Although the Company has achieved another quarter of U.S. cumulative pre-tax earnings based on a rolling three year window the Company has not achieved a level of sustained profitability that would, in its judgement, support the release of the valuation allowance. For the year ended December 31, 2023 the Company recorded income tax expense of $2.6 million. 2023 income tax expense is comprised of $1.9 million of U.S. state income tax expense, and foreign income tax expense of $0.7 million. For the year ended December 31, 2022, the Company recorded income tax expense of $1.5 million. The Company's 2022 income tax expense is comprised of U.S. state income taxes of $1.0 million, Canadian withholding taxes paid on the repatriation of Canadian earnings of $1.7 million, and a foreign income tax benefit of $1.2 million associated with the Company's Canadian subsidiary. The overall increase in tax expense is associated with an increase in earnings in both the U.S. and in Canada.

Liquidity and Capital Resources

	December 31, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 290,407	$ 83,980
Available-for-sale securities	—	26,867
Working capital	346,923	256,127

The Company's cash and cash equivalents and available-for-sale securities increased to $290.4 million at December 31, 2023 from $110.8 million at December 31, 2022. $84.9 million, or 29%, of the Company's $290.4 million in cash, cash equivalents and available-for-sale securities is held by DNAG, the Company's Canadian subsidiary. In 2022, the Company repatriated $65.0 million of cash into the United States and incurred $1.7 million of Canadian withholding tax. Further repatriation of cash from Canada into the United States could have additional adverse tax consequences. It is still the Company's intention going forward to continue to permanently reinvest the historical undistributed earnings of the Company's foreign subsidiaries.

The Company's working capital increased to $346.9 million at December 31, 2023 from $256.1 million at December 31, 2022. Working capital increased primarily due to the increase in cash and cash equivalents and lower accounts receivable, inventory, and lower accounts payable balances. Working capital improved also as a result of receiving final payment under the Company's $109 million manufacturing expansion contract. Working capital is primarily a function of sales, purchase volumes, inventory requirements, and vendor payment terms.

Analysis of the Company's Cash Flows

Operating Activities

During the year ended December 31, 2023, net cash provided by operating activities was $141.6 million. Cash flows from operations can be significantly impacted by factors such as timing of receipt from customers, inventory purchases, and payments to vendors. The Company's net income of $53.7 million included non-cash charges of depreciation and amortization expense of $20.9 million, stock-based compensation expense of $10.7 million, impairment charges taken for idle equipment and intangible assets of $10.8 million, and a decrease in reserve for uncollectible accounts of $0.5 million.

Cash provided by the Company's working capital accounts included a decrease in inventory of $48.2 million as the Company fulfilled demand for its InteliSwab® product and a decrease in accounts receivable of $31.1 million largely associated with collections of monies due from the U.S. government for InteliSwab® shipments. Offsetting these increases

of cash was a $27.0 million decrease in accounts payable due to the timing of invoices received and payments made and a decrease in accrued expenses and other liabilities of $3.4 million.

Investing Activities

Net cash provided by investing activities was $66.2 million for the year ended December 31, 2023, which reflects proceeds from the maturities and redemptions of investments of $102.4 million, $48.7 million in reimbursement received under the Company's $109 million contract with the U.S. government offset by $74.7 million used to purchase investments. Investing activities also included $5.8 million to acquire property and equipment to support normal operations of the business and $4.5 million used to build additional manufacturing capacity as required by the government contract.

Financing Activities

Net cash used in financing activities was $3.0 million for the year ended December 31, 2023, which reflects $1.9 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted awarded to the Company's employees and payments of lease liabilities of $1.3 million.

Resources

The Company's contractual obligations are included in Notes 8 and 13 of its consolidated financial statements. Additionally, the Sapphiros agreement entered into during 2024 has an aggregate commitment of up to $30.0 million to be funded by June 2024, contingent on certain terms and conditions being met. $28.3 million of that commitment has been paid within the first two months of 2024. The Company expects existing cash and cash equivalents will be sufficient to fund this obligation and its operating expenses and capital expenditure requirements over the next twelve months. The Company's cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of its research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors.

Critical Accounting Policies and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations discusses the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that the Company make judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The Company bases its judgments and estimates on historical experience and on various other factors that are believed to be 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.

The Company's significant accounting policies are described in Note 2 of the Notes to the consolidated financial statements included in Item 15 of this Annual Report. The Company considers the following accounting policies, which have been discussed with its Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing its financial statements and the uncertainties that could impact its results of operations, financial condition, and cash flows.

Revenue Recognition.

Product sales. Revenue from product sales is recognized upon transfer of control of a product to a customer based on an amount that reflects the consideration the Company is entitled to, net of allowances for any discounts or rebates.

The Company generally does not grant product return rights to its customers, except for warranty returns and return rights on sales of its OraQuick® In-Home HIV test to the retail trade, and InteliSwab® products to the retail trade and certain customers.

Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, the Company expenses warranty returns as incurred.

Service Revenues

Service revenues represent microbiome laboratory testing and analytical services. The Company recognizes revenues when it satisfies its performance obligations for services rendered.

Arrangements with multiple-performance obligations

In arrangements involving more than one performance obligation, which largely applies to the Company's service revenue stream, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on each respective relative stand-alone selling price. The estimated selling price of each deliverable is determined using an observable cost plus margin approach. The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred for the related goods or services or when the performance obligation has been satisfied.

Inventories

The Company's inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of the Company's inventories are subject to expiration dating, which can be extended in certain circumstances. The Company continually evaluates quantities on hand and the carrying value of its inventories to determine the need for net realizable value adjustments for excess and obsolete inventories, based primarily on prior experience with consideration of expected changes in the business and estimated forecasts of product sales. The Company reserves for unidentified scrap or spoilage based on historical write-off rates. It also considers items identified through specific identification procedures in assessing the adequacy of its reserve. Although the Company makes every effort to ensure the accuracy of its forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of its inventories and reported operating results.

Goodwill

Goodwill is not amortized, but rather is tested annually for impairment or more frequently if the Company believes that indicators of impairment exist. Current generally accepted accounting principles permit the Company to make a qualitative evaluation about the likelihood of goodwill impairment and if it is determined that it is more likely than not that the fair value does not exceed the carrying amount, then a quantitative test is performed. The quantitative goodwill impairment test involves a comparison of the estimated fair value of the reporting unit to the respective carrying amount. An impairment charge is recognized in the amount by which the carrying amount exceeds the reporting unit’s fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The process of evaluating the potential impairment of goodwill is highly subjective and requires significant judgment, including the identification of reporting units, qualitative evaluation of events and circumstances to determine if it is more likely than not that an impairment exists, and, if necessary, the estimation of the fair value of the applicable reporting unit.

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

The information with respect to forward-looking statements within “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report is incorporated herein by reference.

The Company does not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, has no material derivative risk to report under this Item.

As of December 31, 2023, the Company did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 1.0% of the Company's total revenues for the year ended December 31, 2023. The Company does have foreign currency exchange risk related to its operating subsidiaries in Canada and in Belgium. The principal foreign currencies in which it conducts business are the

Canadian dollar and the Euro. Fluctuations in the exchange rate between the U.S. dollar and these foreign currencies could affect year-to-year comparability of operating results and cash flows. The Company's foreign subsidiaries had net assets, subject to translation, of $117.7 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of December 31, 2023. A 10% unfavorable change in the Canadian-to-U.S. dollar and Euro-to-U.S. dollar exchange rates would have increased the Company's comprehensive loss by approximately $11.8 million in the year ended December 31, 2023.

ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this Item is contained in the Company's Consolidated Financial Statements included under Item 15 of this Annual Report.

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

Not applicable.

ITEM 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures.

The Company's management, with the participation of the Company's Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2023. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2023 the Company's disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Management's Report on Internal Control Over Financial Reporting.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company's management, including the Company's principal executive officer and principal financial officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the Company's evaluation under the framework, management concluded that the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles as of December 31, 2023.

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

The effectiveness of the Company's internal control over financial reporting as of December 31, 2023 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

(c) Changes in Internal Control Over Financial Reporting.

In the third quarter ended September 30, 2023, we identified a material weakness in our internal control over financial reporting related to customer pricing in the revenue recognition process. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A control related to the validation of accurate pricing in customer sales orders did not operate effectively to detect an error in prices, which resulted in the recognition of revenue at an inaccurate price during the six months ended June 30, 2023.

Although the resulting error was not material to those financial statements, we concluded that the control deficiency represents a material weakness. The financial statements for the nine months ended September 30, 2023 were not impacted by this material weakness and are not misstated.

During the quarter ended December 31, 2023, the Company implemented controls to validate accurate pricing in customer sales orders and remediated the material weakness.

Except for the foregoing, there was no change in the Company's internal control over financial reporting identified in management's evaluation pursuant to Rules 13a or 15d of the Exchange Act that occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(d) Report of Independent Registered Public Accounting Firm.

To the Stockholders and Board of Directors
OraSure Technologies, Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited OraSure Technologies, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements), and our report dated March 11, 2024 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and

that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 11, 2024

ITEM 9B. Other Information.

Not applicable.

ITEM 9C. Disclosure regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

The Company has omitted from Part III the information that will appear in its Definitive Proxy Statement for its 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement"), which will be filed within 120 days after the end of its fiscal year pursuant to Regulation 14A.

