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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, 2025

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, 2025): $218,472,693.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 28, 2026: 69,126,173 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 2026 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, 2025. 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, 2025 (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., references to “Novosanis” mean Novosanis NV, references to "Sherlock" mean Sherlock Biosciences, Inc. and its wholly owned subsidiaries, and references to "BioMedomics" mean BioMedomics, Inc. References in this Annual Report to "we", "us", "our", "OTI" or the "Company" mean OraSure and its consolidated subsidiaries, DNAG, Diversigen, Novosanis, Sherlock and BioMedomics, 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 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;*
- *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 impact of negative geopolitical and economic conditions on the Company's business, including its ability to maintain sales at existing levels;*
- *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 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 fulfill its commitments under its contracts with the U.S. government for InteliSwab® COVID-19 Rapid Tests;*
- *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 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, including international in-country value-added assembly or "near-shoring";*
- *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®, OTI™, OraQuick®, OraQuick ADVANCE®, ORASURE QUICKFLU®, SUREQUICK®, InteliSwab®, SMART SCIENCE MADE SIMPLE®, Oragene®, DNA Genotek®, OMNImet®, ORAcollect®, OMNIgene®, Diversigen®, CoreBiome®, Boostershot®, MetaGene®, Benchmark®, Novosanis®, Colli-Pee®, UCM®, UAS™, prepIT®, NucleoPrecision™, ProteoPrecision™, HEMAcollect™, and HEMAgene® trademarks. The Company also licenses the SHERLOCK™ mark from The Broad Institute, Inc. The Company also owns many of these marks and others in several foreign countries and it pursues the registration of other trademarks where appropriate.

PART I

ITEM 1. Business.

OTI transforms health through actionable insight and decentralizes diagnostics to connect people to healthcare wherever they are.

Our products and services reside under one reporting hierarchy, with commercial and innovation teams, which are part of a single business unit covering multiple product lines. Our business is principally comprised of the development, manufacture, marketing, sale and distribution of (i) diagnostics products, and (ii) sample management solutions.

In November 2025, the Company acquired BioMedomics, Inc. ("BioMedomics"). BioMedomics' SickleSCAN® test is the world's first rapid point-of-care test for sickle cell disease. The SickleSCAN® test is currently sold in markets outside the U.S.

Products and Services

The Company's business consists of the development, manufacture, marketing, sale and distribution 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 HIV, Hepatitis C virus ("HCV"), Syphilis, Sickle Cell and COVID-19 that are performed on a rapid basis at the point of care. 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 HIV and COVID-19 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 and HCV products, as a self-test to individuals in a number of other countries, including, for the HIV products, as an oral swab in-home test for HIV-1 and HIV-2 in Europe, and for the HCV products, as an OTC test. In December 2025, the Company submitted a premarket notification ("510(k)") the FDA for clearance of its rapid molecular self-test for Chlamydia trachomatis and Neisseria gonorrhoeae ("CT/NG"), which is currently under review.

The Company's business also includes 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 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. Initial sales of this product for research use only are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets. In December 2025, the Company also submitted a 510(k) to the FDA for clearance of its Colli-Pee® at-home urine collection device for sexually transmitted infections, which is currently under review.

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:

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. In November 2022, the US FDA reclassified HIV serological diagnostic tests from Class III to Class II with special controls reducing the regulatory burden for these device types. 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 a Clinical Laboratory Improvement Amendments of 1988 ("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® HIV Self-Test

The OraQuick® HIV Self-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 for individuals 14 years of age and older. The test is performed in the same manner as the OraQuick *ADVANCE*® test, except that it has product labeling and instructions designed for consumers. The OraQuick In-Home HIV Self-Test was rebranded to OraQuick HIV Self-Test as part of a PMA supplement in 2024. In addition, the Company has established toll-free customer telephone support to provide additional information and referral services for consumers that use this product.

OraQuick® HIV Self-Test (International)

The OraQuick® HIV Self-Test (International) is an in-vitro diagnostic home-use test for HIV (HIV-1 and HIV-2) in oral fluid, and is sold for use by individuals. OraQuick® HIV Self-Test (International) 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, PEPFAR and other agencies. In February 2026, the Company announced that the OraQuick® HIV Self-Test (International) received a license from Health Canada for use in Canada and is Canada's first oral HIV self-test.

OraQuick® HCV Rapid Antibody Test and Self-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. In November 2021, the US FDA reclassified Hepatitis C virus (HCV) antibody tests for the qualitative detection of HCV from Class III to Class II with special controls reducing the regulatory burden for these device types. 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.

Additionally, the OraQuick® HCV Self-Test is an OTC self-test, available in certain markets outside the U.S., that operates in substantially the same way as the OraQuick® HCV rapid antibody test. The OraQuick® HCV self-test received WHO pre-qualification in 2024 and is the first hepatitis C self-test to earn this designation.

Diagnostics Direct Syphilis Health Check™

Pursuant to a strategic agreement with Diagnostics Direct, the Company distributes the *Syphilis Health Check*™ rapid diagnostic test. *Syphilis Health Check*™ is the first CLIA-waived treponemal test. The test, which uses fingerstick whole blood and delivers point of care results in 10 minutes, offers the ability to test in non-traditional environments, such as

outreach programs and mobile testing clinics. *Syphilis Health Check*™ is approved for use with people aged 13 years and older.

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 the Biomedical Advanced Research and Development Authority ("BARDA"), pursuant to which BARDA will provide up to $8.6 million in funding to the Company to develop an updated 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 $6.9 million in funding to be used to obtain the appropriate regulatory approvals for the product.

InteliSwab® COVID-19 Rapid Test

The 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 an Emergency Use Authorization ("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.

Through 2025, 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 U.S. Department of Health and Human Services ("HHS")), of more than 100 million tests annually.

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 the Clinical Laboratory Improvement Amendments of 1988 ("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.

SickleSCAN® Test

The Company's SickleSCAN® test is a rapid, multiplexed, qualitative point-of care immunoassay for the diagnosis of Sickle cell disorders, and is made up of three indicators, which detect the presence of hemoglobins A, S, and C, allowing the user to rapidly distinguish between normal, carrier, and sickle cell disease samples. The SickleSCAN®test is the world's first rapid point-of-care test for the diagnosis of sickle cell disease. The SickleSCAN® test is currently sold outside the U.S. through the Company's international sales channels.

Genomic Products

The Company sells 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.

Colli-Pee® Urine Collection Device

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 registered as a class I urine collection device without a claim for preservative. The Colli-Pee® collection device with preservative solution known as NucleoPrecision™ chemistry, does not have FDA clearance and is labeled "For Research Use Only" in the U.S. In December 2025, the Company also submitted a 510(k) to the FDA for clearance of its Colli-Pee® at-home urine collection device, with NucleoPrecision™ chemistry, for sexually transmitted infections, which is currently under review.

HEMAcollect™ • PROTEIN Blood Collection Device

In July, 2025, the Company announced the launch of the HEMAcollect™ • PROTEIN blood collection device, an evacuated blood collection tube ("BCT") designed to preserve and stabilize plasma proteins in whole blood for up to 7 days. The BCT uses our proprietary stabilizing liquid, known as ProteoPrecision™ chemistry, and preserves plasma proteins, facilitating storage and transport of blood samples at ambient temperatures. It is anticipated that its use for sample collection will deliver operational efficiencies to proteomic researchers and support the generation of high-quality data. The HEMAcollect™ • PROTEIN BCT is currently available for research use only.

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.

OMNIgene®•XTRACT

The Company's OMNIgene®•XTRACT kit enables the rapid and efficient extraction of high-quality DNA from fecal samples that are validated for gut microbiome samples.

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.

Substance Abuse Products

- ***Intercept® Drug Testing System*** — Oral fluid collection devices and related laboratory-based and automated assays for drugs-of-abuse testing, including the Intercept® and Intercept i2®he platforms.

- ***Immunoassay Tests and Reagents*** — MICRO-PLATE and AUTO-LYTE immunoassay products and related high-throughput assays used in forensic and clinical laboratory drug testing.

- ***Q.E.D.® Saliva Alcohol Test*** — A point-of-care, FDA-cleared and CLIA-waived saliva-based test for quantitative detection of ethanol.

In November 2024, the Company announced that it intended to exit the substance abuse testing business. Though the Company continued to fulfill final orders for certain of the foregoing products through the first half of 2025, it has ceased the production and sale of substance abuse testing products. The Company's substance abuse testing products were marketed to laboratories serving the workplace testing, forensic toxicology, criminal justice and drug rehabilitation markets in the U.S. and certain international markets.

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 developing an updated Ebola test on the OraQuick® testing platform with funds obtained under its contract with BARDA.

The Company is developing a single-use lateral flow immunoassay intended for the qualitative detection of antigens from viruses within the Marburg virus genus. The Company is developing this test and hopes to achieve FDA 510(k) clearance in whole or in part with federal funds obtained from the HHS Administration for Strategic Preparedness and Response (ASPR); BARDA under Other Transaction Number: 75A50123D00005.

Through its Sherlock subsidiary, the Company is developing a rapid molecular self-test for CT/NG. The Company acquired this program in connection with its acquisition of Sherlock. In December 2025, the Company submitted a 510(k) to the FDA for clearance of the CT/NG test, which is currently under review.

Through its Sherlock subsidiary, the Company is also developing a Covid/Flu molecular test, funded in part with Federal funds obtained from the HHS Administration for Strategic Preparedness and Response (ASPR) under contract number: 75A50124C00055. The Company acquired this program in connection with its Sherlock acquisition.

Sample Management Solutions

In order to intersect evolving customer needs within the academic and commercial markets, the Company's sample management solutions business product development pipeline is focused on extending offerings across different sample types and analytes within genomics, proteomics, microbiome and infectious disease areas. Genomic and proteomic customers are demonstrating an increasing demand for collection and stabilization of cell-free nucleic acids, exosomes, proteins, DNA and RNA, while infectious disease customers have expressed growing interest in at-home urine collection for STI testing. In December 2025, the Company submitted a 510(k) to the FDA for clearance of its Colli-Pee® at-home urine collection device for sexually transmitted infections, which is currently under review. 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.

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.

The *Syphilis Health Check*™ is a CLIA-waived professional test sold for use by clinicians, community health providers and public health agencies and can be used as an initial screening test or in conjunction with a nontreponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection.

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® HIV Self-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 and the Company's OraQuick® HCV Self-Test is the first Hepatitis C self-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 self-test pilots and programs to access international funding to purchase the Company's test.

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® collection device 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 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. In December 2025, the Company submitted a 510(k) to the FDA for clearance of its Colli-Pee® at home urine collection device for sexually transmitted infections.

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,		
	2025	2024	2023
OraQuick® HIV	$ 49,802	$ 60,804	$ 60,823
InteliSwab®	620	45,136	257,493
Genomics	31,546	44,861	47,005

One non-commercial customer accounted for approximately 3% of the Company's consolidated net revenues for the year ended December 31, 2025 and 24% and 63% for the years ended December 31, 2024 and 2023, respectively. The Company had no other customers that accounted for more than 10% of consolidated net revenues for the years ended December 31, 2025, 2024 and 2023.

Supply and Manufacturing

The Company manufactures its InteliSwab® COVID-19 Rapid Test, OraQuick *ADVANCE*® Rapid HIV test, OraQuick® HIV Self-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 achieved manufacturing capacity targets under its 2021 contract with the U.S. DOD, in coordination with the HHS. The Company's Opus Way facility was customized to accommodate increased manufacturing capacity. Throughout 2025, 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.

The Company manufactures the majority of DNAG's products, including the Oragene® and Colli-Pee® product lines at its Bethlehem, Pennsylvania facilities. DNAG maintains two long-term relationships to manufacture additional volumes of certain products. 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 and the United States.

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, 2025, the Company had 500 full-time employees, which compares to 501 employees as of December 31, 2024. 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 authentically and fearlessly. 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® HIV Self-Test 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.

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 have entered the market.

The Company's OMNIgene®• GUT device 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.

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

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.

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 are expected to expire in March 2042.

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 are expected to expire in December 2041. One related design patent is issued in the U.S. and will expire in August 2040, and other 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 November 2044. Two related design patents issued in 2024 in the U.S. and corresponding design applications were registered in Canada, China, India, and Europe. These design patents will expire 2038 and 2039.

The Company has registered design patents for a collection funnel and corresponding plunger device in Europe, Canada China, India, and the U.S.

The Company has an international family 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 between October 2038 and May 2041.

The Company holds, through its subsidiary, DNAG, seventeen issued 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 April 2026, and others will expire through November 2040.

The Company holds 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 April 2034. The Company has also applied for additional patents and designs, in both the United States and certain foreign countries, in novel urine collection devices.

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®, OTI™, OraQuick®, OraQuick ADVANCE®, ORASURE QUICKFLU®, SUREQUICK®, InteliSwab®, SMART SCIENCE MADE SIMPLE®, Oragene®, DNA Genotek®, OMNImet®, ORAcollect®, OMNIgene®, Diversigen®, CoreBiome®, Boostershot®, MetaGene®, Benchmark®, Novosanis®, Colli-Pee®, UCM®, UAS™, prepIT®, NucleoPrecision™, ProteoPrecision™, HEMAcollect™, and HEMAgene® trademarks.. The Company also licenses the SHERLOCK™ mark from The Broad

Institute, Inc. 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 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 Management System Regulations ("QMSRs"), 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 QMSRs, 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 licenses, 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 QMSRs 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.

The Company believes that its facilities and procedures are in material compliance with the requirements of the FDA's QMSR, 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. 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.

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 QMSR 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 QMSR 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) 2017/746 (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 (which was extended in July 2024) 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 EU IVDR (subject to compliance with certain requirements under the EU IVDR, including in respect of post-market surveillance); however, Class A non-sterile devices do not benefit from such transitional provisions and have been required to fully comply with the EU IVDR compliant since May 26, 2022. The transition deadline for other classes of devices ranges from December 31, 2027 to December 31, 2029, provided certain transitional activities are performed by earlier deadlines (e.g. the manufacturer must sign a formal written agreement with a notified body for assessment under the EU IVDR).

In the EU, products that fall under the scope of the MDR and the EU IVDR may not be placed on the EU market without a valid CE mark. Approval of a national regulatory authority is not required to obtain a CE mark; however, 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 UK 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-1/2 Antibody Test, OraQuick® HIV Self-Test, OraQuick® HCV Rapid Antibody Test, and OraQuick® HCV Self-Test.

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.
- 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, and sample collection products.
- 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.
- The Company is subject to risks related to government funding and customer ordering.
- 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

- Delay or failure to obtain FDA approval for new products could delay commercialization of new products and prevent the Company from achieving revenue growth.
- 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 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 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 that may impact the success of our genomics products 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.

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 existing products and products or technologies that may be developed or acquired. In addition, the Company's future revenues will depend on market acceptance of urine as a sample type , and the Company's other product offerings, such as the Company's anticipated CT/NG test and Colli-Pee® device. 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. 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 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.

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 HIV testing in the public health, hospital, insurance and other markets. 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.

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 and Sample Collection Products.

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 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. Additionally, there are a number of products for the detection of antigen to SARS-CoV-2 that compete with the Company's InteliSwab® COVID-19 diagnostic test.

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 government 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. In addition, government funding is subject to the political process, which is inherently fluid and unpredictable. For example, the National Institutes of Health (“NIH”) announced on February 7, 2025, a policy significantly reducing research grants by limiting payments for indirect costs. While, as of the date of this filing, a lower court has imposed a permanent injunction preventing the NIH from adopting the policy, which as been subsequently affirmed by a U.S. Circuit Court of Appeals, there can be no assurance that further adverse actions will not be taken. Further, our revenue may be adversely affected if our clients delay purchases as a result of uncertainties surrounding the approval of government budget proposals, including reduced allocations to government agencies. In addition, government funding is subject to the political process, which is inherently fluid and unpredictable. 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 or previous order patterns.

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 sample management solutions. The Company is also pursuing opportunities to obtain certain governmental or economic incentives by establishing in-country value-added assembly or manufacturing operations (“near-shoring”) in select international markets, including in parts of Africa, which are intended to provide cost, logistics, or market-access benefits.

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 $36.8 million, or 32% of consolidated revenues in 2025, $46.7 million, or 25% of consolidated revenues in 2024, and $43.8 million, or 11% of consolidated net revenues in 2023. In addition, the Company's subsidiary DNAG, which accounted for $39.5 million or 34% of consolidated net revenues in 2025, 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, and tariffs;
- 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 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 certain DNAG 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 resulted in, and potential future pandemics or other public health emergencies 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 such pandemic or other health emergency. Future governmental responses to public health crises, including pandemics and epidemics 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 an updated Ebola test on the OraQuick® testing platform, which was subsequently modified in September 2023 to add an additional $6.8 in funding to be used to obtain the appropriate regulatory approvals. Also in September, 2022, the Company was selected to provide its OraQuick® HIV Self-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.

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.

We believe that our facilities and procedures are in material compliance with the FDA's QMSR requirements, 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. Recently, the United States and certain other countries from which we import materials have imposed or signaled a willingness to impose tariffs on goods coming into the United States and elsewhere. While we cannot be certain how this will impact our supply chain, 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.

In recent years, 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 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, on a limited basis, third-party manufacturers to supply certain products, including its Colli-Pee®, Oragene® and ORAcollect® lines of collection kits.

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.

Additionally, potential future pandemics or other public health emergencies may, in the future, disrupt the normal operations of the Company's third-party suppliers. Furthermore, 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. In late 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.

The Company Expects Revenue Levels From its InteliSwab® COVID-19 Rapid Test to Continue to Decline.

The Company experienced a significant decline in revenues from InteliSwab® COVID-19 Rapid Test sales in 2024 and 2025, and expects revenues to continue to decline in 2026. The Company has seen a reduction in the prevalence of COVID-19 since the height of the pandemic, particularly following the expiration of the public health emergency declarations related to COVID-19 in mid-2023. 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 COVID-19 becomes a seasonal virus or experiences additional fluctuations in prevalence, the Company could experience fluctuations in its revenues associated with its InteliSwab® COVID-19 Rapid Tests. While there is still limited 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.

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.

In early 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 QMSR 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 the Company does.

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. 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 is developed and all applicable regulatory approvals, clearance or certifications are obtained, there may be little or no market for the product 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 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 3% of its net consolidated revenues for the year ended December 31, 2025. 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 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.

The Company is Subject to Risks Related to Government Funding and Customer Ordering.

A portion of our revenues is derived from sales to customers that rely on funding from the U.S. government, including federal agencies, state programs, and entities receiving grants and contracts from the HHS, the U.S. Agency for International Development (“USAID”), the Centers for Disease Control and Prevention (“CDC”), and other government programs. In 2025, the U.S. government implemented funding freezes and delays that have directly affected healthcare and

life sciences procurement. Any reduction, delay, or uncertainty in the availability of such funding could adversely affect the purchasing patterns of these customers, impacting our business, financial condition, and results of operations.

Among factors that could adversely affect our business are the impact of actions, such as the U.S. government implementing funding freezes and delays; other changes in fiscal policies or decreases in available government funding; changes in government funding priorities; changes in government programs or applicable requirements; the impact of the adoption of new laws or regulations or changes to existing laws or regulations on global health initiatives and domestic procurement of essential healthcare supplies; changes in government administration and national and international priorities, including developments in the geopolitical environment; the termination or reduction in certain funding for research and development, including from BARDA; changes in audit policies and procedures of government entities; potential delays or changes in the government appropriations process; and delays in the payment of our invoices by government payment offices.

Customers that rely on these funding sources may reduce, delay, or cancel orders for our products and services, particularly during periods of political uncertainty. If our customers experience prolonged funding uncertainty or reductions in available government funds, we could face disruptions in our revenue streams, increased inventory costs due to unpredictable ordering patterns, and potential declines in profitability. While we actively monitor legislative and regulatory developments, we cannot predict the outcome of government policy shifts that may impact our customers' ability to procure our products.

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.

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. ("Sapphiros"), in December 2024, the Company acquired Sherlock, expanding the Company's product pipeline with the addition of Sherlock's molecular diagnostics platform, and in November 2025, the Company acquired BioMedomics, also expanding the Company's product pipeline with the addition of BioMedomics' SickleSCAN™ test for sickle cell disease. 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 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 NIH and agencies in other countries to pay for the products and services they purchase. These research customers also purchase the Company's single order fulfillment services.

Government funding is subject to the political process, which is inherently fluid and unpredictable. Under the Trump administration, the NIH announced on February 7, 2025, a policy significantly reducing research grants by limiting payments for indirect costs. Indirect costs represented more than 25% of total grant dollars awarded by the NIH in 2023. Our research customers may face increased financial pressure due to this change or any future caps on indirect costs. While, as of the date of this filing, a lower court has imposed a permanent injunction preventing the NIH from adopting the policy, which has been subsequently affirmed by a U.S. Circuit Court of Appeals, there can be no assurance that further adverse actions will not be taken. Further, our revenue may be adversely affected if our research customers delay purchases as a result of uncertainties surrounding the approval of government budget proposals, including reduced allocations to government agencies, such as the NIH.

The Company has also received government funding for certain research and development projects, including, most recently, through the Rapid Response Partnership Vehicle ("RRVP") for the development of a Marburg Virus Disease

("MVD") rapid antigen test. 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. The absence of patent protection in certain 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 has sought, and may in the future 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 inter-parties review processes. These proceedings permit certain persons to challenge the validity of a patent on the grounds that it was known from the prior art. As a result of such proceedings several of the Company's patents have been successfully challenged. 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. 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 devices that are to be placed on the market in the EU must bear a CE mark indicating conformity with the applicable requirements of the EU IVDR. The EU IVDR became applicable on May 26, 2022 and repealed the previous 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 EU IVDR, subject to compliance with certain requirements under the EU IVDR (see the section titled "Governmental Regulation - International" for further information). 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 EU 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 QMSR 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, it could allege that we had misbranded or adulterated our RUO products. If the FDA asserts that our RUO products are subject to marketing authorization, or that our RUO products are adulterated or misbranded, our business, financial condition or results of operations could be adversely affected.

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 QMSR 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.

In addition, from time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance and policies are often revised or reinterpreted by the FDA in ways that may significantly affect the manner in which our products are regulated and marketed. 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.

Disruptions at the FDA and Other Government Agencies, Including Staffing Constraints, and Funding Uncertainty, Could Delay or Prevent the Development, Review, Approval, or Commercialization of Our Products and Adversely Affect Our Business.

Our business depends on the effective functioning of the FDA, the SEC, and other governmental authorities that regulate, review, fund, or otherwise influence the development, approval, manufacturing, and commercialization of our products. In recent periods, these agencies have experienced material disruptions, including government shutdowns, workforce reductions, hiring freezes, funding uncertainty, and shifts in policy priorities, and similar conditions may persist or recur. These disruptions have resulted in longer and less predictable regulatory review timelines, reduced availability of agency personnel, and delays in inspections, meetings, and other regulatory activities. Following a shutdown or funding change, regulatory backlogs and resource constraints may continue for extended periods. As a result, our ability to obtain timely regulatory approvals, clearances, or authorizations for new or modified products may be delayed or impaired, which could postpone product launches, increase development costs, require additional studies or data, or prevent products from being commercialized. Our regulatory risk is further heightened by the FDA's increasing workload, evolving oversight priorities, and constraints on its ability to hire and retain experienced personnel. Reduced staffing or funding at the FDA or other agencies may limit their capacity to meet performance goals, conduct inspections, or provide timely guidance, which could adversely affect our development timelines and commercial plans.

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 ("EU GDPR") as well as other national data protection legislation in force in relevant European Economic Area ("EEA") member states, and the EU GDPR in such form as incorporated into the laws of the UK ("UK GDPR", together with EU GDPR, "GDPR"), 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 (or £17.5 million in the UK). 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 special category personal data (such as health sensitive data), ensuring a legal basis or condition applies to the processing of 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/UK 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, or the EU-US Data Privacy Framework) applies. Any inability to transfer personal data from the EEA/UK 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.

The European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR (the "Adequacy Decision") ensuring transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has also confirmed personal data transfers from the UK to the EEA remain free flowing. Despite Brexit, the UK and EEA data protection regimes remain largely aligned. However, there is increasing risk of divergence in application, interpretation and enforcement of these data protection regimes, creating additional regulatory uncertainty. For example, the UK Data (Use and Access) Act 2025 ("UK Act"), now in force, further differentiates the UK's data protection regime from the EEA. In December 2025, the European Commission adopted a decision determining that the UK continues to provide a level of data protection that is "essentially equivalent" to the EU standards and extended the validity of the UK adequacy decision for six years, through December 2031. While this renewal reduces immediate concerns around the UK's adequacy for transfers of EU personal data, uncertainty remains regarding how UK data protection laws will evolve in the medium to longer term. The lack of clarity on future UK laws and their interaction with EU laws and regulations may affect the Company's efforts to maintain a harmonized approach to processing European personal data and expose the Company to two parallel regimes where the UK GDPR and EU GDPR both apply with differing interpretation and enforcement approaches. This could increase the Company's legal risk and compliance cost associated with the handling of European personal data, and may require the Company to adapt its privacy and data security compliance programs to account for legal and regulatory divergence between the UK and EEA. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country, such that the Company may be unable to operate in a uniform legal landscape across the EEA.

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.

In the U.S., there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including health information privacy laws, security breach notification laws and consumer protection laws. Each of these laws is subject to varying interpretations and is constantly evolving. By way of example, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates (individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity). Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (the FTCA), 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

The Company is also subject to the California Consumer Privacy Act ("CCPA"), which creates individual privacy rights and places stringent privacy and security obligations on businesses covered by the law, including obligations to provide detailed disclosures to California consumers about their data collection, use and sharing practices and provide such consumers with ways to opt out of certain uses of sensitive personal information, including health information. It also provides for civil penalties for violations and allows for a private right of action for data breaches that is expected to increase data breach litigation. The law also created a new state regulatory agency that was vested with authority to implement and enforce the CCPA. 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. Similar laws have been passed and proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. In addition to these comprehensive consumer privacy laws and proposals, a number of other states have passed or proposed more limited privacy laws that focus on specific privacy issues such as biometric data and the privacy of health and medical information, such as Washington state's My Health My Data Act, which went into effect in March 2024. The My Health My Data Act imposes new state restrictions and requirements on the processing and sale of consumer health data and creates a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. The effects of state and federal privacy laws are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

In addition to privacy and data security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, and we may publish marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

We are subject to laws and regulations that govern sending marketing and advertising by electronic means, such as email and telephone. For example, in the United States, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (the "CAN-SPAM Act"), among other things, obligates the sender of commercial emails to provide recipients with the ability to opt out of receiving future commercial emails from the sender. In addition, the Telephone Consumer Protection Act (the "TCPA") imposes certain notice, consent, and opt-out obligations on companies that send telephone or text communications using automatic telephone dialing systems, or artificial or prerecorded voice to consumers, and provides consumers with private rights of action for violations. The FCC and the FTC have responsibility for regulating various aspects of these laws. Among other requirements, the TCPA requires us to obtain prior express written consent for certain telemarketing calls. Many states have similar consumer protection laws regulating telemarketing. These laws limit our ability to communicate with potential customers and reduce the effectiveness of our marketing programs. For violations of the TCPA, the law provides for a private right of action under which a plaintiff may recover monetary damages of $500 for each call or text made in violation of the prohibitions on calls made using an "artificial or pre-recorded voice" or an automatic telephone dialing system. Various state law equivalents of the TCPA may also provide for monetary damages in amounts greater than those provided for under the TCPA. An action may be brought by the FCC, a state attorney general, an individual, or a class of individuals. If in the future we are found to have violated the TCPA, or a state law equivalent, the amount of damages and potential liability could be extensive and adversely impact our business. Accordingly, were such a class certified or if we are unable to successfully defend such a suit, then TCPA or other state law damages could have a material adverse effect on our results of operations and financial condition.

In recent years, there has been increasing public and regulatory scrutiny of the use of cookies by companies in the healthcare space. For example, the FTC has brought enforcement actions against online healthcare services and service providers, and there has been an increase in litigation alleging the unauthorized collection and sharing of sensitive health information in violation of federal and state privacy laws. While we do not collect HIPAA-regulated PHI via the use of cookies on our websites, and we believe our use of cookies on those websites complies with all applicable laws, we may from time to time receive public or regulatory inquiries about our use of tracking technologies. Continued regulation of cookies, changes in the interpretation and enforcement of existing laws and regulations, and increased scrutiny of the use of cookies by healthcare technology companies could restrict our ability to engage in certain activities or require changes to our practices. If we are believed or found to have not complied with our obligations under applicable laws, we may also be subject to litigation, substantial financial penalties, injunctive actions and reputational harm. All of the above could impact our business, financial condition or results of operations.

Changes In Tax Laws Or In Their Implementation Or Interpretation May Adversely Affect Us Or Our Investors.

The rules dealing with the U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future. For example, recent legislation that was signed into law on July 4, 2025 made significant changes to U.S. federal tax law. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

The Use of New And Evolving Technologies, Such As Artificial Intelligence ("AI"), In Our Offerings May Present Risks And Challenges That Can Impact Our Business Including by Posing Security Risks to Our Confidential Information, Proprietary Information, and Personal Data.

We may use and integrate AI into our business practices, including through the adoption of commercially available tools. The evolving nature of AI technologies and the surrounding legal and regulatory environment presents risks and uncertainties related to cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, and reputational challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. The use of AI technology can give rise to intellectual property risks, including disclosures or other compromises to proprietary intellectual property and intellectual property infringement, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In Europe, the EU begin implementing the Artificial Intelligence Act ("AI Act") on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, which entered into force on August 1, 2024 and, with some exceptions, will begin to apply as of August 2, 2026, imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or deploy AI systems that are governed by these laws and regulations, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Even in the absence of dedicated AI laws and regulations, we may be subject to novel legal and business risks relating to our adoption of these new technologies. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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

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 FDA worked 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 April 29, 2024, the FDA published a final rule on LDTs, in which FDA outlines its plan to end enforcement discretion for many LDTs in five stages over a four-year period. However, in March 2025, a federal district court judge issued a decision that vacated the FDA's final rule on the grounds that the FDA did not have authority under the FDCA to promulgate it because LDTs do not fall within the statutory definition of "device." This district court ruling was not appealed, and the FDA's final rule will no longer be implemented or enforced by the FDA.

Stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS, although it is unclear whether any future legislative efforts towards such a goal would be successful. The outcome and ultimate impact on our business of any future changes to the federal government's regulation of LDTs via legislative enactments is difficult to predict.
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. In the past, a number of these companies were purchasing DNAG products. 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, should these enforcement actions continue despite the district court's ruling on FDA's final rule on LDT's, 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 2025, approximately $36.8 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, 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, between 2020 through 2022 and again recorded net losses for the years ended December 31, 2024 and 2025. In addition, as of December 31, 2025, the Company had an accumulated deficit of $172.2 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 sample management solutions and related genomic and microbiome laboratory services;
- The Company's ability to successfully commercialize its products in the United States and internationally;
- Changes in the markets in which the Company operates;
- 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 acquisitions and strategic transactions;
- 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, currency fluctuations and tariffs;
- 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.

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, increased in recent years and continue to be subject to volatility. 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.

Increasing Geopolitical and Economic Risk and Tariffs Could Negatively Affect Our Ability to Maintain Sales at Existing Levels

Geopolitical and macroeconomic developments, including the imposition or expansion of tariffs, non-tariff barriers and trade restrictions, or other protectionist measures have contributed to increased uncertainty and volatility in global markets. These actions could increase the cost of materials, components, or finished goods, make it more difficult for us to attract new customers, retain existing customers, continue to produce and source in an optimal manner, maintain our supply chain, or maintain sales at existing levels, both in the United States and in other countries. Trade-related measures have in the past, and may in the future change with limited notice and could be accompanied by retaliatory actions by other countries. Geopolitical and economic risks, together with trade protectionism have increased over the past few years in many regions of the world, including in the United States. Any of these risks, ensuing retaliation, or the further deterioration of trade relations between countries could make our offerings more expensive or non-competitive in the affected countries. Growing tensions, protectionist trade policies, and tariffs may also lead to a fragmentation of the global economy, a general reduction of international trade in goods and services, and a reduction in the integration of financial markets, any of which could materially and adversely affect our business results, cash flows, financial condition, or prospects. Changes in political leadership, statutory frameworks, or regulatory policy in the United States and abroad may further affect the interpretation, implementation, or enforcement of laws and regulations applicable to our business. If regulatory disruptions, staffing constraints, funding limitations, or trade actions continue or intensify, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

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

At December 31, 2025, the Company's consolidated balance sheet reflected approximately $43.4 million of goodwill and approximately $19.0 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 dollar. 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 subsidiary 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 subsidiary 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 sample management solutions and its OraQuick® HIV Self-Test;
- 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, including the Company's recent acquisition of Sherlock;
- 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, including those related to inflation, interest rates, tariffs and foreign currency exchange rates; 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.

Share Repurchases Could Increase the Volatility of the Trading Price of Our Common Stock and Diminish Our Cash Reserves, and We Cannot Guarantee That Our Stock Repurchase Program Will Enhance Long-Term Stockholder Value.

On March 21, 2025, our Board authorized the repurchase of up to $40.0 million in shares of our common stock pursuant to a stock repurchase program (the “Repurchase Program”). The Repurchase Program does not obligate us to repurchase any minimum dollar amount or number of shares, and can be modified, terminated or suspended at any time. Repurchases of shares of our common stock could affect the trading price of our common stock and increase volatility of such securities. Similarly, the future announcement of the modification, suspension or termination of the Repurchase Program, or our decision not to utilize the full authorized repurchase amount under the Repurchase Program, could result in a decrease in the trading price of our common stock. In addition, the Repurchase Program could have the impact of reducing our cash reserves, which may impact our ability to finance our growth, fund working capital, strategic acquisitions or business opportunities, and other general corporate purposes and execute our strategic plan. Although the Repurchase Program is

intended to enhance long-term stockholder value, there can be no assurance that it will do so because the trading price of our common stock may decline below the levels at which we repurchased our shares and short-term stock price fluctuations could reduce the effectiveness of the Repurchase Program.

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

Our Business Could be Negatively Affected as a Result of Actions of Activist Stockholders.

While we value open dialogue and input from our stockholders, activist stockholders could take actions that could adversely affect our business. Specifically, responding to common actions of an activist stockholder, such as requests for potential nominations of candidates for election to our Board of Directors, requests to pursue a strategic combination, or other transaction or other special requests, could disrupt our operations, be costly and time-consuming, or divert the attention of our management and employees. In addition, perceived uncertainties as to our future direction in relation to the actions of an activist stockholder may result in the loss of potential business opportunities or the perception that we are unstable as a company, which may make it more difficult to attract and retain qualified employees. Our ability to continue to commit to our mission, guiding principles, and culture may also be questioned, which could impact our ability to attract and retain business. Actions of an activist stockholder may also cause fluctuations in our stock price based on speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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® HIV Self-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.

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, which has since been remediated. 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.

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, 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 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. As previously disclosed, the Company has, like others in its industry, 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 amount 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.

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 pandemic has caused disruptions in local, regional, national and global markets and economies, including the United States. These events disrupted the Company's normal operation and the operations of its customers and suppliers.

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 the conflict in Iran, 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. 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 Iran, 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 Iran 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.

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.

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. Where our risk-based evaluation indicates the need, we use a third-party tool to assess the degree of risk posed by the vendor and use a vendor security questionnaire as part of our assessment of third-parties.

We have been subject to cybersecurity incidents in the past, including the publicly disclosed April 2024 security incident. We do not believe that risks from cybersecurity threats, including as a result of any previous cybersecurity incidents have materially affected our operations, financial systems, or financial condition. However, there is no guarantee that past security incidents and any future incidents will not have a material impact on our operations, financial systems, or financial condition in the future. 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 over 25 years experience managing IT teams, including 10 years managing IT security teams. Led by the VP of IT, along with our Director of IT Security, the IT leadership team reviews the Company's cybersecurity objectives at least annually, and more frequently as needed, and takes steps to further the suitability and effectiveness of the Company's information security program. The output from these reviews are reported periodically to senior management. We have also established 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.