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference. The Board of Directors has adopted a Code of Business Conduct and Ethics that applies to the Company's principal executive officer, principal financial officer and principal accounting officer, as well as to the members of its Board of Directors and its other officers and employees. This Code of Business Conduct and Ethics is available on the Company's website at www.orasure.com. The Company intends to satisfy the amendment and waiver disclosure requirements under applicable securities regulations by posting any amendments of, or waivers to, the Code of Business Conduct and Ethics on its website.

ITEM 11. Executive Compensation.

The information required by this Item 11 will be included in the Company's 2024 Proxy Statement 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 12 will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 13 will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

ITEM 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in the Company's 2024 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. Exhibits and Consolidated Financial Statement Schedules.

(a)(1) and (a)(2). Consolidated Financial Statements and Schedules. For a list of the consolidated financial statements filed herewith, see the Index to Consolidated Financial Statements following the signature page to this Annual Report. No schedules are included with the consolidated financial statements because the required information is inapplicable or is presented in the consolidated financial statements or related notes thereto.

(a)(3). Exhibits.

Exhibit Number	Exhibit
3.1.1	Certificate of Incorporation of OraSure Technologies, Inc. is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.2	Second Amended and Restated Bylaws of OraSure Technologies, as of May 9, 2023, is incorporated by referenced to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.
4.1	Description of Securities is incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year-ended December 31, 2019.
10.1	Employment Agreement dated as of January 3, 2018, between OraSure Technologies, Inc. and Stephen S. Tang, Ph.D., is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 4, 2018.*
10.2	Employment Agreement, dated as of January 1, 2019, between Kathleen G. Weber, DNA Genotek, Inc. and OraSure Technologies, Inc. is incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018.*
10.3	Amendment No. 1 to Employment Agreement, dated as of December 20, 2021, between Kathleen G. Weber, DNA Genotek, Inc. and OraSure Technologies, Inc. is incorporated by reference to exhibit 10.10 to the Company's Annual Report on form 10-K for the year ended December 31, 2021*
10.4	Amendment No. 2 to Employment Agreement, dated as of November 7, 2022, between Kathleen G. Weber, DNA Genotek, Inc. and OraSure Technologies, Inc. is incorporated by reference to Exhibit 10.5 of the Company's Annual Report on form 10-K for the year ended December 31, 2022*
10.5	Employment Agreement, dated as of May 20, 2022, between OraSure Technologies, Inc. and Carrie Eglinton-Manner is incorporated by reference to exhibit 10.1 to the company's Current Report on Form 8-K filed on May 26, 2022.*
10.6	Employment Agreement dated August 8, 2022, between OraSure Technologies, Inc. and Kenneth J. McGrath is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 12, 2022.*
10.7	Severance Letter Agreement, dated August 25, 2021, between OraSure Technologies, Inc. and Michele M. Miller is incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.*
10.8	Description of Non-Employee Director Compensation Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on form 8-K filed August 14, 2019.*
10.9	Amended and Restated Epitope, Inc. 1991 Stock Award Plan is incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.*
10.10	OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*

10.11	Amended and Restated OraSure Technologies, Inc. Stock Award Plan, effective April 4, 2020, is incorporated by reference to Exhibit A to the Company's Proxy Statement, filed April 9, 2020, for the 2020 Annual Meeting of Stockholders.*
10.12	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan, Effective March 31, 2023, is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 16, 2023.*
10.13	Form of Restricted Share Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015.*
10.14	Form of Restricted Unit Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016. *
10.15	Form of Restricted Unit Award Agreement (Executive Officers-Employment Agreements) for 2021 awards is incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.*
10.16	Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.17	Nonqualified Stock Option Award General Terms and Conditions (Executive Officers) is incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.18	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.19	OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed December 21, 2011.*
10.20	Adoption Agreement related to OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed December 21, 2011.*
10.21	$109 Million Capital Funding Agreement with the U.S. Department of Defense, in coordination with the Department of Health and Human Services is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on From 10-Q for the period ended September 30, 2021, filed November 4, 2021.
10.22	Industrial Lease between Core5 at Laughman Farms Phase 1, LLC as Landlord and OraSure Technologies, Inc. as Tenant, dated January 3, 2022 is incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.
21.1	Subsidiaries of the Company are incorporated by reference to Exhibit 21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
23.1+	Consent of KPMG LLP.
24.1+	Powers of Attorney.
31.1+	Certification of Carrie Eglinton Manner, required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2+	Certification of Kenneth J. McGrath required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1^	Certification of Carrie Eglinton Manner, required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2^	Certification of Kenneth J. McGrath required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1+	OraSure Technologies Inc. Compensation Recovery Policy.

101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase document
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, has been formatted in Inline XBRL.

+ Filed herewith.
^ This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filings under the Securities Act or the Exchange Act.
* Management contract or compensatory plan or arrangement.

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, on March 11, 2024.

ORASURE TECHNOLOGIES, INC.

By: */s/ Carrie Eglinton Manner*
Carrie Eglinton Manner
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 11, 2024, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ Carrie Eglinton Manner Carrie Eglinton Manner	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Kenneth J. McGrath Kenneth J. McGrath	Chief Financial Officer (Principal Financial Officer)
/s/ Michele Anthony Michele Anthony	Senior Vice President, Controller & Chief Accounting Officer (Principal Accounting Officer)
*MARA G. ASPINALL Mara G. Aspinall	Director
*JAMES A. DATIN James A. Datin	Director
*NANCY J. GAGLIANO Nancy J. Gagliano	Director
*LELIO MARMORA Lelio Marmora	Director
*ROBERT W. MCMAHON Robert W. McMahon	Director
*DAVID J. SHULKIN, M.D. David J. Shulkin, M.D.	Director

*By: */s/Stefano Taucer*
Stefano Taucer
(Attorney-in-Fact)

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
OraSure Technologies, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of OraSure Technologies, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 11, 2024 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 a 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 a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of net realizable value adjustments to inventories for excess and obsolescence

As discussed in Notes 2 and 4 to the consolidated financial statements, the Company has inventories with a carrying value of $47,614 thousand as of December 31, 2023. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The majority of the Company's inventories are subject to expiration dating, which can be extended in certain circumstances. The Company continually evaluates quantities on hand and the carrying value of inventories to determine the need for net realizable value adjustments for excess and obsolete inventories, based primarily on prior experience with consideration of expected changes in the business and estimated forecasts of product sales. The Company reserves for unidentified scrap or spoilage based on historical write-off rates. The Company also considers items identified through specific identification procedures in assessing the adequacy of the reserve.

We identified the evaluation of net realizable value adjustments to inventories for excess or obsolescence as a critical audit matter. Evaluating the Company's specific identification procedures, which included reviewing historical inventory consumption as compared to inventory balances as of year-end and the resulting inventory consumption and the ability to extend inventory expiration dates, required a high degree of auditor judgment.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's process for determining net realizable value adjustments for inventory excess or obsolescence, which included controls related to the review of the specific identification procedures. For a selection of inventory items, we compared actual physical inventory disposals in the current year to the Company's historic estimates of net realizable value adjustments for excess and obsolescence to evaluate the Company's ability to accurately estimate the net realizable value adjustments. In addition, we selected inventory items from the underlying data used in the Company's analysis and evaluated the Company's determination of net realizable value adjustments for those items by: (1) testing historical inventory consumption by independently recalculating the historical consumption and comparing it to the Company determined consumption, (2) comparing that consumption to inventory balances as of year-end, and (3) evaluating changes in the business that could impact future inventory consumption, as applicable. We also selected inventory items from the underlying data used in the Company's analysis and evaluated the ability to extend the expiration dates by inspecting relevant supporting documentation.

/s/ KPMG LLP

We have served as the Company's auditor since 2002.

Philadelphia, Pennsylvania
March 11, 2024

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 290,407	$ 83,980
Short-term investments	—	26,867
Accounts receivable, net of allowance for doubtful accounts of $1,216 and $2,365	40,171	70,797
Inventories	47,614	95,704
Prepaid expenses	6,041	6,273
Other current assets	2,226	41,569
Total current assets	386,459	325,190
Noncurrent Assets:		
Property, plant and equipment, net	45,420	59,413
Operating right-of-use assets, net	12,270	10,399
Finance right-of-use assets, net	576	1,293
Intangible assets, net	1,206	11,694
Goodwill	35,696	35,104
Other noncurrent assets	1,218	1,087
Total noncurrent assets	96,386	118,990
TOTAL ASSETS	**$ 482,845**	**$ 444,180**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 13,151	$ 38,020
Deferred revenue	1,559	2,273
Accrued expenses and other current liabilities	22,710	25,762
Finance lease liability	539	1,179
Operating lease liability	1,577	1,764
Acquisition-related contingent consideration obligation	—	65
Total current liabilities	39,536	69,063
Noncurrent Liabilities:		
Finance lease liability	226	503
Operating lease liability	11,162	9,101
Acquisition-related contingent consideration obligation	—	99
Other noncurrent liabilities	696	581
Deferred income taxes	554	408
Total noncurrent liabilities	12,638	10,692
TOTAL LIABILITIES	52,174	79,755
Commitments and contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 73,528 and 72,734 shares issued and outstanding	—	—
Additional paid-in capital	529,543	520,446
Accumulated other comprehensive loss	(14,941)	(18,435)
Accumulated deficit	(83,931)	(137,586)
Total stockholders' equity	430,671	364,425
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 482,845**	**$ 444,180**