The Company owns a 31,700 square foot facility that houses its primary corporate office, sales and marketing, research and development, human resources, and regulatory and quality offices. The Company also owns a 48,000 square foot facility and a 33,500 square foot facility which are used for manufacturing activities. The Company also leases a 139,000 square foot manufacturing facility. Each of these facilities is located in Bethlehem, Pennsylvania. The Company's subsidiary, DNAG, also leases a 36,000 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. The Company's subsidiary, Sherlock, leases various facilities in the United Kingdom totaling approximately 37,600 square feet, as well as outside Boston, Massachusetts, totaling approximately 5,000 square feet. These facilities house Sherlock's corporate offices, production, and research and development activities. The Company's subsidiary, BioMedomics, leases a building in North Carolina totaling approximately 2,000 square feet. The facility houses BioMedomics' corporate offices, production, and research and development activities.

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

ITEM 3. Legal Proceedings.

Discussion of legal matters is incorporated by reference from Note 14, Commitments and Contingencies, to the Consolidated Financial Statements included in this Annual Report on Form 10-K.

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 23, 2025, there were 241 holders of record and approximately 19,647 holders in street name of the Company's Common Stock, and the closing price of its Common Stock was $2.75 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.

Purchases of Equity Security by the Issuer and Affiliated Purchasers

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]
October 1, 2025 - October 31, 2025	551,044 [2]	2.90	531,201	$28,459,997
November 1, 2025 - November 30, 2025	144,162	2.45	144,162	$28,106,600
December 1, 2025 - December 31, 2025	1,262,230	2.49	1,262,230	$24,960,000
	1,957,436		1,937,593	

(1) In March 2025, the Company's board of directors authorized a stock repurchase program (the "Repurchase Program") effective March 21, 2025, whereby the Company may purchase up to $40.0 million in shares of its common stock over a period of up to two years. The amount and timing of share repurchases under the Repurchase Program may be carried out at the discretion of management through various methods in compliance with applicable state and federal securities laws, including through the use of trading plans intended to qualify under Rule 10b5-1 under the Exchange Act, in accordance with applicable securities laws and regulations.

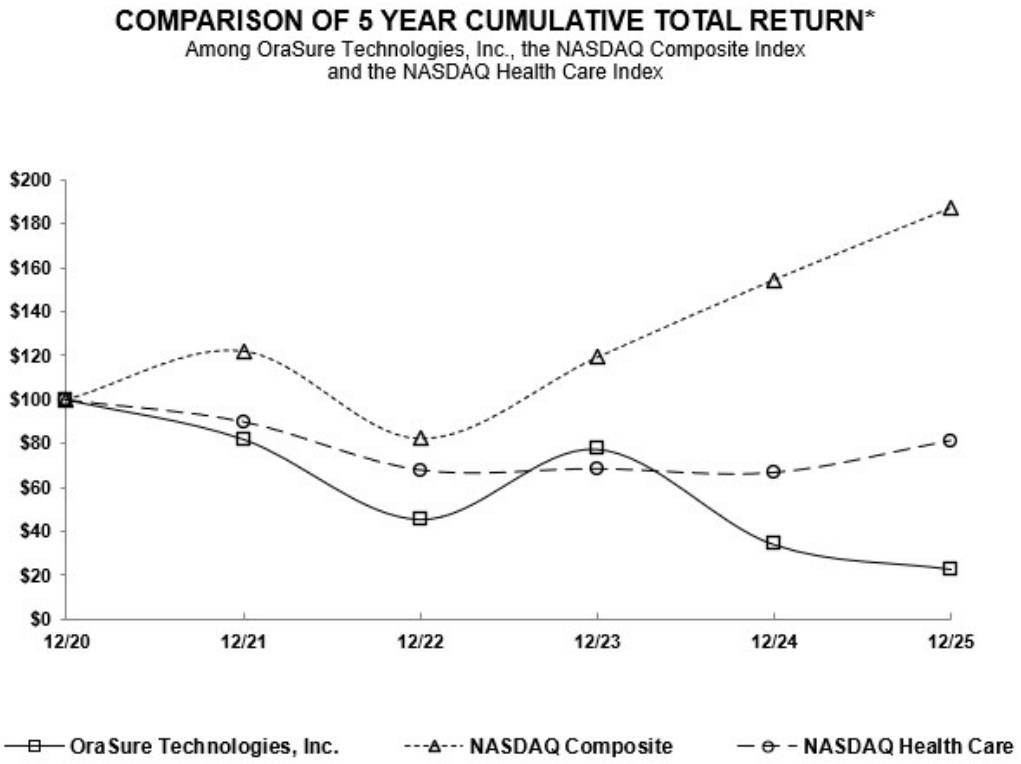
(2) Includes shares retired to satisfy minimum tax withholdings, in connection with the vesting of restricted and performance shares, pursuant to the OraSure Technologies Inc. Stock Award Plan.

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, 2020 through December 31, 2025. The graph assumes that $100 was invested on December 31, 2020 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.



	Fiscal Year Ending December 31,					
	2020	2021	2022	2023	2024	2025
OraSure Technologies, Inc.	**100.00**	**82.10**	**45.54**	**77.47**	**34.10**	**22.86**
NASDAQ Composite	**100.00**	**122.18**	**82.43**	**119.22**	**154.48**	**187.14**
NASDAQ Health Care	**100.00**	**89.96**	**67.65**	**68.20**	**66.46**	**81.27**

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, 2025 (this "Annual Report") generally discusses 2025 and 2024 items and year-to-year comparisons between 2025 and 2024. Discussion of 2023 items and year-to-year comparisons between 2024 and 2023 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, 2024.

Business Overview

The Company's business consists of the development, manufacture, marketing, sale and distribution 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 HIV, Hepatitis C, Syphilis, Sickle Cell and COVID-19 that are performed on a rapid basis at the point of care. 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 HIV and COVID-19 products are also sold in a consumer-friendly format in the OTC market in the U.S. and, in the case of the HIV and HCV products, as a self-test to individuals in a number of other countries, including, for the HIV products, as an oral swab in-home test for HIV-1 and HIV-2 in Europe, and for the HCV products, as an OTC test. In December 2025, the Company submitted a 510(k) to the FDA for clearance of its rapid molecular self-test for CT/NG, which is currently under review.

The Company's business also includes 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, and companion animal 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. Initial sales of this product for research use only are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets. In December 2025, the Company also submitted a 510(k) to the FDA for clearance of its Colli-Pee® at-home urine collection device for sexually transmitted infections, which is currently under review.

Recent Developments

Risk Assessment Testing

In the third quarter of 2024, the Company announced the discontinuance of sales of its risk assessment product line which was completed in the second quarter of 2025. Sales of its risk assessment products contributed $1.9 million and $8.4 million to revenues during the twelve months ended December 31, 2025 and 2024, respectively. During the first quarter of 2025, the Company sold certain assets that made up the risk assessment product line including certain intellectual property, contracts, permits, and equipment.

Acquisition of BioMedomics, Inc.

In November 2025, the Company acquired BioMedomics, Inc. ("BioMedomics"), pursuant to which BioMedomics became a wholly-owned subsidiary of the Company. The BioMedomics acquisition expands the Company's diagnostic portfolio by adding SickleSCAN®, a rapid, point-of-need test for sickle cell disease that is sold outside of the United States.

Results of Operations

The Company's consolidated net loss for the year ended December 31, 2025 was $68.7 million, or $0.94 per share on a fully diluted basis, compared to consolidated net loss of $19.5 million, or $0.26 per share on a fully diluted basis, for the year ended December 31, 2024.

Year ended December 31, 2025 compared to December 31, 2024.

CONSOLIDATED NET REVENUES

The table below shows a summary of total consolidated net revenues (dollars in thousands) for the years ended December 31, 2025 and 2024:

	For the Years Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2025	2024	% Change	2025	2024
Diagnostics [1]	$ 66,497	$ 75,917	(12)%	58 %	41 %
Sample Management Solutions [2]	38,356	51,046	(25)	33	28
Risk Assessment Testing [3]	1,866	8,354	(78)	2	4
Other products and services [4]	1,716	2,453	(30)	1	1
COVID-19 Diagnostics	620	45,136	(99)	1	24
Molecular Services	—	1,705	(100)	—	1
Net product and services revenues	109,055	184,611	(41)	95	99
Non-product and services revenues [5]	5,966	1,216	391	5	1
Net revenues	$ 115,021	$ 185,827	(38)%	100 %	100 %

[1] Includes HIV, HCV, Syphilis, and SureQuick® product revenues.
[2] Includes Genomics, Microbiome, and Colli-Pee® product revenues.
[3] Includes substance abuse testing product revenues.
[4] Includes COVID-19 Sample Management Solutions product revenues.
[5] Includes funded research and development contracts, royalty income, and grant revenues.

Product and Services Revenues

Consolidated net revenues decreased 38% to $115.0 million for the year ended December 31, 2025 from $185.8 million for the year ended December 31, 2024.

Sales of the Company's Diagnostics products decreased 12% to $66.5 million for the year ended December 31, 2025 from $75.9 million for the year ended December 31, 2024. This decrease in revenues is largely due to lower international HIV revenues primarily driven by a decrease in funding and customer ordering patterns in Africa and Asia. Lower sales of the Company's HIV domestic products due to a decrease in overall funding impacting HIV programs also contributed to the decline in diagnostic revenues. Offsetting these decreases in revenues is an increase in Syphilis revenue resulting from the launch in the second quarter of 2024.

Sample Management Solutions revenues decreased by 25% to $38.4 million for the year ended December 31, 2025 compared to $51.0 million for the year ended December 31, 2024. Sales of the Company's Sample Management Solutions are being impacted by a large customer's bankruptcy.

Risk Assessment testing revenues decreased 78% to $1.9 million for the year ended December 31, 2025 from $8.4 million for the year ended December 31, 2024. The Company discontinued this line of business at the end of 2024 and the business wound down in early 2025.

COVID-19 Diagnostics revenues decreased 99% to $0.6 million for the year ended December 31, 2025 from $45.1 million for the year ended December 31, 2024 due to decreased sales of the Company's InteliSwab® tests through its U.S. government procurement contracts. The Company experienced a significant decline in COVID-19 revenues during 2024

due to the fulfillment of these contracts and lower overall demand for COVID-19 testing and anticipates that this trend will continue into the foreseeable future.

Molecular Services revenues, which were largely derived from the Company's microbiome molecular sequencing services, were nil for the year ended December 31, 2025 compared to $1.7 million for the year ended December 31, 2024. The decrease in services revenues was due to the decision to exit this line of business.

Non-Product and Services Revenues

Non-product and services revenues increased 391% to $6.0 million for the year ended December 31, 2025 from $1.2 million for the year ended December 31, 2024 primarily due to the recognition of revenue under funded R&D contracts that were assumed by the Company as a result of the Sherlock acquisition at the end of 2024 as well as an increase in funded R&D under other BARDA contracts.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin decreased to 41.9% for the year ended December 31, 2025 from 42.7% for the year ended December 31, 2024. The largest driver of the margin decline was a negative product mix driven by lower InteliSwab® sales that generate higher gross margins and lower genomics sales that also generate higher gross margins. Also contributing to the decline in margins was lower absorption of fixed overhead costs due to lower revenues and production. The termination of the microbiome molecular sequencing services business which historically dragged down the gross margin rate helped to improve the gross margin rate during the period along with the higher non-product revenues which contribute 100% to gross margin.

Consolidated operating loss for the year ended December 31, 2025 was $72.0 million, compared to a $28.3 million operating loss reported for the year ended December 31, 2024. Results for the year ended December 31, 2025 were negatively impacted by the decrease in revenues, lower gross margins earned on the revenues and by higher operating expenses. Results for the year ended December 31, 2025 included change in the estimated fair value of acquisition-related contingent consideration of $4.6 million offset by gain on sale of assets of $0.7 million. Results for the year ended December 31, 2024 included impairment charges of $4.4 million.

Research and development expenses increased 63% to $42.5 million for the year ended December 31, 2025 from $26.0 million for the year ended December 31, 2024 largely due to higher spend incurred for clinical trials for the CT/NG device and additional research and development operational expense layered in from the acquired Sherlock companies.

Sales and marketing expenses decreased 16% to $26.1 million for the year ended December 31, 2025 from $31.0 million for the year ended December 31, 2024 primarily due to decreased employee costs associated with a reduction in headcount, and lower market research and advertising spend.

General and administrative expenses increased 3% to $47.7 million for the year ended December 31, 2025 from $46.2 million for the year ended December 31, 2024 largely due to higher legal fees relating to the NowDx litigation (discussed further in Note 14, Commitments and Contingencies, to the consolidated financial statements included herein) and costs associated with the Sherlock acquisition. Also contributing to the increase were additional general and administrative expenses layered in from the acquired Sherlock companies which occurred in December 2024. Lower stock compensation expense, consulting fees, and decreased employee costs partially offset the increase in general and administrative spend.

All of the above contributed to the Company's operating loss of $72.0 million for the year ended December 31, 2025, which included non-cash charges of $10.2 million for depreciation and amortization, $10.1 million for stock-based compensation, and $4.6 million for change in the estimated fair value of acquisition-related contingent consideration. The Company's operating loss of $28.3 million for the year ended December 31, 2024 included a non-cash charge of $11.9 million for stock-based compensation, $10.9 million for depreciation and amortization, and impairment charges of $4.4 million.

CONSOLIDATED OTHER INCOME

Other income for the year ended December 31, 2025 was $7.4 million compared to $12.2 million for the year ended December 31, 2024. The decrease in other income is primarily due to lower interest income and 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. The Company has not achieved U.S. cumulative pre-tax earnings based on a rolling three year window as the Company has not achieved a level of sustained profitability that would, in its judgment, support the release of the valuation allowance. For the years ended December 31, 2025 and 2024, the Company recorded income tax expense of $1.8 million.

Liquidity and Capital Resources

	December 31, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	$ 199,278	$ 267,763
Working capital	222,113	299,737

The Company's cash and cash equivalents decreased to $199.3 million at December 31, 2025 from $267.8 million at December 31, 2024. The Company has $86.9 million, or 44% of its $199.3 million of cash, cash equivalents and available-for-sale securities held by DNAG, the Company's Canadian subsidiary.

The Company's working capital decreased to $222.1 million at December 31, 2025 from $299.7 million at December 31, 2024. 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, 2025, net cash used in operating activities was $49.0 million. Cash flows from operations can be significantly impacted by factors such as timing of receipts from customers, inventory purchases, and payments to vendors. The Company's net loss of $68.7 million included non-cash charges of depreciation and amortization expense of $10.2 million, stock-based compensation expense of $10.1 million, change in estimated fair value of acquisition-related contingent consideration of $4.6 million, a loss on equity investment of $2.3 million, and other non-cash charges aggregating to $1.2 million.

Cash used by the Company's working capital accounts included a decrease in accrued expenses and other liabilities of $8.7 million largely attributable to lower bonus accruals, an increase in prepaid expenses and other assets of $2.4 million associated with an increase in the Company's Canadian income tax receivable and increased prepayment of costs associated with the Company's efforts to prepare for production of the CT/NG device, a decrease of $1.7 million in accounts payable, and a decrease in deferred revenue of $1.5 million as work on grant projects is completed and earned. Offsetting these uses of cash is a decrease in inventory balances of $3.6 million related to the discontinuance of sales of the Company's Risk Assessment products and lower demand for its InteliSwab® COVID-19 Rapid test, and a decrease in accounts receivable of $1.9 million as the Company experienced a decline in overall sales.

Investing Activities

Net cash used in investing activities was $6.8 million for the year ended December 31, 2025, associated with proceeds from sale of property and equipment offset by the acquisition of new property and equipment. Investing activities also includes $3.6 million of cash used for the acquisition of BioMedomics.

Financing Activities

Net cash used in financing activities was $16.9 million for the year ended December 31, 2025, which was largely comprised of $15.0 million to repurchase common stock pursuant to the Company's stock repurchase plan and $1.8 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted stock awarded to the Company's employees.

Resources

The Company's contractual obligations are included in Note 14 of its consolidated financial statements. The Company expects existing cash and cash equivalents will be sufficient to fund 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® HIV Self-Test to the retail trade, and InteliSwab® products to the 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 it satisfies its performance obligations for services rendered. Service revenue was discontinued with the closure of the molecular services line of business in 2024.

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 an average cost method, 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 inventory expiring within ninety days, with the exception of inventory that will be consumed or will have expiration dates extended. 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.

The Company performed its annual goodwill impairment analysis and noted there were impairment indicators. A quantitative impairment test was performed on both reporting units. Both reporting units showed fair value exceeded carrying value. The diagnostic reporting unit impairment results reflected a fair value with a narrower margin to its carrying value. As of November 30, 2025, the annual impairment testing date, the diagnostic reporting unit fair value exceeded the carrying value by 13%. As of December 31, 2025, the diagnostic reporting unit had $8.2 million of goodwill. The diagnostic reporting unit goodwill impairment analysis used both an income and market approach. These two approaches were weighted and the income approach was weighed more than the market approach. Key assumptions included estimates of revenues increasing each year as new products are launched and a weighted-average cost of capital based on guideline companies. The revenue and cashflows forecasts assume products are passed by regulatory bodies on a set timeline and market competition of future products is low. The revenues assume market growth will accelerate each year. If there are delays to attaining regulatory approval or successfully launching products, this could have a negative outcome on the goodwill impairment analysis. In addition, if the Company's weighted-average cost of capital is not aligned with guideline companies, this could negatively affect the goodwill impairment outcome.

Business Combinations and Contingent Consideration

Acquired businesses are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to contingent consideration are recorded to the balance sheet at the date of acquisition based on their relative fair values. The purchase price allocation requires us to make significant estimates and assumptions, especially at the acquisition date, with respect to intangible assets. Although we believe the assumptions and estimates we have made are reasonable, they are based in part on historical experience and information obtained from the management of the acquired companies and are inherently uncertain.

We account for contingent consideration in accordance with applicable guidance provided within the business combination accounting guidance. As part of our consideration for the Sherlock acquisition, we are contractually obligated to pay

certain consideration resulting from the outcome of future events. Therefore, we are required to update our underlying assumptions each reporting period, based on new developments, and record such contingent consideration liabilities at fair value until the contingency is resolved. Changes in the fair value of the contingent consideration liabilities are recognized each reporting period and included in our consolidated statements of operations. Our estimates of fair value are based on assumptions we believe to be reasonable, but the assumptions are uncertain and involve significant judgment by management. Updates to these assumptions could have a significant impact on our results of operations in any given period and any updates to the fair value of the contingent consideration could differ materially from the previous estimates.

Examples of critical estimates used in valuing the intangible asset and contingent consideration include:

• future expected cash flows from sales and acquired in-process and research developed technologies;

• the probability of meeting the future events; and

• discount rates used to determine the present value of estimated future cash flows.

These estimates are inherently uncertain and unpredictable, and if different estimates were used the purchase price for the acquisition could be allocated to the acquired assets and liabilities differently from the allocation that we have made. In addition, unanticipated events and circumstances may occur, which may affect the accuracy or validity of such estimates, and if such events occur we may be required to record a charge against the value ascribed to an acquired asset or an increase in the amounts recorded for assumed liabilities.

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, 2025, 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 5% of the Company's total revenues for the year ended December 31, 2025. The Company does have foreign currency exchange risk related to its operating subsidiary in Canada. The principal foreign currency in which the subsidiary conducts business is the Canadian dollar. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. The Company's Canadian foreign subsidiary had net assets, subject to translation, of $112.1 million in U.S. dollars, which are included in the Company’s consolidated balance sheet as of December 31, 2025. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have increased the Company's comprehensive loss by approximately $11.2 million as of December 31, 2025.

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 (CEO), Chief Financial Officer (CFO) and Chief Accounting Officer (CAO), 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, 2025. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2025 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, 2025.

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, 2025 has been audited by GRANT THORNTON LLP, an independent registered public accounting firm, as stated in their report, which is included below.

(c) Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(d) Report of Independent Registered Public Accounting Firm.

Board of Directors and Stockholders
OraSure Technologies, Inc.

Opinion on Internal Control Over Financial Reporting
We have audited the internal control over financial reporting of OraSure Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2025, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2025, and our report dated March 9, 2026 expressed an unqualified opinion on those financial statements.

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

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

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

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

/s/ GRANT THORNTON LLP

Philadelphia, Pennsylvania
March 9, 2026

ITEM 9B. Other Information.

a. None.
b. The following table discloses any director or "officer" as defined in Rule 16a-1(f) under the Exchange Act who adopted or terminated any Rule 10b5-1 trading plan or arrangements or any non-Rule 10b5-1 trading plan or arrangements, in both cases as defined in Item 408(a) of Regulation S-K during the fourth quarter of the fiscal year ended December 31, 2025.

Name and Title	Action Taken (Date of Action)	Type of Trading Arrangement	Nature of Trading Arrangement	Duration or End Date	Aggregate Number of Securities
Carrie Eglinton Manner *President, Chief Executive Officer and Director*	Adoption (November 29, 2025)	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c).	Purchase of the Company's common stock pursuant to the terms of the plan.	Active through August 28, 2026	Up to $165,000 of shares of the Company's common stock
Kenneth McGrath *Chief Financial Officer*	Adoption (November 28, 2025)	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c).	Purchase of the Company's common stock pursuant to the terms of the plan.	Active through August 28, 2026	Up to $165,000 of shares of the Company's common stock

Other than as disclosed above, no other director or officer adopted or terminated any Rule 10b5-1 trading plan or arrangements or any non-Rule 10b5-1 trading plan or arrangements, in both cases as defined in Item 408(a) of Regulation S-K during the fourth quarter of the fiscal year ended December 31, 2025.

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 2026 Annual Meeting of Stockholders (the "2026 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 2026 Proxy Statement and is incorporated herein by reference.

Code of Conduct

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.

Insider Trading Arrangements and Policies

The Board of Directors has adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of securities of OraSure by directors, officers, and employees that the Company believes are reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards. The Company's insider trading policy states, among other things, that its directors, officers, and employees are prohibited from trading in such securities while in possession of material, nonpublic information. In addition, with regard to trading in the Company's own securities, it is the Company's policy to comply with the federal securities laws and the applicable exchange listing requirements. The foregoing summary of the Company's insider trading policies and procedures does not purport to be complete and is qualified by reference to the insider trading policy attached hereto as Exhibit 19.1 and incorporated herein.

ITEM 11. Executive Compensation.

The information required by this Item 11 will be included in the Company's 2026 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 2026 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 2026 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 2026 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
2.1†●	Agreement and Plan of Merger, dated December 19, 2024 by and among OraSure Technologies, Inc., Project Watson Merger Sub, Inc., Sherlock Biosciences, Inc. and Mr. Paul Meister, solely in his capacity as representative of the securityholders of Sherlock Biosciences, Inc. is incorporated by reference to Exhibit 2.1 to the Company's Annual Report on form 10-K for the year ended December 31, 2024.
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.
3.1.3	Certificate of Amendment to Certificate of Incorporation of OraSure Technologies Inc. dated May 16, 2024 is incorporated by reference to Exhibit 3.1 to the Company's Periodic Report on Form 8-K filed on May 17, 2024.
3.2	Third Amended and Restated Bylaws of OraSure Technologies, effective as of August 5, 2025, is incorporated by referenced to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025.
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 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.*
10.2	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*
10.3	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*
10.4	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.*
10.5	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.*
10.6	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.*
10.7	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.*
10.8	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.*

10.90	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.*
10.10	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.*
10.11	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.*
10.12	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan, Effective March 25, 2024, is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 17, 2024.*
10.13	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan, Effective March 24, 2025, is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 14, 2025.*
10.14	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.*
10.15	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. *
10.16	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.*
10.17	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.*
10.18	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.*
10.19	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.*
10.20	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.*
10.21	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.*
10.22	$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.
10.23	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.
19.1+	Insider Trading Policy
21.1+	Subsidiaries of the Company
23.1+	Consent of KPMG LLP.
23.2+	Consent of Grant Thornton 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.
97.10	OraSure Technologies Inc. Compensation Recovery Policy is incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.
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.

† Certain portions of this Exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. The Company hereby agrees to furnish supplementally an unredacted copy of the exhibit to the SEC upon its request.

● Certain schedules, annexes or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K, but will be furnished supplementally to the SEC upon request.

ITEM 16. Form 10-K Summary.

None

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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 9, 2026.

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 9, 2026, 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)
*STEVEN K. BOYD Steven K. Boyd	Director
*NANCY J. GAGLIANO, M.D. Nancy J. Gagliano, M.D.	Director
*JOHN P. KENNY John P. Kenny	Director
*LELIO MARMORA Lelio Marmora	Director
*ROBERT W. MCMAHON Robert W. McMahon	Director

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

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
OraSure Technologies, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of OraSure Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

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, 2025, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 9, 2026 expressed an unqualified opinion.

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

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

Critical audit matter
The critical audit matter communicated below is a matter arising from the current period audit of the 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the 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.

Fair value of the royalty based contingent consideration from the Sherlock Biosciences, Inc. acquisition

As further described in Notes 2 and 13 to the consolidated financial statements, on December 19, 2024, the Company acquired Sherlock Biosciences, Inc. ("Sherlock"), pursuant to the terms of a merger agreement. The purchase consideration transferred in this transaction included, in part, contingent consideration related to royalty payments through December 31, 2034, representing a mid-single digit percentage of future revenues associated with the acquired in-process research and development technology intangible asset. The royalty based contingent consideration is adjusted to fair value at each reporting period. The estimated fair value of the royalty based contingent consideration as of December 31, 2025 was $9.1 million. We identified the fair value determinations of the royalty based contingent consideration as a critical audit matter.

The principal consideration for our determination that the fair value of the royalty based contingent consideration is a critical audit matter is that the inputs and assumptions utilized by management require significant judgment and result in a high degree of estimation uncertainty. The subjectivity of the estimate increases the level of auditor judgment and effort to

evaluate management's significant assumptions, including (i) future expected revenues and (ii) discount rates. Further, changes in these assumptions and judgments could have a significant impact on the recorded fair value.

Our audit procedures related to the fair value of the royalty based contingent consideration included the following, among others:

- Evaluated the design and operating effectiveness of key controls related to management's processes over the development of the fair value estimates and related key inputs and assumptions, and over the evaluation of the competency and objectivity of management's third-party valuation specialist.
- Tested the mathematical accuracy of the valuation models utilized and the completeness, accuracy and relevance of underlying data used in the model.
- Assessed the reasonableness of management's estimated revenues by obtaining an understanding of management's processes for developing projected financial information, including inspection of relevant market data and other supporting documentation.
- Utilized valuation specialists to evaluate the reasonableness of the methodology and discount rates used in the valuation.
- Conducted sensitivity analyses around the future expected revenues and discount rate assumptions utilized by management.

/s/ GRANT THORNTON LLP
We have served as the Company's auditor since 2023.

Philadelphia, Pennsylvania
March 9, 2026

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 statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows of OraSure Technologies, Inc. and subsidiaries (the Company) for the year 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 results of operations of the Company and its cash flows for the year ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our 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 the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We served as the Company's auditor from 2002 to 2024.

Philadelphia, Pennsylvania
March 11, 2024, except for Note 12, as to which the date is March 7, 2025

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

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 199,278	$ 267,763
Accounts receivable, net of allowance for doubtful accounts of $188 and $774	22,203	23,816
Inventories	31,060	34,197
Prepaid expenses	5,221	3,956
Other current assets	4,146	3,488
Total current assets	261,908	333,220
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation	39,179	45,105
Operating right-of-use assets, net	11,996	13,442
Finance right-of-use assets, net	146	145
Intangible assets, net of accumulated amortization	19,046	17,435
Goodwill	43,363	40,330
Investment in equity method investee	25,956	28,300
Deferred tax asset	271	156
Other noncurrent assets	1,303	1,526
Total noncurrent assets	141,260	146,439
TOTAL ASSETS	**$ 403,168**	**$ 479,659**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 6,521	$ 8,173
Deferred revenue	1,518	2,961
Accrued expenses and other current liabilities	11,149	20,179
Finance lease liability	63	41
Operating lease liability	2,164	2,129
Acquisition-related contingent consideration obligation	18,380	—
Total current liabilities	39,795	33,483
Noncurrent Liabilities:		
Finance lease liability	100	113
Operating lease liability	10,870	12,321
Acquisition-related contingent consideration obligation	9,333	22,910
Other noncurrent liabilities	2,243	494
Total noncurrent liabilities	22,546	35,838
TOTAL LIABILITIES	62,341	69,321
Commitments and contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $0.000001, 120,000 shares authorized, 70,391 and 74,598 shares issued and outstanding	—	—
Additional paid-in capital	531,393	538,129
Accumulated other comprehensive loss	(18,404)	(24,360)
Accumulated deficit	(172,162)	(103,431)
Total stockholders' equity	340,827	410,338
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 403,168**	**$ 479,659**

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,		
	2025	2024	2023
NET REVENUES:			
Products and services	$ 109,055	$ 184,611	$ 402,222
Other	5,966	1,216	3,250
	115,021	185,827	405,472
COST OF PRODUCTS AND SERVICES SOLD	66,823	106,437	233,820
Gross profit	48,198	79,390	171,652
OPERATING EXPENSES:			
Research and development	42,528	26,047	33,728
Sales and marketing	26,117	30,986	36,319
General and administrative	47,677	46,215	58,191
Loss on impairments	—	4,392	10,829
Change in the estimated fair value of acquisition-related contingent consideration	4,570	—	(99)
Gain on sale of assets	(725)	—	—
	120,167	107,640	138,968
Operating (loss) income	(71,969)	(28,250)	32,684
OTHER INCOME	7,383	12,249	23,574
(Loss) income before income taxes and equity investment	(64,586)	(16,001)	56,258
INCOME TAX EXPENSE	1,801	1,799	2,603
(LOSS) INCOME BEFORE EQUITY INVESTMENT	(66,387)	(17,800)	53,655
LOSS ON EQUITY INVESTMENT	(2,344)	(1,700)	—
NET (LOSS) INCOME	$ (68,731)	$ (19,500)	$ 53,655
(LOSS) INCOME PER SHARE:			
BASIC	$ (0.94)	$ (0.26)	$ 0.73
DILUTED	$ (0.94)	$ (0.26)	$ 0.72
SHARES USED IN COMPUTING (LOSS) INCOME PER SHARE:			
BASIC	73,485	74,434	73,348
DILUTED	73,485	74,434	74,389

See accompanying notes to the consolidated financial statements.

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

	For the Years Ended December 31,		
	2025	2024	2023
NET (LOSS) INCOME	$ (68,731)	$ (19,500)	$ 53,655
OTHER COMPREHENSIVE INCOME (LOSS)			
Currency translation adjustments	5,956	(9,419)	3,274
Unrealized gain on marketable securities	—	—	220
COMPREHENSIVE (LOSS) INCOME	$ (62,775)	$ (28,919)	$ 57,149

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2025, 2024 and 2023
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2023	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
Common stock issued upon exercise of options	32	—	214	—	—	214
Vesting of restricted stock and performance stock units	1,678	—	—	—	—	—
Purchase and retirement of common shares	(640)	—	(3,548)	—	—	(3,548)
Stock-based compensation	—	—	11,920	—	—	11,920
Net loss	—	—	—	—	(19,500)	(19,500)
Currency translation adjustments	—	—	—	(9,419)	—	(9,419)
Balance at December 31, 2024	74,598	$ —	$ 538,129	$ (24,360)	$ (103,431)	$ 410,338
Shares repurchased and retired in satisfaction of minimum tax withholding for vested restricted stock and performance stock units	1,640	—	—	—	—	—
Purchase and retirement of common shares	(564)	—	(1,843)	—	—	(1,843)
Stock-based compensation	—	—	10,147	—	—	10,147
Shares repurchased and retired in connection with share repurchase program	(5,283)	—	(15,040)	—	—	(15,040)
Net loss	—	—	—	—	(68,731)	(68,731)
Currency translation adjustments	—	—	—	5,956	—	5,956
Balance at December 31, 2025	70,391	$ —	$ 531,393	$ (18,404)	$ (172,162)	$ 340,827

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,		
	2025	**2024**	**2023**
OPERATING ACTIVITIES:			
Net (loss) income	$ (68,731)	$ (19,500)	$ 53,655
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities			
Stock-based compensation	10,147	11,920	10,729
Depreciation and amortization	10,192	10,872	20,936
Loss on impairments	—	4,392	10,829
Other non-cash amortization	(222)	(564)	3
Provision for credit losses	(65)	71	(462)
Unrealized foreign currency loss (gain)	365	(263)	103
Interest expense on finance leases	8	22	51
Loss on equity investment	2,344	1,700	—
Deferred income taxes	1,853	(657)	102
(Gain) loss on sale of fixed assets	(725)	563	—
Change in the estimated fair value of acquisition-related contingent consideration	4,570	—	(99)
Payment of acquisition-related contingent consideration	—	—	(19)
Changes in assets and liabilities:			
Accounts receivable	1,949	15,872	31,116
Inventories	3,562	13,096	48,228
Prepaid expenses and other assets	(2,368)	4,089	(2,499)
Accounts payable	(1,720)	(7,577)	(26,976)
Deferred revenue	(1,519)	(219)	(730)
Accrued expenses and other liabilities	(8,663)	(6,443)	(3,384)
Net cash (used in) provided by operating activities	(49,023)	27,374	141,583
INVESTING ACTIVITIES:			
Purchases of short-term investments	—	(53,244)	(74,652)
Proceeds from maturities and redemptions of investments	—	53,052	102,440
Purchase of equity method investee	—	(30,000)	—
Acquisition of business, net of cash acquired	(3,613)	(5,037)	—
Proceeds from sale of assets	1,000	—	—
Purchases of property and equipment	(4,197)	(3,797)	(5,802)
Purchase of property and equipment under government contracts	—	—	(4,501)
Proceeds from funding under government contracts	—	—	48,669
Net cash (used in) provided by investing activities	(6,810)	(39,026)	66,154
FINANCING ACTIVITIES:			
Cash payments for lease liabilities	(61)	(842)	(1,345)
Proceeds from exercise of stock options	—	214	269
Repurchase of common stock	(15,040)	—	—
Payment of acquisition-related contingent consideration	—	—	(46)
Payment of taxes related to net share settlement of equity awards	(1,843)	(3,548)	(1,901)
Net cash used in financing activities	(16,944)	(4,176)	(3,023)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	4,292	(6,816)	1,713
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(68,485)	(22,644)	206,427
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	267,763	290,407	83,980
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 199,278	$ 267,763	$ 290,407

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(all tabular amounts in thousands)

1. THE COMPANY:

OraSure Technologies transforms health through actionable insight and decentralizes diagnostics to connect 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. The Company's business consists of the development, manufacture, marketing and sale of simple, easy to use specimen collection devices and diagnostic products designed to detect certain infectious diseases including HIV, Hepatitis C, Syphilis and Sickle Cell that are performed on a rapid basis at the point of care. The Company's business also includes 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. During 2024, the Company exited the molecular services business. In October 2024, the Company announced the discontinuance of the sales of its risk assessment product line which was completed in the first half of 2025.

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, DNA Genotek Inc. ("DNAG"), Diversigen, Inc. ("Diversigen"), Novosanis NV ("Novosanis"), BioMedomics, Inc. ("BioMedomics") and Sherlock Biosciences, Inc. ("Sherlock"). Novosanis was legally dissolved in June 2025. 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.

Change in Accounting Principle

Effective January 1, 2025, the Company changed its methodology for valuing certain inventories to the average cost method from the first-in, first-out ("FIFO") cost method. The change was applicable to all inventories. The Company concluded that the average cost basis of accounting is preferable as it results in greater precision in the calculation of acquisition cost of inventory on the balance sheet. The effect of this change in accounting principle was immaterial. Therefore, retroactive application was not determined to be necessary and a cumulative adjustment of $0.1 million was recorded in the statement of operations for the twelve months ended December 31, 2025.

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 fair value of assets acquired and liabilities assumed for business combinations, 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 accruals, 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.

Supplemental Cash Flow Information

The Company paid income taxes of $1.8 million and $1.8 million in 2025 and 2024, respectively, and received income tax refunds of $4.9 million in 2023.

The Company had account receivable write-offs of $0.5 million, $0.5 million, and $0.7 million in 2025, 2024, and 2023, respectively.