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	For the Years Ended December 31,		
	2023	2022	2021
NET REVENUES:			
Products and services	$ 402,222	$ 378,047	$ 226,897
Other	3,250	9,432	6,777
	405,472	387,479	233,674
COST OF PRODUCTS AND SERVICES SOLD	233,820	239,041	116,074
Gross profit	171,652	148,438	117,600
OPERATING EXPENSES:			
Research and development	33,728	36,237	34,170
Sales and marketing	36,319	49,238	44,751
General and administrative	58,191	68,206	50,328
Loss on impairments	10,829	17,101	—
Change in the estimated fair value of acquisition-related contingent consideration	(99)	(188)	(1,485)
	138,968	170,594	127,764
Operating income (loss)	32,684	(22,156)	(10,164)
OTHER INCOME	23,574	6,481	872
Income (loss) before income taxes	56,258	(15,675)	(9,292)
INCOME TAX EXPENSE	2,603	1,458	13,706
NET INCOME (LOSS)	$ 53,655	$ (17,133)	$ (22,998)
INCOME (LOSS) PER SHARE:			
BASIC	$ 0.73	$ (0.24)	$ (0.32)
DILUTED	$ 0.72	$ (0.24)	$ (0.32)
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:			
BASIC	73,348	72,505	71,981
DILUTED	74,389	72,505	71,981

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	For the Years Ended December 31,		
	2023	2022	2021
NET INCOME (LOSS)	$ 53,655	$ (17,133)	$ (22,998)
OTHER COMPREHENSIVE INCOME (LOSS)			
Currency translation adjustments	3,274	(8,572)	(894)
Unrealized gain (loss) on marketable securities	220	214	(86)
COMPREHENSIVE INCOME (LOSS)	$ 57,149	$ (25,491)	$ (23,978)

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2023, 2022 and 2021
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2021	71,738	$ —	$ 505,123	$ (9,097)	$ (97,455)	$ 398,571
Common stock issued upon exercise of options	33	—	246	—	—	246
Vesting of restricted stock and performance stock units	451	—	—	—	—	—
Purchase and retirement of common shares	(153)	—	(2,113)	—	—	(2,113)
Stock-based compensation	—	—	7,807	—	—	7,807
Net loss	—	—	—	—	(22,998)	(22,998)
Currency translation adjustments	—	—	—	(894)	—	(894)
Unrealized loss on marketable securities	—	—	—	(86)	—	(86)
Balance at December 31, 2021	72,069	$ —	$ 511,063	$ (10,077)	$ (120,453)	$ 380,533
Common stock issued upon exercise of options	2	—	15	—	—	15
Vesting of restricted stock and performance stock units	992	—	—	—	—	—
Purchase and retirement of common shares	(329)	—	(2,254)	—	—	(2,254)
Stock-based compensation	—	—	11,622	—	—	11,622
Net loss	—	—	—	—	(17,133)	(17,133)
Currency translation adjustments	—	—	—	(8,572)	—	(8,572)
Unrealized gain on marketable securities	—	—	—	214	—	214
Balance at December 31, 2022	72,734	$ —	$ 520,446	$ (18,435)	$ (137,586)	$ 364,425
Common stock issued upon exercise of options	44	—	269	—	—	269
Vesting of restricted stock and performance stock units	1,098	—	—	—	—	—
Purchase and retirement of common shares	(348)	—	(1,901)	—	—	(1,901)
Stock-based compensation	—	—	10,729	—	—	10,729
Net income	—	—	—	—	53,655	53,655
Currency translation adjustments	—	—	—	3,274	—	3,274
Unrealized gain on marketable securities	—	—	—	220	—	220
Balance at December 31, 2023	73,528	$ —	$ 529,543	$ (14,941)	$ (83,931)	$ 430,671

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Years Ended December 31,		
	2023	**2022**	**2021**
OPERATING ACTIVITIES:			
Net income (loss)	$ 53,655	$ (17,133)	$ (22,998)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Stock-based compensation	10,729	11,622	7,807
Depreciation and amortization	20,936	15,308	11,658
Loss on impairments	10,829	17,101	—
Other non-cash amortization	3	228	837
Provision for credit losses	(462)	(1,032)	(253)
Unrealized foreign currency (gain) loss	103	(161)	(210)
Interest expense on finance leases	51	94	82
Deferred income taxes	102	(1,651)	1,026
Loss on sale of fixed assets	—	729	—
Change in the estimated fair value of acquisition-related contingent consideration	(99)	(188)	(1,485)
Payment of acquisition-related contingent consideration	(19)	—	(142)
Changes in assets and liabilities:			
Accounts receivable	31,116	(25,162)	(6,451)
Inventories	48,228	(43,274)	(21,210)
Prepaid expenses and other assets	(2,499)	(7,091)	(8,674)
Accounts payable	(26,976)	2,634	3,234
Deferred revenue	(730)	(596)	(1,891)
Accrued expenses and other liabilities	(3,384)	1,370	3,288
Net cash provided by (used in) operating activities	141,583	(47,202)	(35,382)
INVESTING ACTIVITIES:			
Purchases of short-term investments	(74,652)	(22,873)	(25,822)
Proceeds from maturities and redemptions of short-term investments	102,440	47,415	67,925
Proceeds from sale of assets	—	121	—
Purchases of property and equipment	(5,802)	(6,774)	(21,893)
Purchase of property and equipment under government contracts	(4,501)	(57,135)	(26,224)
Proceeds from funding under government contract	48,669	60,331	531
Other investing activities	—	—	(18)
Net cash provided by (used in) investing activities	66,154	21,085	(5,501)
FINANCING ACTIVITIES:			
Cash payments for lease liabilities	(1,345)	(1,381)	(686)
Proceeds from exercise of stock options	269	15	246
Payment of acquisition-related contingent consideration	(46)	(208)	(264)
Repurchase of common stock	(1,901)	(2,254)	(2,113)
Net cash used in financing activities	(3,023)	(3,828)	(2,817)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	1,713	(2,837)	(340)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	206,427	(32,782)	(44,040)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762	160,802
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 290,407	$ 83,980	$ 116,762

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts, unless otherwise indicated)

1. THE COMPANY:

OraSure Technologies transforms health through actionable insight by powering the shift that connects people to healthcare wherever they are. In February 2023, the Company announced a corporate restructuring to combine the commercial and innovation teams across two segments, being the "Diagnostics" segment and the "Molecular Solutions" segment, into one business unit with sales, marketing, product development, and research teams covering multiple product lines. This change is intended to accelerate innovation, enhance customer experience and result in operational synergies. As a result, all products and services reside under one reporting hierarchy.

The Company's product portfolio is broadly divided into diagnostics products and molecular sample management solutions. The Company's business consists of the development, manufacture, marketing and sale of simple, diagnostic products and specimen collection devices designed to detect certain infectious diseases including COVID-19, HIV and Hepatitis C that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. The Company's business also includes molecular sample management solutions and molecular services that are used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of OraSure Technologies, Inc. ("OraSure") and its wholly-owned subsidiaries, DNAG, Diversigen, and Novosanis. All intercompany transactions and balances have been eliminated. References herein to "we", "us", "our", or the "Company" mean OraSure and its consolidated subsidiaries, unless otherwise indicated.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for property, plant and equipment, intangible assets and goodwill, as well as estimates related to taxes, contingent consideration, and performance-based compensation expense. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Employee Retention Credit

In December 2021, the Company applied for the Employee Retention Credit for payroll taxes paid in the first and second quarters of 2021 as provided by the Coronavirus Aid, Relief and Economic Security Act. The amount due from the Internal Revenue Service of $5.7 million was recorded in other current assets in the Company's consolidated balance sheet as of December 31, 2022. The amount was received in 2023. The credit is reported in the Company's consolidated statement of operations for the year ended December 31, 2021 within cost of products and services sold, research and development, sales and marketing and general and administrative costs in the amounts of $2.5 million, $1.1 million, $0.9 million, and $1.2 million, respectively.

Supplemental Cash Flow Information

The Company received income tax refunds of $4.9 million in 2023, and paid income taxes of $9.4 million and $13.7 million in 2022 and 2021, respectively.

The Company had account receivable write-offs of $0.7 million, $2.3 million, and $0.1 million in 2023, 2022, and 2021, respectively.

As of December 31, 2023, 2022 and 2021, the Company had accruals for purchases of property and equipment of $0.2 million, $0.2 million and $8.2 million, respectively.

Cash Equivalents & Short-Term Investments

The Company considers all investments in debt securities to be available-for-sale securities. These securities are comprised of guaranteed investment certificates and corporate bonds with purchased maturities greater than ninety days. Securities with maturities ninety days or less are considered cash equivalents. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

The Company records an allowance for credit loss for the Company's available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, the Company reviews factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value, and the probability that the scheduled cash payments will continue to be made.

The Company had no available-for-sale debt securities as of December 31, 2023. The following is a summary of the Company's available-for-sale securities as of December 31, 2022:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2022				
Guaranteed investment certificates	$ 22,109	$ —	$ —	$ 22,109
Corporate bonds	4,978	—	(220)	4,758
Total available-for-sale securities	$ 27,087	$ —	$ (220)	$ 26,867

Fair Value of Financial Instruments

As of December 31, 2023 and 2022, the carrying values of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The Company had no available-for-sale debt securities as of December 31, 2023. All of the Company's available-for-sale debt securities as of December 31, 2022 are measured as Level 2 instruments. The Company's guaranteed investment certificates are measured as Level 1 instruments as of December 31, 2022.