As of December 31, 2025, 2024 and 2023, the Company had accruals for purchases of property and equipment of $0.5 million, $0.5 million and $0.2 million, respectively.

The Company acquired BioMedomics which included contingent consideration of $0.3 million for the year ended December 31, 2025.

The Company acquired Sherlock which included contingent consideration of $22.9 million for the year ended December 31, 2024.

Cash Equivalents & Short-Term Investments

The Company considers all investments in debt securities to be available-for-sale securities. These securities consist of guaranteed investment certificates purchased with 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 securities as of December 31, 2025 and December 31, 2024.

The Company maintains cash balances in the United States in excess of the federally insured limits. The Company periodically evaluates financial institutions and believes the risk of loss to be remote due to this evaluation.

Fair Value of Financial Instruments

As of December 31, 2025 and 2024, 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).

To the extent that valuation is based on models or inputs that are unobservable in the market, determining fair value requires more judgment. Because of the inherent uncertainty of valuation, estimated values may be materially higher or lower than the values that would have been used had a ready market for the investments existed. Therefore, the degree of judgment exercised in determining fair value is greatest for assets or liabilities categorized in Level 3.

	Level	December 31, 2025	December 31, 2024
Guaranteed investment certificates	1	$ 13,114	$ 66,584
Trading securities	1	543	724
Contingent consideration:	3		
Current portion		$ 18,380	$ —
Long-term portion		9,333	22,910
		$ 27,713	$ 22,910

Included in cash and cash equivalents at December 31, 2025 and 2024 was $13.1 million and $66.6 million, respectively, invested in guaranteed investment certificates.

Included in cash and cash equivalents at December 31, 2025 and 2024, was $68.4 million and $118.5 million, respectively, invested in government money market funds. These funds have investments in U.S. government securities and are 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 and Company stock. The fair value of the plan assets as of December 31, 2025 and 2024 was $0.5 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

As discussed further in Note 13, Business Combinations, the Company has identified its contingent consideration obligations as Level 3 liabilities due to significant inputs that are required to measure the fair value of these obligations. The contingent consideration is comprised of three different tranches: milestone payments, royalty payments, and earnout payments. The significant quantitative unobservable inputs for the milestone payments are the discount rate and probability achievement of a milestone of a regulatory approval.

The fair value methodology for royalty payments is based on a discounted cash flow model. Significant quantitative unobservable inputs are internally developed future expected cash flows, discount rate and probability achievement of a milestone of a regulatory approval. The royalty payments represent a mid-single digit percentage of the net sales through 2034 associated with the acquired in-process and research and development intangible asset.

The fair value methodology for earnout payments is based on a Monte Carlo model. Significant quantitative unobservable inputs are future expected cash flows, discount rate and volatility rate.

There was an increase of $4.6 million in the fair value of the Company's contingent consideration from date of acquisition to December 31, 2025 for the milestone and royalty payments.

	Fair Value
Balance at December 31, 2024	$ 22,910
Additions	233
Change in fair value	4,570
Balance at December 31, 2025	$ 27,713

Equity Method Investee

In January 2024, the Company led the Series B financing and entered into wide-ranging strategic distribution agreements with KKR Sapphiros L.P. ("Sapphiros"), a privately held consumer diagnostic portfolio company, and certain of its related entities. Through this 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. As of December 31, 2025, the Company had funded $30.0 million for its interest in Sapphiros. The Company recorded the investment using the equity method in accordance with Accounting Standards Codification ("ASC") Topic 323, *Investments—Equity Method and Joint Ventures—Overall.* In accordance with the equity method, the Company's equity investment is presented net of its share of any gains or losses of the investee. The Company has elected as its accounting policy to recognize its share of any income or loss in Sapphiros on a three-month lag. The investment in Sapphiros of $26.0 million as of December 31, 2025 is included in the investment in equity method investee line of the Company's balance sheet. The Company has no unconditional obligations or guarantees to, or in support of, its equity method investee and its operations. In conjunction with the preparation of the Company's December 31, 2025 financial statements, the Company evaluated the investment in Sapphiros for impairment and concluded there was no such impairment. The Company's investment in Sapphiros was valued at $28.3 million as of December 31, 2024.

Related Party

The Company loaned Sapphiros $0.3 million during the year ended December 31, 2025. The loan plus interest is due in December 2026. During the year ended December 31, 2025, the Company entered into an agreement with Sapphiros to develop certain products for Sapphiros. A total of $0.2 million of revenue was recognized from this agreement.

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.

	December 31,		
	2025	**2024**	**2023**
Accounts receivable	$ 22,203	$ 23,816	$ 40,171
Allowance for doubtful accounts	$ 188	$ 774	$ 1,216

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on an average cost method, 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 inventory expiring within ninety days, with the exception of inventory that will be consumed or will have expiration dates extended. 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 as follows:

- buildings twenty years;
- leasehold improvements, the lesser of the useful life of the improvement or the remaining life of the building or lease;
- computer equipment and software three years;
- machinery and equipment five years; and

- furniture and fixtures seven years

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, in-process research and development 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 Note 5 for discussion of property, plant and equipment impairments, recorded for the year ended December 31, 2024. See Note 6 for discussion of definite-lived intangible asset impairments, 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 in a business combination. 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 historically performed an annual goodwill impairment assessment as of July 31. During the three months ended December 31, 2023, the Company changed the date of the annual impairment assessment to November 30, to better align with the Company's annual forecasting process. On November 30, 2025, the Company performed a quantitative goodwill impairment test which concluded that the carrying value of the Company's goodwill for both the diagnostic and collection devices reporting units was below its fair value indicating there was no impairment.

As of November 30, 2025, the diagnostic reporting unit fair value exceeded its carrying value by 13%. As of December 31, 2025, the diagnostic reporting unit had $8.2 million of goodwill. The diagnostic reporting unit goodwill impairment analysis used both an income and market approach. These two approaches were weighted and the income approach was weighed more than the market approach. Key assumptions included revenues increasing each year as products are launched and a weighted-average cost of capital based on guideline companies. The revenue and cashflows assumes products are passed by regulatory bodies on a set timeline and market competition of future products is low. The revenues assume market growth will accelerate each year. If there are delays to attaining regulatory approval or successfully launching products, this could have a negative outcome on the goodwill impairment analysis. In addition, if the Company's weighted-average cost of capital is not aligned with guideline companies, this could negatively affect the goodwill impairment outcome.

The below table illustrates the discount rate and exit multiple sensitivity to the fair value of the diagnostic reporting unit goodwill when performing the goodwill impairment analysis as of November 30, 2025. In the annual goodwill impairment analysis as of November 30, 2025, the diagnostic reporting unit utilized a 14% discount rate with an exit multiple of one.

Discount Rate	Exit Multiple 0.80	0.90	1.00	1.10	1.20
13%	$ 208,132	$ 217,464	$ 226,796	$ 236,128	$ 245,460
14%	205,252	214,254	**223,256**	232,258	241,259
15%	202,501	211,188	219,875	228,562	237,249
16%	199,868	208,254	216,640	225,025	233,411
17%	197,339	205,436	213,533	221,630	229,726

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® HIV Self-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. Service revenues are associated with the Diversigen business, which was discontinued in 2024. There were zero service revenues for the year ended December 31, 2025.

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. Arrangements with multiple performance obligations are associated with the Diversigen business, which was discontinued in 2024.

Other revenues. Other revenues consist primarily of royalty income and funding from grants of research and development efforts. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. The Company accounts for government grants by analogy to International Accounting Standard 20, *Accounting for Government Grants and Disclosure of Government Assistance ("IAS 20"),* as U.S. GAAP does not provide specific guidance. Grants are recognized when there is reasonable assurance that conditions will be met and the grant will be received, and are recognized in earnings over the periods in which the related costs are incurred. 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.

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

	For the Years Ended December 31,		
	2025	2024	2023
HIV	$ 49,802	$ 60,804	$ 60,823
Sample Management Solutions [1]	38,356	51,046	54,274
HCV	13,759	14,024	12,871
Other product and services revenues [2]	4,648	3,506	2,265
Risk Assessment Testing [3]	1,866	8,354	9,736
COVID-19 [4]	624	45,172	257,779
Molecular Services	—	1,705	4,474
Net product and services revenues	$ 109,055	$ 184,611	$ 402,222
Non-product and services revenues [5]	5,966	1,216	3,250
Net revenues	$ 115,021	$ 185,827	$ 405,472

[1] Includes Genomics, Microbiome and Colli-Pee® product revenues.
[2] Includes Syphilis revenues.
[3] Includes substance abuse testing product revenues.
[4] Includes COVID-19 Diagnostics and COVID-19 Sample Management Solutions revenues.
[5] Includes 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,		
	2025	2024	2023
United States	$ 78,252	$ 139,161	$ 361,660
Africa	23,993	32,745	29,254
Europe	7,393	8,424	8,111
Other regions	5,383	5,497	6,447
	$ 115,021	$ 185,827	$ 405,472

Customer Concentrations. The following table represents customer concentration risk:

	For the Years Ended December 31,	
Net Revenues	2025	2024
Non-commercial customer	N/A	24%

	December 31,	
Accounts Receivable	2025	2024
Commercial customer	15%	10%

Vendor Concentrations. 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.

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, 2025, 2024, and 2023 was comprised of customer prepayments of $1.2 million, $3.0 million, and $1.2 million, respectively. Deferred revenue as of December 31, 2025 was also comprised of $0.4 million of unearned grant income. Deferred revenue as of December 31, 2023 also included $0.4 million 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 was recognized at that average price. The $0.4 million associated with the long-term contract at December 31, 2023 met the criteria to be recognized as revenue during the year ended December 31, 2024, and as such there was no equivalent balance remaining in deferred revenue at December 31, 2025 or 2024.

	December 31,		
	2025	2024	2023
Deferred Revenue	$ 1,518	$ 2,961	$ 1,559

The following table represents deferred revenue recognized:

	For the Years Ended December 31,	
Deferred Revenue Recognized	2025	2024
Accrued at beginning of year	$ 2,484	$ 3,680

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 the years ended December 31, 2025, 2024, and 2023, the Company incurred $0.6 million, $0.5 million, and $1.6 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.

Uncertain Tax Positions

Assets and liabilities are established for uncertain tax positions taken or positions expected to be taken in income tax returns when such positions fail to meet the "more likely than not" threshold based on the technical merits of the positions. The Company assesses whether previously unrecognized tax benefits may be recognized when tax positions are (1) more likely than not of being sustained based on their technical merits, (2) effectively settled through examination, negotiation or litigation, or (3) settled through actual expiration of the relevant tax statutes. The assessment of an uncertain tax position requires significant judgment.

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 $(0.9) million, $1.2 million, and $(0.1) million for the years ended December 31, 2025, 2024, and 2023, 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,		
	2025	2024	2023
Net (loss) income	$ (68,731)	$ (19,500)	$ 53,655
Weighted average shares of common stock outstanding:			
Basic	73,485	74,434	73,348
Dilutive effect of stock options, restricted stock, and performance stock units	—	—	1,041
Diluted	73,485	74,434	74,389
Loss (earnings) per share:			
Basic	$ (0.94)	$ (0.26)	$ 0.73
Diluted	$ (0.94)	$ (0.26)	$ 0.72

For the years ended December 31, 2025 and 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 572 and 896 shares, respectively, were excluded from the computation of diluted loss per share. 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 antidilutive.

Accumulated Other Comprehensive Loss

The Company classifies items of other comprehensive income (loss) by their nature and discloses the accumulated balance of other comprehensive income (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.

Change in accumulated other comprehensive loss by component is listed below:

	Foreign Currency	Total
Balance at December 31, 2024	$ (24,360)	$ (24,360)
Other comprehensive gain	5,956	5,956
Balance at December 31, 2025	$ (18,404)	$ (18,404)

Recent Accounting Pronouncements

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 has implemented on a prospective basis for the year ended December 31, 2025.

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses*. The purpose of this update was to require disclosure, in the notes to financial statements, of specified information about certain costs and expenses on a disaggregated basis. The amendments in the ASU are effective for all public business entities for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The amendments are to be applied either prospectively to financial statements issued for reporting periods after the effective date of the update or retrospectively to any or all prior periods presented in the financial statements. Management is evaluating the impact on the Company's consolidated financial statements.

In March 2024, the FASB issued ASU No. 2024-01, *Compensation—Stock Compensation (Topic 718), Measurement of Credit Losses for Accounts Receivable and Contract Assets*. The purpose of this update was to provide illustrative examples to demonstrate how an entity should apply guidance to determine whether profits interests and similar awards should be accounted for in accordance with Topic 718. For public business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2024, and interim periods within those fiscal periods. The amendments may be applied prospectively or retrospectively, and early adoption is permitted. Management does not expect an impact on the Company's consolidated financial statements.

In July 2025, the FASB issued ASU No. 2025-05, *Financial Instruments—Credit Losses (Topic 326), Scope Application of Profits Interest and Similar Awards*. The purpose of this update was to address challenges encountered when applying the guidance in Topic 326, Financial Instruments—Credit Losses, to current accounts receivable and current contract assets arising from transactions accounted for under Topic 606, *Revenue from Contracts with Customers* illustrative examples to demonstrate how an entity should apply guidance to determine whether profits interests and similar awards should be accounted for in accordance with Topic 718. For all business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2025, and interim periods within those fiscal periods. The amendments are applied prospectively, and early adoption is permitted. Management does not expect an impact on the Company's consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40), Targeted Improvements to the Accounting for Internal-Use Software*. The purpose of this update was to modernize the accounting for software costs. For all business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal periods. The amendments can be applied prospectively, a modified transition or retrospectively. Early adoption is permitted as of the beginning of an annual reporting period. Management does not expect an impact on the Company's consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topic 832), Accounting for Government Grants Received by Business Entities*. The purpose of this update was to improve US GAAP by establishing authoritative guidance on the accounting for government grants received by business entities. For public business entities, the amendments in this ASU are effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods in which financial statements have not yet been issued or made available for issuance. The amendments can be applied under a modified prospective approach, a modified retrospective approach, or a retrospective approach. Management is evaluating the impact on the Company's consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270), Narrow-Scope Improvements*. The purpose of this update was to improve the navigability of the required interim disclosures and clarifying when that guidance is applicable. The update also provides additional guidance on what disclosures should be provided in interim periods and adds a principal that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. For public business entities, the amendments in this ASU are effective for interim

reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments in this update can be applied either prospectively or retrospectively to any or all prior periods presented in the financial statements. Management is evaluating the impact on the Company's consolidated financial statements.

3. GOVERNMENT CAPITAL CONTRACTS:

In September 2021, the Company entered into an agreement for $109.0 million in funding from the U.S. Department of Defense (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 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 receiving funds from the DOD in January 2022 and 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 no such income during the years ended December 31, 2025 and 2024. The Company recognized $2.8 million of such income during the year ended December 31, 2023. 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 during 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. The Company recognized no such costs during the years ended December 31, 2025 and 2024. The Company recognized $2.0 million of such costs during the year ended December 31, 2023.

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

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

4. INVENTORIES:

	December 31, 2025	December 31, 2024
Raw materials	$ 14,831	$ 17,002
Work in process	56	420
Semi-finished goods	1,965	2,890
Finished goods	14,208	13,885
	$ 31,060	$ 34,197

During the years ended December 31, 2025, 2024, and 2023, the Company recorded writedowns to inventory which had a cost of $2.9 million, $2.6 million, and $8.9 million, respectively. Adjustments for the year ended December 31, 2025 were primarily driven by the write down of COVID-19 inventory and normal operating scrap. Adjustments for the year ended December 31, 2024 were primarily driven by the write down of inventory associated with the Company's exit of the Risk Assessment Testing business and normal operating scrap. Adjustments for the year ended December 31, 2023 were primarily related to reduction in COVID-19 demand and the need to reserve for excess inventory levels.

5. PROPERTY, PLANT, AND EQUIPMENT, NET:

	December 31, 2025	December 31, 2024
Land	$ 1,118	$ 1,118
Buildings and improvements	39,071	36,152
Machinery and equipment	46,202	51,015
Computer equipment and software	11,101	11,502
Furniture and fixtures	1,632	1,621
Construction in progress	2,931	9,615
	102,055	111,023
Accumulated depreciation	(62,876)	(65,918)
	$ 39,179	$ 45,105

During the first quarter of 2024, the Company initiated a strategic plan to transition away from the microbiome molecular sequencing services business and to cease operations at its Belgium location. As a result of these decisions, the Company determined that the carrying values of all of associated property, plant, and equipment were not recoverable and recorded an aggregate pre-tax asset impairment charge of $1.8 million during the year ended December 31, 2024. All of these assets were disposed of as of December 31, 2024.

During the second quarter of 2024, the Company determined a manufacturing line will no longer be utilized. As a result of this decision, the Company determined that the carrying value of the equipment was not recoverable and recorded an aggregate pre-tax impairment charge of $1.1 million during the year ended December 31, 2024.

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 were 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, 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 2023, recorded in cost of products and services sold. Also during 2023, the Company shortened the useful lives of leasehold improvements and equipment due a lease termination. This reduction in useful lives resulted in an additional $0.5 million of accelerated depreciation recorded in cost of products and services sold.

Depreciation expense for 2025, 2024, and 2023 was $9.9 million, $9.8 million, and $17.9 million, respectively.

6. GOODWILL AND OTHER INTANGIBLE ASSETS:

Changes in goodwill are as follows:

	Reporting Unit		
	Diagnostics	Collection Devices	Total
Balance at January 1, 2024	$ —	$ 35,696	$ 35,696
Acquisition	6,388	—	6,388
Change related to foreign currency translation	—	(1,754)	(1,754)
Balance at December 31, 2024	6,388	33,942	40,330
Acquisition	1,775	—	1,775
Change related to foreign currency translation	—	1,258	1,258
Balance at December 31, 2025	$ 8,163	$ 35,200	$ 43,363

On November 30, 2025, the Company performed its quantitative annual goodwill impairment test. The Company utilizes a combination of the income approach and market approach in determining the fair value of its two reporting units. The test concluded that the carrying value of the Company's reporting units was below fair value indicating there was no impairment of goodwill.