Included in cash and cash equivalents at December 31, 2023 and 2022, was $112.7 million and $1.7 million, respectively, invested in government money market funds. These funds have investments in United States government securities and are

measured as Level 1 instruments. Included in cash and cash equivalents at December 31, 2023 was $71.7 million of guaranteed investment certificates which are also measured as Level 1 instruments.

The Company offers a nonqualified deferred compensation plan for certain eligible employees and members of the Company's Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds. The fair value of the plan assets as of December 31, 2023 and 2022 was $0.8 million and $0.7 million, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in both current assets and other noncurrent assets with the same amounts included in accrued expenses and other noncurrent liabilities in the accompanying consolidated balance sheets.

Contingent consideration obligations are measured as Level 3 liabilities due to the unobservable inputs that are required to measure the fair value of these obligations. The Company had no contingent consideration obligations outstanding as of December 31, 2023.

Accounts Receivable

Accounts receivable has been reduced by an estimated allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management’s evaluation of specific balances as they become past due, the financial condition of the Company's customers and the Company's historical experience related to write-offs.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of the Company's inventories are subject to expiration dating, which can be extended in certain circumstances. The Company continually evaluates quantities on hand and the carrying value of the Company's inventories to determine the need for net realizable value adjustments for excess and obsolete inventories, based primarily on prior experience with consideration of expected changes in the business and estimated forecasts of product sales. The Company reserves for unidentified scrap or spoilage based on historical write-off rates. The Company also considers items identified through specific identification procedures in assessing the adequacy of the Company's reserve. Although the Company makes every effort to ensure the accuracy of expected changes in the business and of its forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of its inventories and reported operating results.

Property, Plant and Equipment

Property, plant and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are typically depreciated over twenty years, while computer equipment and software, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of operations.

Intangible Assets

Intangible assets consist of customer relationships, patents and product rights, acquired technology and trade names. Patents and product rights consist of costs associated with the acquisition of patents, licenses and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of five to fifteen years.

Impairment of Long-Lived Assets

Long-lived assets, which include property, plant and equipment and definite-lived intangible assets, are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company assesses the recoverability of the Company's long-lived assets by determining

whether the carrying value of such assets can be recovered through the sum of the undiscounted future cash flows generated from the use and eventual disposition of the asset. If indicators of impairment exist, the Company measures the amount of such impairment by comparing the carrying value of the assets to the fair value of the assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the assets. Expected future cash flows reflect the Company's assumptions about selling prices, volumes, costs and market conditions over a reasonable period of time. See Notes 5 and 6 for discussion of property, plant and equipment and intangible asset impairments, respectively, recorded for the year ended December 31, 2023.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. Goodwill is not amortized but rather is tested annually for impairment or more frequently if the Company believes that indicators of impairment exist. Current generally accepted accounting principles permit the Company to make a qualitative evaluation about the likelihood of goodwill impairment. If the Company concludes that it is more likely than not that the carrying value of a reporting unit is greater than its fair value, then the Company would be required to recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The Company has historically performed an annual goodwill impairment assessment as of July 31. On July 31, 2023, the Company performed a quantitative goodwill impairment test which concluded that the carrying value was below fair value indicating there was no impairment. During the three months ended December 31, 2023, the Company changed the date of its the annual impairment assessment to November 30, to better align with the Company's annual forecasting process. As of November, 30, 2023, the Company performed a qualitative analysis that concluded it was more likely than not that the fair value of the Company's reporting units is greater than their carrying value.

A more frequent evaluation is performed if an event occurs or circumstances change between annual tests that could more likely than not reduce the fair value of a reporting unit below its carrying amount.

Revenue

Product sales. Revenue from product sales is recognized upon transfer of control of a product to a customer based on an amount that reflects the consideration the Company is entitled to, net of allowances for any discounts or rebates.

The Company generally does not grant product return rights to its customers, except for warranty returns and return rights on sales of the Company's OraQuick® In-Home HIV test to retail trade customers, and InteliSwab® products to retail trade and certain other customers.

Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, the Company expenses warranty returns as incurred.

The Company records shipping and handling charges billed to the Company's customers as product revenue and the related expense as cost of products sold.

Service revenues. Service revenues represent microbiome laboratory testing and analytical services. The Company recognizes revenues when the Company satisfies its performance obligations for services rendered.

Arrangements with multiple-performance obligations. In arrangements involving more than one performance obligation, which largely applies to the Company's service revenue stream, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on their respective relative stand-alone selling price. The estimated selling price of each performance obligation is determined using an observable cost plus margin approach. The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred for the related goods or services or when the performance obligation has been satisfied.

Other revenues. Other revenues consist primarily of royalty income and funding from grants of research and development efforts. For the year ended December 31, 2021, other revenue also included cost reimbursements under a charitable support

agreement which ended in June 2021. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Research and development grant revenue is recognized pursuant to International Accounting Standard 20, *Accounting for Government Grants and Disclosure of Government Assistance ("IAS 20")*. The expenses are recorded in research and development expense and the reimbursements are recorded in other revenue. Funding of research and development efforts and charitable support reimbursements are recorded as the activities are performed in accordance with the respective agreements.

Deferred revenue. The Company records deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of December 31, 2023 and 2022 included customer prepayments of $1.2 million and $1.5 million, respectively. Deferred revenue as of December 31, 2023 and 2022 also included $0.4 million and $0.7 million, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of the contract was determined and revenue is recognized at that average price.

Financing and payment. The Company's payment terms vary by the type and location of the customer and products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation.

For certain products or services and customer types, the Company may require payment before the products are delivered or services are rendered to the customer.

Practical expedients and exemptions. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

Sales commissions are expensed when incurred if the amortization period is one year or less. These costs are recorded in sales and marketing expense in the consolidated statements of operations. If the amortization period exceeds one year, the Company defers the cost of the commission and expenses it over the life of the related sales contract.

Revenues by product. The following table represents total net revenues by product line:

	For the Years Ended December 31,		
	2023	2022	2021
COVID-19 [1]	$ 257,779	$ 243,325	$ 76,874
HIV	60,823	38,812	42,144
Molecular Sample Management Solutions [2]	54,274	63,342	72,603
HCV	12,871	13,369	11,783
Risk assessment testing	9,736	10,269	9,678
Molecular Services	4,474	7,296	11,840
Other product and services revenues	2,265	1,634	1,975
Net product and services revenues	402,222	378,047	226,897
Non-product and services revenues [3]	3,250	9,432	6,777
Net revenues	$ 405,472	$ 387,479	$ 233,674

[1] Includes COVID-19 Diagnostics and COVID-19 Molecular Products.
[2] Includes Genomics, Microbiome and Novosanis product revenues.
[3] Non-product and services revenues include funded research and development contracts, royalty income and grant revenues.

Revenues by geographic area. The following table represents total net revenues by geographic area, based on the location of the customer:

	For the Years Ended December 31,		
	2023	2022	2021
United States	$ 361,660	$ 350,206	$ 188,383
Europe	8,111	11,536	13,799
Other regions	35,701	25,737	31,492
	$ 405,472	$ 387,479	$ 233,674

Customer and vendor concentrations. The Company had one customer that accounted for more than 40% of the Company's consolidated accounts receivable as of December 31, 2023 and 57% as of December 31, 2022. The same customer accounted for approximately 63% of the Company's consolidated net revenues for the year ended December 31, 2023 and 58% for the year ended December 31, 2022. The Company had no customers that accounted for more than 10% of the Company's consolidated net revenues for the year ended December 31, 2021.

The Company currently purchases certain products and critical components of the Company's products from sole-supply vendors. If these vendors are unable or unwilling to supply the required components and products, the Company could be subject to increased costs and substantial delays in the delivery of the Company's products to its customers. Third-party suppliers also manufacture certain products. The Company's inability to have a timely supply of any of these components and products could have a material adverse effect on the Company's business, as well as the Company's financial condition and results of operations.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development costs are charged to expense as incurred.

Advertising Expenses

Advertising costs are charged to expense as incurred. During 2023, 2022, and 2021, the Company incurred $1.6 million, $4.8 million, and $5.1 million, respectively, in advertising expenses.

Stock-Based Compensation

The Company accounts for stock-based compensation to employees and directors using the fair value method. The Company recognizes compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. The Company recognizes compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. The Company evaluates these target assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate. To satisfy the exercise of stock options, issuance of restricted stock, or redemption of performance-based restricted stock units, the Company issues new shares rather than purchase shares in the open market.

Income Taxes

The Company follows the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax basis of assets and liabilities, as well as operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates for the respective taxing jurisdiction that are expected to apply to taxable income in the years in which those temporary differences and operating loss and credit carryforwards are expected to be recovered, settled or utilized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company assesses the realizability of its net deferred tax assets on a quarterly basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, the Company reduces its net deferred tax assets by a valuation allowance. The realization of the net deferred tax

assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the Company's net operating loss carryforwards.

Foreign Currency Translation

The assets and liabilities of the Company's foreign operations are translated into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in the Company's consolidated statements of operations in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions included in other income in the Company's consolidated statements of operations were $(0.1) million, $1.6 million, and $(0.7) million for the years ended December 31, 2023, 2022, and 2021, respectively.

Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted-average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, unvested restricted stock or performance stock units, unless the impact is anti-dilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares and performance stock units were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market price during the reporting period. Basic and dilutive computations of net loss per share are the same in periods in which a net loss exists as the dilutive effects of excluded items would be anti-dilutive.

	For the Years Ended December 31,		
	2023	2022	2021
Net income (loss)	$ 53,655	$ (17,133)	$ (22,998)
Weighted average shares of common stock outstanding:			
Basic	73,348	72,505	71,981
Dilutive effect of stock options, restricted stock, and performance stock units	1,041	—	—
Diluted	74,389	72,505	71,981
Earnings per share:			
Basic	$ 0.73	$ (0.24)	$ (0.32)
Diluted	$ 0.72	$ (0.24)	$ (0.32)

For the year ended December 31, 2023, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,778 shares were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the years ended December 31, 2022, and 2021 outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 436, and 769 shares, respectively, were excluded from the computation of diluted loss per share.

Accumulated Other Comprehensive Loss

The Company classifies items of other comprehensive income (loss) by their nature and discloses the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of the Company's consolidated balance sheets.

The Company has defined the Canadian dollar as the functional currency of the Company's Canadian subsidiary, DNAG, and the Company has defined the Euro as the functional currency of the Company's Belgian subsidiary, Novosanis. The results of operations are translated into U.S. dollars, which is the reporting currency of the Company. Changes in accumulated other comprehensive loss by component is listed below:

	Foreign Currency	Marketable Securities	Total
Balance as of December 31, 2022	$ (18,215)	$ (220)	$ (18,435)
Other comprehensive gain	3,274	220	3,494
Balance as of December 31, 2023	$ (14,941)	$ —	$ (14,941)

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures*. The purpose of the update was to improve financial reporting by requiring disclosures of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The amendments in this ASU are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted and requires retrospective application to all periods presented in the consolidated financial statements. Management is evaluating the impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740), Improvements to Income Tax Disclosures.* The purpose of the update was to address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and incomes taxes paid information. The amendments in this ASU are effective for annual periods beginning after December 15, 2024. The amendments may be applied prospectively or retrospectively, and early adoption is permitted. Management is evaluating the impact on the Company's consolidated financial statements.

Immaterial Correction of Errors

In the first quarter of 2023, the Company identified an immaterial error that was corrected in its consolidated financial statements. Inventories, accounts payable and cost of products and services were reduced by $0.5 million, $1.3 million and $0.8 million, respectively, as of and for the year ended December 31, 2022 to correct for the accounting of a vendor rebate earned in 2022. Furthermore, stockholder's equity at December 31, 2022 increased $0.8 million to reflect the reduction in cost of products and services sold. The tax impact of the vendor rebate was negligible. This correction was deemed to be immaterial to the consolidated financial statements as of and for the year ended December 31, 2022. The respective operating activities on the consolidated statement of cash flows for the year ended December 31, 2022 have also been adjusted.

3. GOVERNMENT CAPITAL CONTRACTS:

In September 2021, the Company entered into an agreement for $109.0 million in funding from the DOD, in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for its InteliSwab® COVID-19 Rapid Tests as part of the nation's pandemic preparedness plan. In accordance with the agreement, funding was paid to the Company based on achievement of milestones for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment, as set forth in the agreement. In accordance with the milestone payment schedule, 15% of the total was not billed and funded until the completion of the final validation testing, which occurred in October 2023. The Company began making payments to vendors for the capital project during the fourth quarter of 2021. The Company began receiving funds from the DOD in January 2022 and has received $109.0 million as of December 31, 2023. In connection with the completion of the contract in the fourth quarter of 2023, all funds were received.

Activity for these capital contracts is accounted for pursuant to International Accounting Standards ("IAS") 20, *Accounting for Government Grants and Disclosure of Government Assistance*. Funding received in relation to capital-related costs incurred for government contracts is recorded as a reduction to the cost of property, plant and equipment and reflected within investing activities in the consolidated statements of cash flows and associated unpaid liabilities and government proceeds receivable are considered non-cash changes in such balances within the operating section of the consolidated statements of cash flows.

Amounts earned for the Company's guaranteed profit which covered project management costs were recognized straight-line in other income over the term of the government contract. The Company recognized $2.8 million, $2.2 million and

$0.6 million of such income, which is reported as other income in the Company's consolidated statement of operations for the years ended December 31, 2023, 2022 and 2021, respectively. Additionally, in connection with the completion of the contract, the Company recognized $12.8 million in excess of the guaranteed profit in other income in the Company's consolidated statement of operations for the year ended December 31, 2023, which reflects the difference in overall spend compared to the firm fixed price contract amount of $109.0 million.

The DOD also reimbursed the Company for certain engineering consulting costs. These expenses are reflected in research and development expenses as incurred with the corresponding amount presented in other income. For the years ended December 31, 2023 and 2022, $2.0 million and $1.4 million was recorded in research and development expenses and other income, respectively.

Additionally, during 2021, the Company received $0.5 million in funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development, for the purchase of machinery and equipment as part of an expansion of manufacturing operations in Pennsylvania. All related purchases were completed in 2021.

The balances corresponding to government contracts included in the Company's consolidated balance sheet are as follows:

	December 31, 2022
Other current assets:	
Billed receivables	$ —
Unbilled receivables	27,013
Total other current assets	27,013
Other noncurrent assets	—
Accrued expenses and other current liabilities	$ (318)

The activity corresponding to the government contracts included in the Company's consolidated statements of cash flows is as follows:

	December 31, 2023	December 31, 2022
Cost of assets, cumulative	$ 86,993	$ 83,359
Reduction for funding earned to date, not yet received	—	(22,497)
Reduction for funding received to date	(86,993)	(60,862)
Total property, plant and equipment, net	$ —	$ —

4. INVENTORIES:

	December 31, 2023	December 31, 2022
Raw materials	$ 20,727	$ 42,445
Work in process	1,900	2,335
Finished goods	24,987	50,924
	$ 47,614	$ 95,704

During the years ended December 31, 2023, 2022, and 2021, the Company recorded adjustments to inventory which had a cost of $8.9 million, $15.6 million, and $13.4 million, respectively. The adjustments in 2021 included a write-off of $3.0 million of COVID-19 antibody inventory, which the Company did not believe it could sell as a result of the decision to no longer pursue an emergency use authorization for the enzyme-linked immunosorbent assay ("ELISA") antibody test. Additionally, a significant portion of the Company's 2022 and 2021 adjustments were related to production and tech-transfer issues associated with the Company's COVID-19 rapid test. The year ended December 31, 2023 adjustments were primarily related to reduction in COVID-19 demand and the need to reserve for excess inventory levels.

5. PROPERTY, PLANT AND EQUIPMENT:

	December 31,	
	2023	2022
Land	$ 1,118	$ 1,118
Buildings and improvements	34,606	35,582
Machinery and equipment	64,156	60,725
Computer equipment and software	17,739	16,681
Furniture and fixtures	3,748	4,064
Construction in progress	9,196	11,124
	130,563	129,294
Accumulated depreciation	(85,143)	(69,881)
	$ 45,420	$ 59,413

During the year ended December 31, 2023, the Company determined several manufacturing lines would not be utilized due to changes in forecasted demand for the products the lines are intended to produce. Additionally, the Company elected not to proceed with certain leasehold improvements to its research and development laboratories. As a result of these decisions, the Company determined that the carrying values of the equipment and leasehold improvements are not recoverable and recorded aggregate pre-tax asset impairment charges of $2.3 million for the year ended December 31, 2023.

During the year ended December 31, 2022, the Company determined several manufacturing lines and associated supporting assets would not be utilized due to changes in forecasted demand for the products the lines are intended to produce. As a result of this decision, the Company determined that the carrying values of the equipment and supporting assets were not recoverable and recorded aggregate pre-tax asset impairment charges of $13.5 million for the year ended December 31, 2022. Due to the extremely specialized nature of the equipment and various market data points, the estimated fair value was zero. These charges are reported within loss on impairments in the consolidated statement of operations.

During the second quarter of 2023, the Company shortened the useful lives of machinery and equipment utilized for InteliSwab® production in Thailand. This reduction in useful lives resulted in $6.9 million of accelerated depreciation during the second quarter of 2023, recorded in cost of products and services sold. During the fourth quarter of 2023, the Company shortened the useful lives of leasehold improvements and equipment due a lease termination. This reduction in useful lives resulted in $0.5 million of accelerated depreciation during the fourth quarter of 2023, recorded in cost of products and services sold.

Depreciation expense for 2023, 2022, and 2021 was $17.9 million, $11.7 million, and $7.5 million, respectively.

6. GOODWILL AND OTHER INTANGIBLE ASSETS:

Changes in goodwill are as follows:

	December 31,	
	2023	2022
Balance as of January 1	$ 35,104	$ 40,279
Impairment	—	(3,604)
Change related to foreign currency translation	592	(1,571)
Balance as of December 31	$ 35,696	$ 35,104

On July 31, 2023, the Company performed a quantitative goodwill impairment test which concluded that the carrying value of its reporting units were below fair value indicating there was no impairment. The Company performed a quantitative goodwill impairment test due to the depressed market price of the Company's common stock and concluded no impairment of goodwill.

During the second quarter of 2022, the Company determined that a triggering event occurred in relation to the depressed market price of the Company's common stock and corresponding decline in the Company's market capitalization. As a

result, the Company performed an interim quantitative goodwill impairment test and concluded that the carrying value of the Company's Diagnostics reporting unit exceeded its estimated fair value and the goodwill balance for that segment was fully impaired. The Company recognized a pre-tax impairment charge of $3.6 million during the year ended December 31, 2022, which is reported in loss on impairments in the Company's consolidated statement of operations.