Intangible assets consist of the following:

		December 31, 2025		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Definite Life Intangible Assets				
Customer relationships	10	$ 9,134	$ (9,134)	$ —
Patents and product rights	5	7,596	(7,596)	—
Developed technology	7-15	8,995	(7,095)	1,900
Trade names	5-15	3,501	(3,355)	146
		29,226	(27,180)	2,046
Indefinite Life Intangible Assets				
IPR&D technology (Note 13)	N/A	17,000	—	17,000
		$ 46,226	(27,180)	19,046

		December 31, 2024		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Definite Life Intangible Assets				
Customer relationships	10	$ 10,858	$ (10,858)	$ —
Patents and product rights	5	7,495	(7,399)	96
Developed technology	7-10	10,169	(10,169)	—
Trade names	5-15	4,327	(3,988)	339
		32,848	(32,413)	435
Indefinite Life Intangible Assets				
IPR&D technology (Note 13)	N/A	17,000	—	17,000
		$ 49,848	$ (32,413)	$ 17,435

During 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.

Also in 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 2025, 2024, and 2023 was $0.3 million, $0.7 million, and $2.0 million, respectively.

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

2026	$ 336
2027	190
2028	190
2029	190
2030	190
Beyond	950
	$ 2,046

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	December 31, 2025	December 31, 2024
Payroll and related benefits	$ 5,255	$ 11,147
Professional fees	1,938	2,469
Sales tax payable	1,152	1,339
Other	2,804	5,224
	$ 11,149	$ 20,179

8. TERMINATION BENEFITS:

2023 Reduction in Workforce

During the first and second quarters of 2023, the Company executed a reduction in workforce. This was accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*. The charges for termination benefits 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
	$ 3,265

As of December 31, 2024 the Company had fully paid the $3.3 million related to the reduction in workforce. This reduction in workforce was completed by June 30, 2024.

Q1 2024 Reduction in Workforce

During the first quarter of 2024, the Company executed a reduction in workforce largely affecting its COVID-19 manufacturing workforce. The charges for termination benefits included in the Company's consolidated statement of operations are as follows:

	For the Year Ended December 31, 2024
Cost of products and services sold	$ 231
Research and development	87
Sales and marketing	69
General and administrative	17
	$ 404

As of December 31, 2024, the Company had fully paid the $0.4 million related to the reduction in workforce. This reduction in workforce was completed by December 31, 2024.

Q2 2024 Reduction in Workforce

During the second quarter of 2024, the Company executed an additional reduction in workforce as the Company notified employees of its intention to consolidate its Novosanis site in Belgium into other locations by the end of December 31, 2024, discontinue the Diversigen molecular services line of business by the end of June 30, 2024, and consolidate facilities by bringing third-party manufacturing activities into its Pennsylvania facilities by the end of the third quarter of 2025. The charges for termination benefits included in the Company's consolidated statements of operations are as follows:

	For the Year Ended December 31, 2024
Cost of products and services sold	$ 889
Research and development	478
Sales and marketing	125
General and administrative	160
	$ 1,652

As of December 31, 2025 the Company had $0.1 million accrued and had paid $1.5 million related to the reduction in workforce. No additional expenses were incurred during the year ended December 31, 2025. The Company expects this reduction in workforce to be completed by March 2026.

Q3 2024 Reduction in Workforce

During the third quarter of 2024, the Company executed a reduction in workforce largely as the Company notified certain employees of its intention to discontinue its risk assessment business. Additional employees were notified in the fourth quarter of 2024. The charges for termination benefits included in the Company's consolidated statements of operations are as follows:

	For the Year Ended December 31, 2024
Cost of products and services sold	$ 246
Research and development	33
Sales and marketing	782
General and administrative	141
	$ 1,202

As of December 31, 2025 the Company had $0.1 million accrued and had paid $1.1 million related to the reduction in workforce. No additional expense was incurred during the year ended December 31, 2025. The Company expects this reduction in workforce to be completed by September 2026.

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, 2025, the Company is the lessee in all lease agreements. The Company's leases have remaining lease terms of one to eight 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 one year.

The Company also subleased two of its leased corporate offices. One of the subleases was terminated during the third quarter of 2025 as the Company exited the head lease agreement. The Company's remaining sublease has a remaining term of approximately one 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.

During the first quarter of 2024, the Company identified a triggering event to test for the recoverability of all the ROU assets of both the Diversigen and Novosanis subsidiaries, given the Company's decision to initiate a strategic plan to transition away from the microbiome molecular sequencing services business and close its Belgian operations. The Company performed an undiscounted cash flow analysis and determined the carrying values of the ROU assets could not be recovered through the sum of the undiscounted future cash flows and were impaired. During the year ended December 31, 2024 the Company recognized aggregate pre-tax impairment charges of $1.2 million and $0.3 million to its operating and finance ROU assets, respectively. These charges are reported in the Company's consolidated statement of operations.

The components of lease expense are as follows:

	For the Years Ended December 31,		
	2025	2024	2023
Operating lease cost	$ 2,285	$ 1,729	$ 2,407
Variable and short-term lease cost	37	549	381
Sublease income	(161)	(151)	(155)
Finance lease cost:			
Amortization of right-of use assets	61	331	1,091
Interest on lease liabilities	8	22	51
Total finance lease cost	69	353	1,142
Total lease cost	$ 2,230	$ 2,480	$ 3,775

Supplemental cash flow information related to leases is as follows:

	For the Years Ended December 31,		
	2025	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 2,156	$ 1,901	$ 1,863
Operating cash flows from financing leases	8	22	51
Financing cash flows from financing leases	61	842	1,345
Non-cash activity:			
Right-of-use assets obtained in exchange for operating lease obligations	169	4,086	4,363
Right-of-use assets obtained in exchange for finance lease obligations	62	193	334

Supplemental balance sheet information related to leases is as follows:

	December 31,	
	2025	2024
Weighted Average Remaining Lease Term		
Weighted-average remaining lease term — operating leases	6.70 years	7.57 years
Weighted-average remaining lease term — finance leases	2.70 years	3.74 years
Weighted Average Discount Rate		
Weighted-average discount rate — operating leases	4.48 %	4.44 %
Weighted-average discount rate — finance leases	5.10 %	4.82 %

As of December 31, 2025, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2026	$ 70	$ 2,548
2027	65	2,287
2028	34	2,157
2029	6	2,097
2030	—	2,106
Thereafter	—	3,778
Total minimum lease payments	175	14,973
Less: imputed interest	(12)	(1,939)
Present value of lease liabilities	$ 163	$ 13,034

10. INCOME TAXES:

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

	For the Years Ended December 31,		
	2025	2024	2023
United States	$ (62,742)	$ (21,523)	$ 61,671
Foreign	(1,844)	5,522	(5,413)
	$ (64,586)	$ (16,001)	$ 56,258

In July of 2025, the One Big Beautiful Bill Act of 2025 (the "OBBBA") was enacted in the U.S. The OBBBA includes several significant tax provisions, including the reinstatement of full expensing of domestic research and development costs among other domestic and international changes. The OBBBA is not expected to have a significant impact on the Company's tax expense or cash paid for taxes. Our results for the year ended December 31, 2025 include the impact of the OBBBA on our consolidated financial statements.

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

	For the Years Ended December 31,		
	2025	2024	2023
Current			
Federal	$ —	$ 229	$ —
State	124	111	1,896
Foreign	(176)	2,116	605
	(52)	2,456	2,501
Deferred			
Federal	(11,186)	(2,962)	13,570
State	870	1,368	(382)
Foreign	10,355	4,365	(1,867)
	39	2,771	11,321
Increase (decrease) in valuation allowance	1,814	(3,428)	(11,219)
	1,853	(657)	102
Total income tax expense	$ 1,801	$ 1,799	$ 2,603

For the year ended December 31, 2025, the Company recorded net foreign tax benefit of $0.3 million. For the years ended December 31, 2024, and 2023 the Company recorded net foreign income tax expense of $1.4 million, and $0.7 million, respectively. For the years ended December 31, 2025, 2024, and 2023 the Company recorded U.S. federal tax expense of

$0.2 million, $0.2 million, and $0.0 million, respectively and state tax expense of $1.9 million, $0.1 million, and $1.9 million respectively.

Total cash paid for income taxes was as follows:

	For the Year Ended December 31, 2025
Federal	$ —
State:	
Utah	(100)
Other	74
	(26)
Foreign:	
Canada	2,539
United Kingdom	(672)
	1,867
Total cash paid for income taxes (net of refunds) [1]	$ 1,841

[1] Total cash paid for income taxes during the year ended December 31, 2024 was $1.8 million. The Company received income tax refunds of $4.9 million for year ended December 31, 2023 (prior to adoption of ASU 2023-09).

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,		
	2025	2024	2023
Statutory U.S. federal income tax rate	21.0 %	21.0 %	21.0 %
Nondeductible executive compensation	(1.1)	(8.5)	0.5
Impact of stock-based payment awards	(1.8)	(2.3)	(0.3)
Tax effect of foreign items	(0.6)	(1.9)	(0.4)
State income taxes, net of federal benefit	1.3	(9.1)	2.0
U.S. and foreign tax credits	1.3	1.2	1.3
Uncertain tax positions	(2.9)	—	—
Nondeductible expenses and other	1.2	(2.4)	0.9
Nondeductible transaction costs	(0.2)	(2.1)	—
NOL adjustment, domestic	(2.2)	—	—
NOL adjustment, foreign	25.5	(31.4)	—
Change in the estimated fair value of acquisition-related contingent consideration	(1.4)	—	—
Acquisition adjustments	(8.7)	—	—
Non-controlling interests	(0.7)	2.2	—
Change in valuation allowance, federal and state	(14.4)	(10.0)	—
Change in valuation allowance, foreign	(19.0)	32.1	(20.4)
Effective tax rate	(2.7) %	(11.2) %	4.6 %

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

	For the Year Ended December 31, 2025	
	Dollars	Percentage
Statutory U.S. federal income tax rate	$ (14,055)	21.0 %
State and local income taxes, net of federal income tax effect [1]	325	(0.5)%
Foreign tax effects		
United Kingdom		
Change in NOL limitation	(17,062)	25.5 %
Intangible acquisition adjustment	4,524	(6.7)%
Change in valuation allowances	12,728	(19.0)%
Other	(195)	0.3 %
Other foreign jurisdictions	114	(0.2)%
Effect of changes in tax laws/rates enacted in the current period	—	— %
Effect of cross-border tax laws		
Global intangible low-taxed income	523	(0.8)%
Tax credits		
Research and development tax credits	(536)	0.8 %
Changes in valuation allowances	8,700	(13.0)%
Nontaxable or nondeductible items		
Share based payment awards	773	(1.1)%
Nondeductible officer's compensation	714	(1.1)%
Change in the estimated fair value of acquisition-related contingent consideration	960	(1.4)%
Other	192	(0.3)%
Changes in unrecognized tax benefits	1,728	(2.6)%
Acquisition adjustments	1,285	(1.9)%
NOL adjustment	1,441	(2.2)%
Other adjustments	(358)	0.5 %
Effective tax rate	$ 1,801	(2.7)%

[1] The tax effect in this category was primarily driven by state taxes in Pennsylvania (greater than 50%).

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,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 54,859	$ 55,583
Inventories	2,108	2,344
Capitalized research and development costs	10,889	12,946
Accruals and reserves currently not deductible	1,805	2,754
Depreciation and amortization	114	—
Lease liabilities	2,254	2,497
Stock-based compensation	3,244	3,303
Tax credit carryforwards	6,628	4,184
Net deferred tax asset	81,901	83,611
Valuation allowance	(77,006)	(75,191)
Total deferred tax assets	$ 4,895	$ 8,420
Deferred tax liabilities:		
Depreciation and amortization	—	(2,017)
Acquired intangible assets	(2,220)	(3,981)
Right-of-use assets	(2,073)	(2,266)
Deferred compensation	(331)	—
Total deferred tax liabilities	$ (4,624)	$ (8,264)
Net deferred tax asset	$ 271	$ 156

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. The Company has not achieved a level of sustained profitability that would, in the Company's judgment, support the release of the valuation allowance. Management believes the full valuation allowance is still appropriate as of December 31, 2025 and 2024. As a result, no U.S. federal income tax benefit was recorded for the years ended December 31, 2025, 2024, and 2023.

The Company's federal NOL carryforwards consist of $232.9 million from existing business along with $12.9 million of acquired NOL carryforwards. None of these NOL carryforwards have an expiration date. The Company does not have any foreign NOL carryforwards as of December 31, 2025. As of December 31, 2024, the Company's foreign NOL carryforwards consisted of $63.0 million of acquired NOL carryforwards. The foreign NOLs were reduced to zero due to loss limitation rules. The Company's state NOL carryforwards consist of $57.6 million from existing business along with $7.2 million of acquired NOL carryforwards. The state NOL carryforwards have expirations as follows:

Year of Expiration	NOLs
2026 - 2041	$ 30,419
2042 - 2055	20,023
Non-Expiring	14,350
	$ 64,792

The Tax Reform Act of 1986 contains provisions under Internal Revenue Code (“IRC”) Section 382 and Section 383 that limit the annual amount of federal and state NOL carryforwards and tax credits 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. The Company acquired 382 limited NOL carryforwards as part of its acquisition of BioMedomics. These NOL carryforwards have no expiration date. The Company has not undertaken any formal 382 or 383 studies that would indicate any limitations to its NOL or credit carryforwards. However, any such study could potentially limit the NOL and credit carryforwards of the Company.

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, 2025.

As of December 31, 2025, the Company's gross unrecognized tax benefits totaled $2.1 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 2025 addition of $1.7 million is not offset by the valuation allowance and its reversal would 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 $0.2 million in 2025, and immaterial in 2024 and 2023. As a result of the Company's NOL carryforward position, the Company has been 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, 2025.

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

	2025	2024	2023
Balance at January 1	$ 333	$ 304	$ 373
Additions for tax positions of prior periods	1,729	29	—
Reductions for tax positions of prior periods	—	—	(69)
Balance at December 31	$ 2,062	$ 333	$ 304

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, 2025, 5,959 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	**2025**	**2024**	**2023**
Risk-free interest rate [1]	4.04 %	4.14 %	4.23 %
Expected dividend yield	—	—	—
Expected stock price volatility [2]	53 %	53 %	51 %
Expected life of stock options (in years) [2]	6	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, 2025, 2024, and 2023 was $3.43, $3.68 and $3.24, respectively.

Compensation expense recognized in the financial statements related to stock options was $1.6 million, $1.4 million, and $1.3 million for the years ended December 31, 2025, 2024, and 2023, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2025, 2024, and 2023 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $0.0 thousand, $38.4 thousand, and $43.0 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, 2025	2,237	$ 8.73		
Granted	1,393	3.43		
Exercised	—	—		
Expired	(132)	9.02		
Forfeited	(119)	4.72		
Outstanding on December 31, 2025	3,379	$ 6.68	6.97	$ —
Vested or expected to vest as of December 31, 2025	3,376	$ 6.67	5.00	$ —
Exercisable on December 31, 2025	1,655	$ 9.24	5.00	$ —

As of December 31, 2025, there was $3.2 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 $— million, $0.2 million and $0.3 million for the years ended December 31, 2025, 2024, and 2023, 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, 2025:

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
$2.46 - $6.56	1,855	8.40	$ 4.17	382	$ 6.00
$7.13 - $10.69	1,157	5.86	7.84	907	8.00
$12.90 - $19.35	324	3.42	14.89	324	14.89
$21.64 - $32.46	43	2.03	$ 21.65	43	$ 21.65
	3,379	6.97	$ 6.67	1,656	$ 9.24

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 $6.1 million, $6.9 million and $7.6 million related to restricted shares was recognized during the years ended December 31, 2025, 2024, and 2023, 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, 2025	1,694	$ 6.60
Granted	2,226	3.25
Vested	(1,128)	6.05
Forfeited	(182)	4.55
Issued and unvested, December 31, 2025	2,610	$ 4.13
Issued and expected to vest, December 31, 2025	2,610	$ 4.13

As of December 31, 2025, there was $6.3 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 1.7 years.

In connection with the vesting of restricted shares during the years ended December 31, 2025, 2024, and 2023, the Company purchased and immediately retired 363, 617 and 262 shares with aggregate values of $1.2 million, $3.4 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 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 $2.4 million, $3.6 million and $1.8 million related to the PSUs was recognized during the years ended December 31, 2025, 2024, and 2023, respectively.

The following table summarizes PSU activity under the Stock Plan:

	Units	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2025	1,454	$ 7.19
Granted [1]	1,009	4.30
Performance adjustment [2]	12	N/A
Vested	(513)	5.18
Forfeited	(181)	5.93
Issued and unvested, December 31, 2025	1,781	$ 6.24
Issued and expected to vest, December 31, 2025	1,781	$ 6.24

[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, 2025, there was $3.7 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, 2025, 2024 and 2023, the Company purchased and immediately retired 201, 23, and 86 shares with aggregate values of $0.6 million, $0.2 million and $0.5 million, respectively.

Stock Repurchase Program

In March 2025, the Company's Board of Directors approved a stock repurchase program effective March 21, 2025, whereby the Company may purchase up to $40.0 million in shares of its common stock over a period of up to two years. The amount and timing of share repurchases under the program may be carried out at the discretion of the Company's management through various methods in compliance with applicable state and federal laws. For the year ended December 31, 2025, 5.3 million shares, totaling $15.0 million, were purchased and retired.

12. BUSINESS SEGMENT INFORMATION:

The Company is organized on the basis of products and services into a single reportable segment. All products and services reside under the same reporting hierarchy. The Company's reportable segment derives its revenues from the sale of diagnostics products and sample management solutions, as described in Note 2 Summary of Significant Accounting Policies. As the Company has only one reportable segment, there are no inter-segment sales or transfers.

The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The CODM uses consolidated net income (loss) as reported in the consolidated statement of operations as the primary measure of the reportable segment's profit or loss. The CODM uses consolidated net income (loss) to assess the performance of the segment and make decisions about resource allocation. Consolidated gross profit and consolidated operating income (loss), as reported in the consolidated statement of operations, are also used by the CODM as measures of segment profit or loss. The CODM uses gross profit to assess the impact of the Company's efforts to achieve manufacturing efficiencies and consolidate its production activities. The CODM uses operating income (loss) to assess the impact of the Company's recent restructurings, reduction in workforce, and efforts to streamline its operations to achieve cost savings. The CODM uses consolidated total assets as the measure of segment assets, as reported on the consolidated balance sheet.