Intangible assets consist of the following:

		December 31, 2023		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer relationships	10	$ 11,629	$ (11,629)	$ —
Patents and product rights	5	7,673	(7,102)	571
Developed technology	7-10	10,926	(10,926)	—
Trade names	5-15	4,626	(3,991)	635
		$ 34,854	$ (33,649)	$ 1,206

		December 31, 2022		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer relationships	10	$ 14,286	$ (11,011)	$ 3,275
Patents and product rights	5	7,620	(6,615)	1,005
Developed technology	7-10	15,478	(9,940)	5,538
Trade names	5-15	5,387	(3,511)	1,876
		$ 42,771	$ (31,077)	$ 11,694

During the third quarter of 2023, the Company identified a triggering event to test for the recoverability of intangible assets given the decline in the Company's market capitalization leading up to and as of its annual goodwill impairment testing date. The Company performed an undiscounted cash flow analysis and determined the carrying value of the developed technology, trade names, and customer relationships intangible assets could not be recovered through the sum of the undiscounted future cash flows. The Company used an income approach to determine the fair value of the developed technology and customer relationships intangible assets and the relief from royalty method for the trade names. As a result of this analysis, the Company determined the intangible assets associated with Diversigen and Novosanis were impaired as the fair value of the developed technology, trade names, and customer relationships did not exceed their carrying value. The Company recognized a pre-tax impairment charge of $6.2 million during the year ended December 31, 2023, which is reported in loss on impairments in the Company's consolidated statement of operations.

During the fourth quarter of 2023, the Company determined that its remaining developed technology intangible asset was fully impaired. As a result of failed stability studies, the Company decided to no longer pursue the technology. The Company recognized a pre-tax impairment charge of $2.4 million during the year ended December 31, 2023, which is reported in loss on impairments in the Company's consolidated statement of operations.

Amortization expense for 2023, 2022, and 2021 was $2.0 million, $2.3 million, and $3.3 million, respectively.

Amortization expense for each of the five succeeding fiscal years and beyond is estimated as follows:

2024	$ 679
2025	314
2026	213
2027	—
2028	—
Beyond	—
	$ 1,206

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	December 31,	
	2023	2022
Payroll and related benefits	$ 14,654	$ 14,103
Professional fees	2,827	4,685
Sales tax payable	1,245	1,519
Other	3,984	5,455
	$ 22,710	$ 25,762

8. TERMINATION BENEFITS:

During the first and second quarters of 2023, the Company executed a reduction in workforce. This was accounted for pursuant to Accounting Standards Codification ("ASC") 420, *Exit or Disposal Cost Obligations*.

The expense included in the Company's consolidated statements of operations are as follows:

	For the Year Ended December 31, 2023
Cost of products and services sold	$ 369
Research and development	566
Sales and marketing	1,543
General and administrative	787
Total	$ 3,265

As of December 31, 2023 the Company had $0.4 million accrued and had paid $2.9 million related to the reduction in workforce.

9. LEASES:

The Company determines whether an arrangement is a lease at inception. The Company has operating and finance leases for corporate offices, warehouse space and equipment (including vehicles). As of December 31, 2023, the Company is the lessee in all lease agreements. The Company's leases have remaining lease terms of 1 to 10 years, some of which include options to extend the leases based on agreed upon terms, and some of which include options to terminate the leases within 1 year. The Company presents the operating right-of-use asset amortization and the change in operating lease liabilities on the other non-cash amortization line item of the consolidated statements of cash flows.

As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

The Company has lease agreements that contain both lease and non-lease components (e.g., common-area maintenance). For these agreements, the Company accounts for lease components separately from non-lease components.

The components of lease expense are as follows:

	For the Years Ended December 31,		
	2023	2022	2021
Operating lease cost	$ 2,407	$ 2,910	$ 2,226
Variable and short-term lease cost	381	521	201
Finance lease cost:			
Amortization of right-of use assets	1,091	1,299	900
Interest on lease liabilities	51	94	82
Total finance lease cost	1,142	1,393	982
Total lease cost	$ 3,930	$ 4,824	$ 3,409

Supplemental cash flow information related to leases is as follows:

	For the Years Ended December 31,		
	2023	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 1,863	$ 2,209	$ 3,733
Operating cash flows from financing leases	51	94	82
Financing cash flows from financing leases	1,345	1,381	686
Non-cash activity:			
Right-of-use assets obtained in exchange for operating lease obligations	4,363	3,963	6,480
Right-of-use assets obtained in exchange for finance lease obligations	334	117	2,074

Supplemental balance sheet information related to leases is as follows:

	December 31,	
	2023	2022
Weighted Average Remaining Lease Term		
Weighted-average remaining lease term — operating leases	8.51 years	6.24 years
Weighted-average remaining lease term — finance leases	1.71 years	1.33 years
Weighted Average Discount Rate		
Weighted-average discount rate — operating leases	3.71 %	4.06 %
Weighted-average discount rate — finance leases	3.45 %	3.44 %

As of December 31, 2023, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2024	$ 578	$ 2,016
2025	97	2,005
2026	95	1,745
2027	45	1,559
2028	—	1,499
Thereafter	—	5,999
Total minimum lease payments	815	14,823
Less: imputed interest	(50)	(2,084)
Present value of lease liabilities	$ 765	$ 12,739

10. INCOME TAXES:

Income (loss) before income tax expense consists of the following:

	For the Years Ended December 31,		
	2023	2022	2021
United States	$ 61,671	$ (7,111)	$ (60,500)
Foreign	(5,413)	(8,564)	51,208
	$ 56,258	$ (15,675)	$ (9,292)

The components of income tax expense (benefit) are as follows:

	For the Years Ended December 31,		
	2023	2022	2021
Current			
Federal	$ —	$ —	$ —
State	1,896	955	163
Foreign	605	2,154	12,517
	2,501	3,109	12,680
Deferred			
Federal	13,570	(2,250)	(10,318)
State	(382)	(633)	(965)
Foreign	(1,867)	(2,617)	(151)
	11,321	(5,500)	(11,434)
Increase (decrease) in valuation allowance	(11,219)	3,849	12,460
	102	(1,651)	1,026
Total income tax expense	$ 2,603	$ 1,458	$ 13,706

For the years ended December 31, 2023, 2022, and 2021 the Company recorded net foreign income tax expense of $0.7 million, $0.5 million, and $13.5 million, respectively. The Company's 2022 foreign income tax expense includes $1.7 million of Canadian withholding taxes paid on the repatriation of Canadian earnings offset by a foreign income tax benefit of $1.2 million associated with the Company's Canadian subsidiary. For the years ended December 31, 2023, 2022, and 2021 the Company recorded U.S. state tax expense of $1.9 million, $1.0 million, and $0.2 million respectively.

The reconciliation of the statutory United States federal income tax rate to the Company's effective tax rate is as follows:

	For the Years Ended December 31,		
	2023	2022	2021
Statutory U.S. federal income tax rate	21.0 %	21.0 %	21.0 %
Nondeductible executive compensation	0.5	(5.8)	(6.1)
Impact of stock-based payment awards	(0.3)	(5.1)	(3.3)
Tax effect of foreign items	(0.4)	(6.0)	(30.8)
State income taxes, net of federal benefit	2.0	(0.8)	6.8
U.S. and foreign tax credits	1.3	3.7	2.5
Nondeductible expenses and other	0.9	8.7	(4.0)
Change in valuation allowance, federal and state	(20.4)	(25.0)	(133.6)
Effective tax rate	4.6 %	(9.3) %	(147.5) %

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting purposes and tax purposes, and net operating loss and tax credit carryforwards. Significant components of the Company's deferred tax assets (liabilities) are as follows:

	December 31,	
	2023	2022
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 28,014	$ 39,783
Inventories	2,654	4,504
Capitalized research and development costs	3,897	6,505
Accruals and reserves currently not deductible	3,324	2,799
Acquired intangible assets	(164)	(2,641)
Depreciation and amortization	(3,567)	(6,227)
Right-of-use assets	(3,010)	(2,775)
Lease liabilities	3,173	2,990
Stock-based compensation	3,467	3,032
Tax credit carryforwards	3,326	4,509
Net deferred tax asset	41,114	52,479
Valuation allowance	(41,668)	(52,887)
Net deferred tax liability	$ (554)	$ (408)

In assessing the realizability of the Company's deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent upon several factors, including the generation of sufficient taxable income, to realize the NOL carryforwards. In 2008, the Company established a full valuation allowance against the Company's U.S. deferred tax asset, and although the Company has achieved another year of U.S. pre-tax earnings based on a rolling three year window the Company has not achieved a level of sustained profitability that would, in the Company's judgement, support the release of the valuation allowance. Management believes the full valuation allowance is still appropriate as of December 31, 2023 and 2022. As a result, no U.S. federal income tax benefit was recorded for the years ended December 31, 2023, 2022, and 2021.

The Company's federal NOL carryforwards of $100.0 million have no expiration date.

The Tax Reform Act of 1986 contains provisions under Internal Revenue Code (“IRC”) Section 382 that limit the annual amount of federal and state NOL carryforwards that can be used in any given year in the event a significant change in ownership. The Company does not believe that there is a Section 382 limitation that will impair the Company's future ability to utilize NOLs to offset the Company's future taxable income. The Company continues to review ownership

changes on an annual basis and the Company does not believe it has had a subsequent ownership change that would impact the NOLs.