The accounting policies of the Company's reportable segment are the same as those described in Note 2 Summary of Significant Accounting Policies.

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

	December 31,	
	2025	2024
United States	$ 36,254	$ 40,286
United Kingdom	10,061	12,849
Canada	4,642	5,468
Other regions	364	89
	$ 51,321	$ 58,692

The following table represents reported segment revenues, segment profit (loss), and significant segment expenses:

	For the Years Ended December 31,		
	2025	2024	2023
Net revenues	$ 115,021	$ 185,827	405,472
Cost of products and services sold [3]	66,823	106,437	233,820
Gross profit	48,198	79,390	171,652
Research and development [3]	42,528	26,047	33,728
Sales and marketing [3]	26,117	30,986	36,319
General and administrative [3]	47,677	46,215	58,191
Loss on impairments	—	4,392	10,829
Change in the estimated fair value of acquisition-related contingent consideration	4,570	—	(99)
Gain on sale of assets	(725)	—	—
Operating (loss) income	(71,969)	(28,250)	32,684
Other income (expense) [1]	229	(380)	17,836
Interest revenue	8,078	11,469	5,862
Other segment items [2]	(924)	1,160	(124)
(Loss) income before income taxes and equity investment	(64,586)	(16,001)	56,258
Income tax expense	1,801	1,799	2,603
Loss on equity investment	(2,344)	(1,700)	—
Net (loss) income	$ (68,731)	$ (19,500)	$ 53,655

[1] Includes $12.8 million of excess profits recognized on government contracts in 2023.
[2] Includes interest expense and foreign currency gains (losses).
[3] The following tables represent additional significant segment expense categories:

	For the Years Ended December 31,		
	2025	2024	2023
Stock-based Compensation			
Cost of products and services sold	$ 707	734	564
Research and development	1,046	839	1,159
Sales and marketing	863	1,129	1,181
General and administrative	7,531	9,218	7,826
	$ 10,147	$ 11,920	$ 10,729

	For the Years Ended December 31,		
	2025	2024	2023
Depreciation and Amortization			
Cost of products and services sold	$ 4,527	$ 6,343	$ 15,311
Research and development	2,081	1,029	1,208
Sales and marketing	80	189	571
General and administrative	3,504	3,311	3,846
	$ 10,192	$ 10,872	$ 20,936

13. BUSINESS COMBINATIONS:

BioMedomics

On November 12, 2025, the Company acquired all of the outstanding stock of BioMedomics, pursuant to the terms of an acquisition agreement (the "Acquisition Agreement"). The Company began operating this entity as of the November 12, 2025 closing date.

The primary reason for the acquisition of BioMedomics was to expand the Company's diagnostic portfolio by adding SickleSCAN®, a rapid, point-of-need test for sickle cell disease that is sold outside of the United States.

The initial aggregate purchase price of this transaction was funded with cash on hand as shown in the table below:

Cash paid to BioMedomics	$	2,865
Transaction expenses		403
Debt paid off		330
Earnout contingent consideration		325
Expense fund		40
Initial aggregate purchase price	$	3,963

Pursuant to the Acquisition Agreement, the Company agreed to pay up to $5.0 million of contingent consideration based on the achievement of sales thresholds before December 31, 2031 as defined in Acquisition Agreement. The acquisition-date fair value of the earnout contingent consideration was $0.3 million. The range of outcome for the earnout contingent consideration is zero to $5.0 million.

During the year ended December 31, 2025, the Company incurred a total of $0.5 million of acquisition related costs, including accounting, legal, and other professional fees, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2025.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

Assets Acquired		
Other current and non current assets	$	10
Inventory		284
Operating right-of-use assets		120
Developed technology intangible asset		1,900
Goodwill		1,775
Total assets acquired		4,089
Liabilities Assumed		
Accounts payable		34
Current liabilities		17
Deferred revenue		72
Operating lease liability		120
Total liabilities assumed		243
Net Assets Acquired		3,846
Estimated fair value of contingent consideration		(233)
Net Cash Paid (net of cash acquired of $25)	$	3,613

The purchase price was allocated to the tangible assets and identifiable intangible asset acquired and liabilities assumed based on their acquisition-date estimate fair values. The identifiable intangible asset was developed technology. The developed technology was all assigned a ten year useful life.

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the intangible asset and contingent consideration of BioMedomics. The fair values recorded as of November 12, 2025 are based on significant inputs that are not observable in the market and thus represent a fair value measurement categorized within Level 3 of the fair value hierarchy.

The fair value of the acquired developed technology was determined using the multi-period excess earnings method, which required judgment in estimating appropriate cashflows, discount rate, survival factor, and remaining useful life.

The fair value of the earnout contingent consideration was determined using the Monte Carlo simulation model, which require judgment in estimating expected revenue, volatility, expected discount rate and risk-free interest rate.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of the net assets acquired, and represents the future economic benefits that we expect to achieve as a result of the acquisition. The Company believes the goodwill related to the acquisition was a result of BioMedomics providing a product that will enable the Company to leverage the products with existing and new customers. The goodwill is not deductible for income tax purposes.

The Company continues to evaluate the fair value of assets acquired and liabilities assumed. Additional information, which existed as of the acquisition date, but was at that time unknown to the Company, may become known during the remainder of the measurement period. Changes to amounts recorded as a result of the final determination may result in a corresponding adjustment to these assets and liabilities, including goodwill. The determination of the estimated fair values of all assets acquired is expected to be completed within one year from the date of acquisition.

Revenues from BioMedomics consist of sales from the SickleSCAN® test. Effective as of November 12, 2025, the financial results of BioMedomics are included in the consolidated financial results of the Company. BioMedomics contributed $0.1 million and $1.1 thousand of revenue and net income, respectively, to the consolidated statement of operations for the year ended December 31, 2025.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the BioMedomics acquisition as if it had been consummated as of January 1, 2024. The unaudited pro forma results include, amortization of the acquired intangible assets, stock compensation, and lease expense adjustments to income before income taxes but do not include changes in the fair value of the Company's contingent consideration obligations. Material nonrecurring charges, directly attributable to the transactions, including direct acquisition costs, are also excluded. In addition, the unaudited pro forma results do not include any expected benefits of the acquisitions. Accordingly, the unaudited pro forma results are not necessarily indicative of either future results of operations or results that might have been achieved had the acquisitions been consummated as of January 1, 2024.

	For the Years Ended December 31,	
	2025	2024
Net revenues	$ 115,797	$ 187,041
Net loss	$ (68,964)	$ (20,889)

Sherlock Biosciences

On December 19, 2024, the Company acquired all of the outstanding stock of Sherlock, pursuant to the terms of a merger agreement (the "Merger Agreement"). The Company began operating this entity as of the December 19, 2024 closing date.

The primary reason for the acquisition was Sherlock's first test for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG), which is in clinical studies and was submitted to the FDA in late 2025. Subject to regulatory approvals, this test is expected to expand the Company's portfolio for rapid diagnostics for sexually transmitted infections.

The initial aggregate purchase price of this transaction was funded with cash on hand as shown in the table below:

Milestone contingent consideration	$	15,910
Royalty based contingent consideration		7,000
Cash paid to Sherlock		5,000
Legal expenses		389
Insurance policy expense		50
Initial aggregate purchase price	$	28,349

Pursuant to the Merger Agreement, the Company agreed to pay up to $20.0 million of contingent consideration based on the achievement of a regulatory milestone on or before December 31, 2026 as defined in the Merger Agreement. The acquisition-date fair value of the milestone contingent consideration was $15.9 million. The range of outcome for the milestone contingent consideration is zero to $20.0 million. There is also a mid-single digits quarterly royalty fee based on future sales until 2034 as defined in the Merger Agreement, the fair value of which was determined as part of the contingent consideration. The estimated acquisition-date fair value of the royalty fee acquisition-related contingent consideration was $7.0 million. The range of outcome for the royalty payment cannot be determined due to the fact it is based on future sales associated with the acquired in-process research and development technology through 2034 and thus does not have an upper limit.

During the year ended December 31, 2024, the Company incurred a total of $1.0 million of acquisition related costs, including accounting, legal, and other professional fees, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2024.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

Assets Acquired		
Other current assets	$	2,570
Property, plant, and equipment, net		9,244
Other noncurrent assets		462
Operating right-of-use assets		4,080
In-process research and development technology intangible asset		17,000
Goodwill		6,382
Total assets acquired		39,738
Liabilities Assumed		
Accounts payable		2,449
Current liabilities		3,621
Deferred revenue		1,641
Operating lease liability		4,080
Total liabilities assumed		11,791
Net Assets Acquired		27,947
Estimated fair value of contingent consideration		(22,910)
Net Cash Paid (net of cash acquired of $402)	$	5,037

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition-date estimate fair values. The identifiable intangible assets included in-process research and development technology ("IPR&D Technology"), which is an indefinite lived asset.

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the assets and contingent consideration of Sherlock. The income approach was used to value the acquired intangibles, and the fair value measurements were primarily based on significant inputs that are not observable in the market and are considered Level 3 fair value measurements. The income approach estimates fair value for an asset based on the present value of cash flows projected to be generated by the asset. Projected cash flows are discounted at a required rate of return that reflects the relative risk of achieving the cash flows and the time value of money.

The regulatory milestone scenario based model was used to value the assumed milestone contingent consideration, and the fair value measurements were primarily based on significant unobservable inputs and are considered Level 3 fair value measurements. The regulatory milestone scenario based model estimates fair value for contingent consideration based on the probability of on the achievement of a certain milestone as defined under the agreements and the discount rate.

The income approach was used to value the royalty based contingent consideration, and the fair value measurements were primarily based on significant unobservable inputs and are considered Level 3 fair value measurements. The fair value of contingent payments approach was primarily based on projected cash flows, probability of on the achievement of a regulatory milestone as defined under the agreements, and discount rate.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of the net assets acquired, and represents the future economic benefits that we expect to achieve as a result of the acquisition. The Company believes the goodwill related to the acquisition was a result of Sherlock providing a product offering that will enable the Company to leverage those products with existing and new customers. The goodwill is not deductible for income tax purposes.

The Company has completed the fair value of the assets acquired and liabilities assumed.

Revenues from Sherlock primarily consist of grant revenues for research and development purposes. Effective as of December 19, 2024, the financial results of Sherlock are included in the consolidated financial results of the Company.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the Sherlock acquisition as if it had been consummated as of January 1, 2023. The unaudited pro forma results include depreciation of the acquired property plant and equipment and the estimated tax effect of adjustments to income before income taxes, but do not include changes in the fair value of the Company's contingent consideration obligations. Material nonrecurring charges, directly attributable to the transactions, including direct acquisition costs, are also excluded. In addition, the unaudited pro forma results do not include any expected benefits of the acquisitions. Accordingly, the unaudited pro forma results are not necessarily indicative of either future results of operations or results that might have been achieved had the acquisitions been consummated as of January 1, 2023.

	For the Years Ended December 31,	
	2024	2023
Net revenues	$ 188,126	$ 406,381
Net income loss	$ (41,459)	$ 7,992

14. CONTINGENCIES:

Collaborations

Sherlock has active third-party license agreements entered into in order to advance and obtain technologies and services related to the business. Under these licenses, the Company is required to make up to $3.8 million of cash payments upon the achievement of certain scientific and commercial milestones as well as low single digit royalty payments on product sales. The Company has the right to terminate the licenses.

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.

On November 14, 2024 the Company filed a complaint against NowDiagnostics, Inc. ("NowDx"), Jody Berry ("Berry") and Janean Young ("Young") in the United States District Court for the Eastern District of Pennsylvania alleging misappropriation and misuse of the Company's proprietary information and trade secrets by NowDx, Berry and Young in violation of the Federal Defend Trade Secrets Act and the Pennsylvania Uniform Trade Secrets Act. The complaint also alleges breach of contract and duty of loyalty by Young, unfair competition by NowDx, and tortious interference with contractual relations by Berry and NowDx. NowDx filed Counterclaims against the Company on January 13, 2025 and the Company filed its Answer to the Counterclaims on February 3, 2025. Young filed a Motion to Dismiss the claims against her, which was denied by the court on February 4, 2025. NowDx, Berry, and Young agreed to a preliminary injunction which the Court entered on February 27, 2025. The case is currently in the discovery phase and the schedule for any further proceedings is currently 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 $4.0 thousand per year. The Company contributed $1.1 million, $1.2 million and $1.6 million to the 401(k) Plan, net of forfeitures, in 2025, 2024, and 2023, 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, 2025 and 2024, the value of the assets associated with this plan was $0.5 million and $0.7 million, respectively, and is included in other current assets and other noncurrent 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

noncurrent liabilities in the Company's consolidated balance sheets. As of December 31, 2025 and 2024, the Company's total obligation under this plan was $0.5 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 $4.0 thousand CAD per year. The Company contributed $0.3 million, $0.4 million and $0.4 million to the RRSP in 2025, 2024, and 2023, respectively.

Substantially all British employees are eligible to participate in the People's Pension Plan (the “PPP”). The PPP permits voluntary employee contributions which may be excluded from an employee’s current taxable income and receive tax-preferred treatment with HM Revenue and Customs. The PPP also provides for the Company to match employee contributions. The Company contributed $0.1 million to the PPP in 2025.

16. SUBSEQUENT EVENTS:

In February 2026, the Company terminated certain non-production employees, which was less than 10% of its work force. The termination was to align the Company's cost structure.

ORASURE TECHNOLOGIES, INC.

POLICY STATEMENT ON DEALING WITH COMPANY INFORMATION, INCLUDING INSIDE INFORMATION AND INSIDER SECURITIES TRADING

(Effective as of September 9, 2025)

In the course of conducting the business of OraSure Technologies, Inc. (the "Company") and its subsidiaries, you may at times have information about the Company or its subsidiaries or another entity that generally is not available to the public. Because of your relationship with the Company or its subsidiaries, you have certain responsibilities under the federal securities laws and to the Company regarding insider information and the trading of the Company's securities. This Policy Statement is intended to explain your obligations to the Company and under the law.

This Policy Statement applies to all employees of the Company and the officers (at the level of Vice President and above) of and each of its subsidiaries, and to all members of the Company's Board of Directors (collectively, "Covered Persons").

The officer responsible for compliance with this Policy Statement is the Company's General Counsel (the "Compliance Officer").

Please note: As discussed more fully below, all directors, officers and employees must receive prior written approval as provided in this Policy Statement before buying or selling any Company securities.

INSIDE INFORMATION

A. *What is Inside Information*?

"Inside" information is material information about the Company or its subsidiaries that is not available to the public. Information generally becomes available to the public after it has been disclosed by the Company or third parties in a press release or other public statement, including any filing with the Securities and Exchange Commission ("SEC").

B. *What is Material Information?*

Information generally is considered "material" if its disclosure to the public would be reasonably likely to affect (i) investors' decisions to buy or sell the securities of the Company or (ii) the market price of the securities. Both positive and negative information may be material. Some examples of material information include the following: (a) a merger or acquisition involving the Company or its subsidiaries; (b) information regarding the Company's or its subsidiaries' revenues or earnings; (c) the status of U.S. Food and Drug Administration ("FDA") or other regulatory submissions, approvals, investigations, reviews, audits or other actions or proceedings; (d) major litigation and disputes with significant business partners; (e) the public or private sale of additional securities of the Company; (f) a tender offer by the Company for another company's securities or for the Company's securities by a third party; (g) senior

management changes; or (h) significant changes regarding the business of key customers or suppliers. Obviously, what is material information cannot be enumerated with precision, since there are many gray areas and varying circumstances. The determination of whether information was material is almost always made after the fact when the effect on the market can be quantified. Therefore, any trading is risky. When doubt exists, the information should be presumed to be material. **If you are unsure whether information of which you are aware is material or nonpublic, you should discuss this issue with the Company's Compliance Officer prior to trading.**

Material information not yet ripe for public disclosure may often exist within the Company or its subsidiaries. For example, during the early stages of discussions regarding a significant acquisition or disposition, the information about the discussions may be too tentative or premature to require, or even permit, public announcement by the Company. On the other hand, that same information may be highly material. If you have access to material information, you (i) are prohibited from disclosing such information to others, and (ii) may be precluded from trading in the Company's securities. If you have access to material inside information and have doubts about your ability to trade in securities, you should refrain from trading until you seek and obtain clearance from (1) the Compliance Officer and, (2) if you are a director or executive officer, the Company's Chief Executive Officer.

The principles discussed in this Policy Statement also apply to inside information obtained in the course of your employment about another public corporation, such as a customer or a corporation with which the Company or any of its subsidiaries is involved in a transaction. If you obtain material nonpublic information about another public company, you should refrain from trading in the securities of that company until the material information has been publicly disseminated.

C. *Reasons for Maintaining Confidentiality*.

The federal securities laws strictly prohibit any person who obtains material inside information and has a duty not to disclose it from using such information in connection with the purchase and sale of securities. It does not matter how that information has been obtained, whether in the course of employment, from friends, relatives, acquaintances or strangers, or from overhearing the conversations of others. Congress enacted this prohibition because the integrity of the securities markets would be seriously undermined if the "deck were stacked" against persons not privy to such information. Your failure to maintain the confidentiality of material nonpublic information about the Company or its subsidiaries could greatly harm the Company's ability to conduct business. In addition, you could be exposed to significant penalties and legal action.

D. *Safeguarding Material Information*.

During the period that material information relating to the Company, its subsidiaries or their respective businesses is unavailable to the general public, it must be kept in strict confidence. Accordingly, such information should be discussed only with persons who have a "need to know" and should be confined to as small a group as possible. The utmost care and

circumspection must be exercised at all times. Therefore, conversations in public places, such as elevators, restaurants and airplanes, should be limited to matters that do not involve information of a sensitive or confidential nature.

PROCEDURES FOR DISCLOSURE OF MATERIAL NONPUBLIC INFORMATION

The SEC has enacted rules regarding the selective disclosure of material nonpublic information by public companies to securities market professionals before making full disclosure of the same information to the general public. In order to facilitate effective communication with the public securities markets and prohibit the selective disclosure of material information, the Company has adopted a Fair Disclosure Policy regarding communications with securities market professionals and stockholders.