In January 2022, approximately $65.0 million was repatriated from the Company's Canadian subsidiary as a one-time event. Associated with this repatriation the Company paid $1.7 million in Canadian withholding tax which is included in the Company's foreign income tax expense within the table further above. It is still the Company's intention to continue to permanently reinvest the historical undistributed earnings of the Company's foreign subsidiary to the extent that the Company will not incur any additional tax expense associated with foreign withholding or other local tax expense on the future cash transfers. As such, deferred taxes have not been recorded on the unremitted earnings of the foreign subsidiary as of December 31, 2023.

As of December 31, 2023, the Company's gross unrecognized tax benefits totaled $0.3 million, and based upon the valuation allowance for the Company's U.S. operations, the recognition of any tax benefit would not impact the Company's effective tax rate. The Company records interest and penalties related to unrecognized tax benefits as a component of income tax expense. Interest and penalties were immaterial in 2023, 2022, and 2021. As a result of the Company's net operating loss carryforward position, the Company is subject to audit by the Internal Revenue Service since the Company's inception, as well as by several jurisdictions for the years ended September 30, 1998 through December 31, 2023.

The reconciliation of the Company's unrecognized tax benefits is as follows:

	2023	2022	2021
Balance as of January 1	$ 373	$ 805	$ 1,172
Additions for tax positions of prior periods	—	1	1
Reductions for tax positions of prior periods	(69)	(433)	(368)
Balance as of December 31	$ 304	$ 373	$ 805

11. STOCKHOLDERS' EQUITY:

Stock-Based Awards

The Company grants stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended (the "Stock Plan"). The Stock Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards.

As of December 31, 2023, 4,581 shares were available for future grants under the Stock Plan.

Under the terms of the Stock Plan, nonqualified stock options may be granted to eligible employees, including the Company's officers at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may be either unlimited or have a specified period in which to vest and be exercised. To date, options generally have been granted with ten-year exercise periods and an exercise price not less than the fair market value on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years.

The fair value of each stock option was estimated on the date of the grant using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	For the Years Ended December 31,		
Black-Scholes Option Valuation Assumptions	**2023**	**2022**	**2021**
Risk-free interest rate[1]	4.23 %	1.65 %	0.47 %
Expected dividend yield	—	—	—
Expected stock price volatility[2]	51 %	50 %	50 %
Expected life of stock options (in years)[2]	5	5	5

(1) Based on the constant maturity interest rate of U.S. Treasury securities whose term is consistent with the expected life of the Company's stock options.

(2) Based upon historical experience.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2023, 2022, and 2021 was $3.24, $4.15 and $6.14, respectively.

Compensation expense recognized in the financial statements related to stock options was $1.3 million, $1.5 million, and $1.1 million for the years ended December 31, 2023, 2022, and 2021, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2023, 2022, and 2021 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $43.0 thousand, $4.0 thousand, and $130.0 thousand, respectively.

The following table summarizes the stock option activity under the Stock Plan:

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding on January 1, 2023	1,758	$ 10.25		
Granted	617	6.18		
Exercised	(44)	6.14		
Expired	(89)	9.42		
Forfeited	(172)	8.92		
Outstanding on December 31, 2023	2,070	$ 9.27	6.27	$ —
Vested or expected to vest as of December 31, 2023	2,070	$ 9.27	6.27	$ —
Exercisable on December 31, 2023	1,234	$ 10.58	4.58	$ —

As of December 31, 2023, there was $2.6 million of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 2.6 years.

Net cash proceeds from the exercise of stock options were $0.3 million, $0.02 million and $0.2 million for the years ended December 31, 2023, 2022, and 2021, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises for these periods.

The following table summarizes information about stock options outstanding as of December 31, 2023:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Exercise Price Per Share	Number Exercisable	Weighted-Average Exercise Price Per Share
$5.37 - $8.86	1,422	7.20	$ 7.19	628	$ 7.58
$8.87 - $13.31	323	3.65	10.78	323	10.78
$14.95 - $22.43	325	4.81	16.83	283	17.02
	2,070	6.27	$ 9.27	1,234	$ 10.58

The Stock Plan also permits the Company to grant restricted shares and restricted units of the Company's common stock to eligible employees, including officers, and the Company's outside directors. Generally, these shares or units are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by the Company's Compensation Committee or Board of Directors. The market value of these shares and units at the date of grant is recognized on a straight-line basis over the period during which the vesting restrictions lapse. Compensation cost of $7.6

million, $9.2 million and $4.1 million related to restricted shares was recognized during the years ended December 31, 2023, 2022, and 2021, respectively.

The following table summarizes restricted stock award and restricted stock units activity under the Stock Plan:

	Units	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2023	2,573	$ 6.51
Granted	912	6.05
Vested	(813)	7.13
Forfeited	(151)	8.22
Issued and unvested, December 31, 2023	2,521	$ 6.04
Issued and expected to vest, December 31, 2023	2,518	$ 6.04

As of December 31, 2023, there was $7.7 million of unrecognized compensation expense related to unvested restricted stock awards and unvested restricted stock units that is expected to be recognized over a weighted average period of 1.5 years.

In connection with the vesting of restricted shares during the years ended December 31, 2023, 2022, and 2021, the Company purchased and immediately retired 262, 241 and 107 shares with aggregate values of $1.4 million, $1.6 million and $1.4 million, respectively, in satisfaction of minimum tax withholding and exercise obligations.

The Company grants performance-based restricted stock units (“PSUs”) to certain executives. Vesting of these PSUs is dependent upon achievement of certain performance-based metrics during a one-year or three-year period, from the date of grant. Assuming achievement of each performance-based metric, the executive must also generally remain in the Company's service for three years from the grant date. Performance shares were granted based on the achievement of three-year cumulative revenue metrics with a market-based condition, or a total shareholder return modifier. PSUs are converted into shares of the Company's common stock once vested and the number of shares actually earned at the end of the performance period will vary, based on actual performance, from 0% to 150% of the target number of performance share units granted. Upon grant of the PSUs, the Company recognizes compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these target assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate.

Compensation cost of $1.8 million, $0.9 million and $2.7 million related to the PSUs was recognized during the years ended December 31, 2023, 2022, and 2021, respectively.

The following table summarizes PSU activity under the Stock Plan:

	Units	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2023	715	$ 6.86
Granted [1]	548	6.32
Performance adjustment [2]	107	N/A
Vested	(285)	7.17
Forfeited	(94)	6.67
Issued and unvested, December 31, 2023	991	$ 6.52
Issued and expected to vest, December 31, 2023	991	$ 6.52

(1) Grant activity for all PSUs disclosed at target.
(2) Reflects the performance adjustment based on actual performance measured at the end of the performance period.

As of December 31, 2023, there was $4.4 million of unrecognized compensation expense related to unvested performance stock units that is expected to be recognized over a weighted average period of 1.9 years.

In connection with the vesting of performance stock units during the year ended December 31, 2023, 2022 and 2021, the Company purchased and immediately retired 86, 88, and 46 shares with aggregate values of $0.5 million, $0.6 million and $0.7 million, respectively.

Share Repurchase Program

On August 5, 2008, the Company's Board of Directors approved a share repurchase program pursuant to which the Company is permitted to acquire up to $25.0 million of the Company's outstanding common shares. No shares were purchased and retired in 2023, 2022, and 2021.

12. TRANSITION COSTS

On December 31, 2021, the Company's Board of Directors approved the termination of Stephen S. Tang, the Company's President and Chief Executive Officer, without cause under his existing employment agreement with the Company, with such termination effective as of March 31, 2022. On January 2, 2022, Dr. Tang and the Company entered into a Transition Agreement providing for the terms of the cessation of Dr. Tang's employment with the Company, including the cessation of his service as President and Chief Executive Officer of the Company and as a member of the Board. Under the Transition Agreement, Dr. Tang's service to the Company in all capacities ended on March 31, 2022.

Pursuant to the Transition Agreement, Dr. Tang received severance of $1.6 million, which was accrued in the consolidated financial statements at December 31, 2021 and paid in April 2022. Additionally, in accordance with his Transition Agreement, certain of his unvested time-vesting restricted stock awards and unvested PSUs that were outstanding at March 31, 2022 vested on April 8, 2022. His remaining unvested time-vesting restricted stock awards and PSUs were forfeited on March 31, 2022. These payments, rights and benefits are substantially similar to the severance benefits contemplated by his previous employment agreement in respect to a termination without cause thereunder. In aggregate, the Company recognized $1.5 million of expense in relation to Dr. Tang's stock compensation for the year ended December 31, 2022.

13. BUSINESS SEGMENT INFORMATION:

The Company is organized on the basis of products and services under a new organizational structure. All products and services reside under the same reporting hierarchy. Historically there was separate management leading the Company's Diagnostics and Molecular Solutions businesses. In February 2023, the Company announced a corporate restructuring to combine the commercial and innovation teams across the Diagnostics and Molecular Solutions segments into one operating segment with sales, marketing, product development and research teams covering all product lines and reporting to a Chief Product Officer. Resources are allocated and performance is assessed on a consolidated basis by the Company's Chief Executive Officer, whom the Company has determined to be its Chief Operating Decision Maker ("CODM"). The CODM reviews the business based on individual product success. Therefore, the Company's historical reportable segments - Diagnostics and Molecular Solutions - are considered one reportable segment and there is no longer is a distinction between Diagnostics and Molecular Solutions, only the Company holistically.

The following table represents total long-lived assets by geographic area:

	December 31,	
	2023	2022
United States	$ 48,311	$ 60,751
Canada	8,777	8,526
Other regions	1,178	1,828
	$ 58,266	$ 71,105

14. COMMITMENTS AND CONTINGENCIES:

Purchase Commitments

As of December 31, 2023, the Company had manufacturing agreements with certain third party vendors, in which minimum purchase commitments are required. If the minimum commitments are not achieved, the Company will be required to make annual penalty payments over the next three years. Based on current forecasts, these penalties aggregate to approximately $1.0 million and are accrued for in the consolidated balance sheet. These estimated penalties can fluctuate based on changes in forecasted demand. The table below represents an estimate of future purchases under those agreements.

2024	$	3,964
2025		2,407
2026		—
2027		—
2028		—
	$	6,371

Litigation

From time to time, the Company is involved in certain legal actions arising in the ordinary course of business. In management’s opinion, based upon the advice of counsel, the outcomes of such actions are not expected, individually or in the aggregate, to have a material adverse effect on the Company's future financial position or results of operations.

Spectrum Patent Litigation

In June 2021, the Company filed a complaint against Spectrum Solutions, LLC (“Spectrum”) in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum filed an answer to the initial complaint, asserting that its device does not infringe the Company’s patent and that the Company’s patent is invalid. In August 2021, the Company amended its complaint to add a second patent to this litigation. Spectrum responded to the Company's amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation and subsequently filed a request for review of the second patent at the Patent and Trademark Office (“PTO”), which was granted by the PTO. The District Court issued multiple pretrial orders, resolving the infringement, antitrust, and inequitable conduct claims without trial. First, the District Court granted Spectrum’s motion for summary judgment of noninfringement, holding that Spectrum’s saliva collection devices are not “kits for collecting and preserving a biological sample,” among other rulings. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. The appeal is pending, with oral argument expected in the second half of 2024. Second, the Court denied Spectrum’s motion to supplement its allegations of alleged antitrust violations, finding that if such an amendment were allowed, Spectrum’s claims would not survive a motion for summary judgment. Spectrum thereafter withdrew its antitrust and inequitable conduct counterclaims. Spectrum did not appeal the District Court's denial of its motion to amend. On February 7, 2024, the PTO issued a Final Written Decision regarding the second patent in the litigation, holding that claims 1, 3–8, 11, and 12 of U.S. Patent No. 11,002,646 B2 are unpatentable. The Company is considering its appellate options. On September 15, 2023, Spectrum filed a separate petition for *inter partes* review of a third patent, which DNAG did not assert in the District Court. The Company filed a preliminary patent owner response on December 28, 2023. That petition remains pending.

15. RETIREMENT PLANS:

Substantially all of the Company's U.S. employees are eligible to participate in the OraSure Technologies, Inc. 401(k) Plan (the “401(k) Plan”). The 401(k) Plan permits voluntary employee contributions to be excluded from an employee’s current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The 401(k) Plan also provides for the Company to match employee contributions up to $4 thousand per year. The Company contributed $1.6 million, $1.8 million and $1.3 million to the 401(k) Plan, net of forfeitures, in 2023, 2022, and 2021, respectively.

In addition to the Company's 401(k) plan, the Company offers a nonqualified deferred compensation plan to permit eligible directors and highly compensated employees of the Company to defer receipt and taxation of their compensation each year.

The Company also may make discretionary contributions to the accounts of the participating employees in any amount either in cash or stock. Participants in the plan may not purchase OraSure stock as an investment vehicle. As of December 31, 2023 and 2022, the value of the assets associated with this plan was $0.8 million and $0.7 million, respectively, and is included in current assets and other assets in the Company's consolidated balance sheets. The Company's obligation related to the deferred compensation plan is included in accrued expenses and other liabilities in the Company's consolidated balance sheets. As of December 31, 2023 and 2022, the Company's total obligation under this plan was $0.8 million and $0.7 million, respectively.

Substantially all regular full-time Canadian employees are eligible to participate in the DNA Genotek Registered Retirement Savings Plan (the “RRSP”). The RRSP permits voluntary employee contributions to be excluded from an employee’s current taxable income and receive tax preferred treatment with Canada Revenue Agency. The RRSP also provides for DNAG to match employee contributions up to $4 thousand CAD per year. The Company contributed $0.4 million, $0.5 million and $0.4 million to the RRSP in 2023, 2022, and 2021, respectively.

16. SUBSEQUENT EVENTS:

In January 2024, the Company announced that it is leading the Series B financing and has entered wide-ranging strategic distribution agreements with Sapphiros, a privately held consumer diagnostics portfolio company based in Boston, and certain of its related entities. Through this strategic relationship, the Company expects to be able to offer a more comprehensive range of low-cost diagnostic tests and molecular sample management solutions to its customers globally.

On January 2, 2024 and on February 13, 2024, the Company invested $10.0 million and $18.3 million, respectively in Sapphiros for a minority interest, which will be accounted for using the cost basis of accounting. There are future investment commitments of $1.7 million to be paid by June 2024, contingent on certain terms and conditions being met.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-262633) on Form S-3 and registration statements (Nos. 333-273731, 333-270863, 333-270861, 333-248424, 333-220148, 333-198237, 333-176315, 333-151077, 333-138814, 333-118385, 333-102235, 333-50340) on Form S-8 of our reports dated March 11, 2024, with respect to the consolidated financial statements of OraSure Technologies, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 11, 2024

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2023, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2024.

/s/ Mara G. Aspinall
Signature

Mara G. Aspinall
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2023, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2024.

/s/ James A. Datin
Signature

James A. Datin
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2023, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2024.

/s/ Nancy J. Gagliano, M.D.
Signature

Nancy J. Gagliano, M.D.
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2023, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2024.

/s/ Lelio Marmora
Signature

Lelio Marmora
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2023, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2024.

/s/ Robert W. McMahon
Signature

Robert W. McMahon
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2023, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2024.

/s/ David J. Shulkin, M.D.
Signature

David J. Shulkin, M.D.
Print Name

Exhibit 31.1

Certification

I, Carrie Eglinton Manner., certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 11, 2024

/s/ Carrie Eglinton Manner

Carrie Eglinton Manner

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

Certification

I, Kenneth J. McGrath, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 11, 2024

/s/ Kenneth J. McGrath

Kenneth J. McGrath
Chief Financial Officer
(Principal Executive Officer)

Exhibit 32.1

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

In connection with the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carrie Eglinton Manner., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Carrie Eglinton Manner
Carrie Eglinton Manner
President and Chief Executive Officer

March 11, 2024

Exhibit 32.2

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

In connection with the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kenneth J. McGrath, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Kenneth J. McGrath
Kenneth J. McGrath
Chief Financial Officer

March 11, 2024

EXHIBIT 97.1

ORASURE TECHNOLOGIES, INC.

COMPENSATION RECOVERY POLICY

Adopted as of November 14, 2023

OraSure Technologies, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer and any other person designated by the Board or the Committee as being subject to this Policy. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of such person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "GAAP" means generally accepted accounting principles in the United States of America.

l. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and any other equity-based compensation provided by the Company or any of its subsidiaries, including, without limitation, stock options, restricted stock awards, restricted stock units and stock appreciation rights.

m. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

n. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Recovery from Participating Employees

In addition to (and without limiting) the provisions of paragraph 2 above, in the event the Company is required to prepare a Financial Restatement after the Effective Date, the Company will use reasonable efforts to recover from any current or former employee of the Company who is not a Covered Person (each a "Participating Employee") and who received Incentive-Based Compensation from the Company during the three completed fiscal years immediately preceding the date on which the Board or the Audit Committee of the Board (the "Audit Committee") determines that the Company is required to prepare a Financial Restatement, the amount that exceeds what would have been paid to the Participating Employee under the Financial Restatement; provided that, this paragraph 5 will apply only to the extent the Board (or a duly established committee thereof), in its sole discretion, determines that the Participating Employee committed any act or omission that materially contributed to the circumstances requiring the Financial Restatement and such act or omission involved any of the following: (i) misconduct, wrongdoing or a violation of any of the Company's rules or of any applicable legal or regulatory requirements in the course of the Participating Employee's employment by the Company; or (ii) a breach of a fiduciary duty to the Company or its stockholders by the Participating Employee.

6. Recovery Where Intentional Misconduct

In addition to (and without limiting) the provisions of paragraphs 2 and 5 above, in the event the Company is required to prepare a Financial Restatement after the Effective Date and the Board (or a duly established committee thereof), in its sole discretion, determines that a Covered Person's or a Participating Employee's act or omission contributed to the circumstances requiring the Financial Restatement and such act or omission involved any of the following: (i) willful, knowing or intentional misconduct or a willful, knowing or intentional violation of any of the Company's rules or any applicable legal or regulatory requirements in the course of the Covered Person's or the Participating Employee's employment by the Company or (ii) fraud in the course of the Covered Person's or the Participating Employee's employment by the Company, the Company will use reasonable efforts to recover from such Covered Person or Participating Employee up to 100% (as determined by the Board or a duly established committee thereof in its sole discretion) of the Incentive-Based Compensation received by such Covered Person or Participating Employee from the Company during the three fiscal years preceding the date on which the Company determined that it is required to prepare a Financial Restatement.

7. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

8. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

9. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

10. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

11. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.