To assure that Company confidences are protected to the maximum extent possible, in accordance with the Fair Disclosure Policy, no individuals other than specifically authorized personnel may release information to the public or respond to inquiries from the media, stockholders, securities market professionals such as analysts, brokers or investment advisors or others outside the Company. All other officers, directors and employees should refrain from disclosing Company business to stockholders and securities market professionals. All contacts with stockholders or securities market professionals should be promptly reported to the Compliance Officer. Scripts, talking points, presentations or other materials for use in pre- planned contacts with stockholders and securities market professionals should be reviewed by the Compliance Officer before use.

In the event the Compliance Officer determines that a selective disclosure of material nonpublic information to a stockholder or securities market professional has occurred, the Company shall promptly disseminate the same information through the filing of a Current Report on Form 8-K, or through another method (or combination of methods) of disclosure that is reasonably designed to provide broad, non-exclusionary distribution of the information to the public. Such dissemination shall occur not later than 24 hours after the Compliance Officer learns of such selective disclosure.

INSIDER TRADING OF SECURITIES

"Insider Trading" has been an enforcement priority of the SEC and the Department of Justice for many years. Criminal prosecution and the imposition of fines and/or imprisonment is common place.

Anyone who violates the insider trading prohibitions contained in the federal securities laws is subject to potential civil damages and criminal penalties. The civil damages can consist of disgorgement of profits and a fine of up to three times the profit gained or the loss avoided. The criminal penalties can be as much as $5,000,000 and 20 years imprisonment for each violation.

In addition, the SEC can seek a civil penalty against a company as a "controlling person" that fails to take appropriate steps to prevent illegal trading. The SEC can also seek a civil

penalty against directors and supervisory personnel as "controlling persons" who fail to take appropriate steps to prevent illegal trading. Although the Securities Exchange Act of 1934 does not define a "controlling person," its legislative history suggests that directors, officers and certain managerial personnel could become controlling persons subject to liability if they knew of, or recklessly disregarded, a likely insider trading violation by an employee under their control. A successful action by the SEC under this provision could result in a civil fine of $1,000,000 or three times the profit gained or the loss avoided, whichever is greater. Criminal penalties can be up to $25,000,000.

In addition to the possible imposition of civil damages and criminal penalties on violators and their controlling persons, any appearance of impropriety could not only damage the Company's reputation for integrity and ethical conduct but also impair investor confidence in the Company.

If a Covered Person violates the Company's Policy Statement, the Company can take disciplinary action, including removal from a position as director or officer or dismissal as an employee of the Company or its subsidiaries. Even if the SEC does not prosecute a case, involvement in an investigation (by the SEC or the Company) can tarnish the Covered Person's reputation and damage his or her career.

Any person who has supervisory authority over any Company or subsidiary personnel must promptly report to the Company's Compliance Officer any trading in the Company's securities by the Company or subsidiary personnel or disclosure of material "nonpublic" information by the Company or subsidiary personnel which he or she has reason to believe may violate this Policy Statement or the securities laws of the United States.

Restrictions on Trading and Tipping

In light of the Company's responsibilities under the federal securities laws, the Company has adopted the following policies regarding your trading in securities:

1. No Trading on Basis of Material Nonpublic Information.

Directors, officers and employees of the Company or any of its subsidiaries may not buy or sell securities of the Company or any other publicly traded company while in possession of material nonpublic information. Neither you nor any person affiliated with you may buy or sell securities or engage in any other action to take advantage of, or pass on to others, nonpublic material information. This rule applies both to securities purchases (to make a profit based on good news) and securities sales (to avoid a loss based on bad news) regardless of how or from whom the material nonpublic information has been obtained. This prohibition extends not only to transactions involving Company securities but also transactions involving securities of other companies (1) with which the Company has an existing business relationship, including but not limited to, the Company's distributors, vendors, customers or suppliers or collaboration, marketing, research, development or licensing partners, or (2) with which the Company is in active discussions concerning a potential transaction or business relationship. However, trading

may be permitted while in possession of, but not on the basis of, material nonpublic information if pursuant to a validly created Rule 10b5-1 Plan that has been approved in accordance with the terms of this Policy Statement.

Additionally, if you believe you may be in possession of nonpublic information about the Company that could potentially have a material effect on the stock price of another company with which the Company does not have an existing business relationship or with which the Company is not discussing a potential transaction or business relationship, you should exercise caution when trading in the securities of that company because the SEC has successfully brought an insider trading claim against an insider in those circumstances.

For purposes of this Policy Statement, "affiliates" include:

- your "Family Members" ("Family Members" are (a) your spouse or domestic partner, children, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws who reside in the same household as you, (b) your children or your spouse's children who do not reside in the same household as you but are financially dependent on you, (c) any of your other family members who do not reside in your household but whose transactions are directed by you, and (d) any other individual over whose account you have control and to whose financial support you materially contribute. Materially contributing to financial support would include, for example, paying an individual's rent but not just a phone bill.);

- all trusts, family partnerships and other types of entities formed for your benefit or for the benefit of a member of your family and over which you have the ability to influence or direct investment decisions concerning securities;

- all persons who execute trades on your behalf; and

- all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that this provision shall not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if the entity has established its own insider trading controls and procedures in compliance with applicable securities laws and it (or an affiliated entity) has represented to the Company that its affiliated entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with securities laws; and (c) are aware the securities laws prohibit any person or entity who has material nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

2. Prior Approval of All Trades.

Directors and executive officers of the Company may not buy or sell securities of the Company without prior consultation with and receipt of written approval by both the Company's Chief Executive Officer and the Compliance Officer. The Chief Executive Officer must consult with and receive the written approval of the Chairman of the Board and the Compliance Officer before buying or selling Company securities. All other employees of the Company and any officers (at the level of Vice President and above) of its subsidiaries must consult with and obtain written approval from the Company's Compliance Officer prior to buying or selling securities of the Company. This prior consultation and approval requirement provides a means of enforcing the policies specified above and also applies to any person affiliated with such Covered Person (which generally includes family members and business entities in which such director, officer or employee is a director, officer or significant stockholder). Written approval shall be obtained using the form substantially as set forth in Exhibit A attached hereto. Advanced approval of a Rule 10b5-1 Plan made in accordance with the terms of this Policy Statement shall constitute the approval of all trades made pursuant to such Rule 10b5-1 Plan.

3. Trading Windows.

Covered Persons will be subject to regular earnings "black-out" periods during which they will not be permitted to trade in the Company's securities. The timing and duration of the black-out periods will depend on a person's position with the Company or its subsidiaries, as follows:

A. Directors and Senior Managers.

For directors and senior managers (as defined below), the regular "black-out" period will begin on the first day of the last month of each quarterly and annual reporting period (i.e. March 1, June 1, September 1 and December 1) and last until the first business day following the public release of the Company's earnings information for that quarterly or annual period. In other words, directors and senior managers may only trade, (i) pursuant to a validly created and approved Rule 10b5-1 Plan, or (ii) subject to Section 2, above, during the period commencing on the second business day following the release of the Company's annual or quarterly earnings and continuing through the last day of the second month of the fiscal quarter in which such results are released, so long as they are not otherwise in possession of material nonpublic information regarding the Company or its subsidiaries. For purposes of this Policy Statement, the term "senior managers" shall mean executive officers and all other employees at or above the director level at the Company and all employees at or above the level of Vice President and above at any of the Company's subsidiaries.

B. Other Employees.

For all other employees of the Company, the regular "black-out" period will begin on the fifteenth (15th) day of the last month of each quarterly and annual reporting period (i.e. March 15, June 15, September 15 and December 15) and last until the first business day following the public release of the Company's earnings information for that quarterly or annual period. In other words, such other employees may only trade, (i) pursuant to a validly created and approved Rule 10b5-1 Plan, or (ii) subject to Section 2, above, during the period commencing on the second business day following the release of the Company's annual or quarterly earnings and continuing through the fourteenth (14th) day of the third month of the fiscal quarter in which such results are released, so long as they are not otherwise in possession of material nonpublic information regarding the Company. Employees below the level of Vice President at any of the Company's subsidiaries are generally not subject to trading "black-out" periods, although they must still comply with Section 1, above, Sections 4, and 6, below, and the "Trading Prohibitions" set forth at the end of this policy.

Because directors, senior managers and employees are at times especially likely to receive regular nonpublic information regarding the Company or its subsidiaries and their respective financial performance, prohibiting trading during these regularly scheduled black-out periods will help prevent trading based on material information that is not available to the public. Notice of the beginning and end of regularly scheduled black-out periods will be provided to directors, senior managers and employees by the Compliance Officer.

C. Exception for Stock Option Exercises.

Generally, during a regular "black-out" period, Covered Persons may exercise a stock option (unless the stock option exercised has a reload feature). However, during a regular "black-out" period, Covered Persons may not sell the underlying common shares received upon a stock option exercise or execute a cashless exercise of a stock option through a broker, which entails selling at least a portion of the underlying common shares to cover the costs of exercise. All stock option exercises shall be subject to the prior approval requirement set forth in Section 2, above.

4. Other Black-Out Periods.

The Company's Chief Executive Officer and/or Compliance Officer may impose additional, unscheduled "black-out" periods during which Covered Persons or other specified employees (and affiliated persons of each such Covered Person and employee) will not be permitted to buy or sell the Company's securities. From time to time, the Company's Chief Executive Officer and/or Compliance Officer may determine that material nonpublic information is available within the Company or its subsidiaries and may elect to impose a black-out on trading which has not been pre-scheduled. An unscheduled black-out may apply to some or all of the Company's directors, officers and employees or employees of its subsidiaries. During such periods, the affected directors,

officers and employees will not be permitted to trade in the Company's securities. Notice of such unscheduled black-out periods shall be provided by the Compliance Officer.

5. Pre-Planned Trading Programs.

Directors, executive officers and employees of the Company and officers of its subsidiaries may be permitted to establish sales plans pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, and buy or sell the Company's securities under such plans, if such plans are adopted at a time the person adopting the plan is not in possession of material nonpublic information and approved in writing in advance by the Company's Chief Executive Officer and Compliance Officer. Where the Chief Executive Officer desires to enter into a Rule 10b5-1 plan, such person will need to obtain the prior written approval of the Chairman of the Board and the Compliance Officer. Rule 10b5-1 permits an individual who is not in possession of material inside information to enter into a plan to buy or to sell a predetermined amount of the Company's securities at a predetermined price over a certain period of time even though that individual may subsequently come into possession of material nonpublic information. Both the act of entering into a Rule 10b5-1 plan and the terms of such plan must be approved in writing in advance using the form set forth in Exhibit A attached hereto. Any modification or termination of a Rule 10b5-1 Plan previously approved by the Compliance Officer requires a new approval by the Compliance Officer. The Compliance Officer may require as a condition to such approval that the modification or termination occur during an open trading window, that the person seeking to modify or terminate such 105b-1 Plan not be aware of material nonpublic information and that additional conditions, such as a cooling off period, must be satisfied.

6. No Communication of Material, Nonpublic Information.

Directors and employees of the Company and employees of the Company's subsidiaries may not communicate material nonpublic information to other persons prior to its public disclosure and dissemination. Directors and persons at the Company or its subsidiaries who come into possession of material nonpublic information must not communicate that information to other persons prior to its public disclosure and dissemination. There is, therefore, a need to exercise care when speaking with other Company or its subsidiaries personnel who do not have a "need to know" and when communicating with family, friends and other persons not associated with the Company or its subsidiaries. To avoid even the appearance of impropriety, it is wise to refrain from discussing the Company's or its subsidiaries business or prospects or making recommendations about buying or selling the securities of the Company or other entities with which the Company or any of its subsidiaries has a relationship. This concept of unlawful tipping includes passing on such information to friends, family members or acquaintances under circumstances that suggest that you were trying to help them make a profit or avoid a loss. In addition, directors, executive officers and employees should not discuss the Company, its subsidiaries or their respective businesses or prospects or the

Company's securities in any Internet chat room or other public forum, such as Facebook, Twitter, etc.

7. Reporting Purchases and Sales.

Directors and executive officers of the Company must report purchases and sales of securities to the Company's Compliance Officer. All directors, executive officers and the Principal Accounting Officer (which may include officers of the Company's subsidiaries) must notify the Company's Compliance Officer, in advance and no later than one (1) business day after the transaction, of all transactions in the Company's securities made by themselves, any family members living in the same household and entities in which they have a 5% or more ownership interest. The notification should be reported in the form of Exhibit B attached hereto or other form acceptable to the Compliance Officer. This is necessary to permit the Company to file a Form 4 with the SEC to report the transaction publicly. Failure to timely report your transaction will result in a violation of SEC regulations and require the Company to publicly disclose the violation in its next Proxy Statement.

8. Former, Temporary or Retired Directors, Executive Officers and Employees.

The Company's Policy Statement and the legal prohibition on insider trading in any security while in possession of material nonpublic information obtained while in the employment of or conducting any business or activity on behalf of the Company or its subsidiaries applies to all former, temporary or retired directors, executive officers or employees of the Company and its subsidiaries. Any person in possession of material nonpublic information when their employment with or service to the Company terminates may not trade in the Company's stock until that information has become public or is no longer material. To assist Directors and employees in complying with this obligation, it is recommended that such individuals, and particularly directors and executive officers of the Company, refrain from trading in the Company's stock for at least thirty (30) days after the termination of their employment or service to the Company.

TRADING PROHIBITIONS

The Company believes that it is improper and inappropriate for any personnel of the Company or its subsidiaries personnel to engage in short-term or speculative transactions involving Company securities. The Company believes that this type of trading can reflect badly on the Company and that Company personnel should not engage in any types of transactions that are commonly viewed as a form of "betting" for or against the Company. In addition, the Company believes that it is improper for personnel of the Company and its subsidiaries personnel to pledge any Company securities as collateral for any type of borrowing. Accordingly, it is the Company's policy that directors, officers and employees must not engage in any of the following activities with respect to securities of the Company:

1. "Short" sales of the Company stock (i.e. where a person borrows the Company's stock, sells it, and then buys the Company's stock at a later date to replace the borrowed shares or where a person already has sufficient shares of the Company's stock to sell, but does not deliver them until a later date).

2. Buying or selling puts or calls of the Company's shares. A put is an option or right to sell a specific stock at a specific price prior to a set date, and a call is an option or right to buy a specific stock at a specific price prior to a set date. Call options are purchased when a person believes that the price of a stock will rise, whereas put options are purchased when a person believes that the price of a stock will fall.

3. Buying shares of the Company's stock on margin.

4. Buying or using any financial instrument, including, without limitation, any prepaid variable forward contracts, equity swaps, collars and exchange funds that are designed to hedge or offset any decrease in the price or market value of shares of Company stock. This applies to all shares of Company stock held, whether held directly or indirectly, including shares granted by the Company to the holder as compensation.

Pledging the Company’s stock as collateral.

EXHIBIT A

OraSure Technologies, Inc.
Approval of Securities Transactions

To: [Chairman of the Board; Chief Executive Officer; Compliance Officer] From:

Date:

Subject: Proposed Securities Transaction

I propose to enter into the following transaction involving securities of OraSure Technologies, Inc.:

_____
_____
_____
_____
_____

I have discussed this proposed transaction with the Company's Compliance Officer and do not possess material inside information that would preclude me from entering into this transaction.

_____
(Signed)
_____(Print Name)

Approved:

_____
Chairman of the Board/Chief Executive Officer
_____Compliance Officer

Date:

EXHIBIT B

ORASURE TECHNOLOGIES, INC.
CONFIDENTIAL MEMORANDUM

To: Compliance Officer

From:

Date:

Subject: Transaction Report

As of __, 20_, my OraSure Technologies, Inc. security holdings were changed as follows:

Number of Common Shares __ Number of Stock Options Number of Restricted Shares
Date of Transaction __ Date of Transaction __ Date of Transaction__
__ acquired __ sold __ acquired __ sold __ acquired __ sold
__ transferred __other __ exercised __ other __ transferred __ other

If acquisition or transfer was effected indirectly (e.g., by or for your spouse or other family member, through an individual or entity who has agreed with you to acquire or transfer the securities on your behalf, etc., or by or for an entity of which you are a partner, member or 5% or greater stockholder), in addition to the above information, please identify the person through whom the transaction was effected and your relationship with such person:

Name of Individual
of Entity: __

Relationship with you: __

_____(Signed)

_____
(Print Name)

(THIS REPORT IS DUE IN ADVANCE OF, BUT NO LATER THAN, ONE BUSINESS DAY AFTER THE DATE OF EACH TRANSACTION IN WHICH A CHANGE IN BENEFICIAL SHARE OWNERSHIP OCCURS, EITHER DIRECTLY OR INDIRECTLY. IF APPLICABLE, A FORM 4 WILL BE PREPARED FOR YOUR SIGNATURE AND FILING WITH THE SECURITIES AND EXCHANGE COMMISSION BY THE END OF THE SECOND BUSINESS DAY FOLLOWING THE DAY IN WHICH A TRANSACTION RESULTING IN A CHANGE IN SHARE HOLDINGS WAS EXECUTED.)

Exhibit 21.1

Subsidiaries of the Registrant

Subsidiary	Place of Incorporation/ Organization
DNA Genotek Inc.	Canada
Sherlock Biosciences, Inc	Delaware
Sense Biodetection Limited	England and Wales
BioMedomics, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-287446) on Form S-3 and registration statements (Nos. 333-287450, 333-281500, 333-273731, 333-270863, 333-270861, 333-248424, 333-220148, 333-198237, 333-176315, 333-151077, 333-138814, 333-118385, 333-102235, 333-50340, 333-48662) on Form S-8 of our report dated March 11, 2024, except for note 12, as to which the date is March 7, 2025, with respect to the consolidated financial statements of OraSure Technologies, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 9, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 9, 2026, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of OraSure Technologies, Inc. on Form 10-K for the year ended December 31, 2025. We consent to the incorporation by reference of said reports in the Registration Statements of OraSure Technologies, Inc. on Forms S-3 (File No. 333-287446) and on Forms S-8 (File No. 333-287450, File No. 333-281500, File No. 333-273731, File No. 333-270863, File No. 333-270861, File No. 333-248424, File No. 333-220148, File No. 333-198237, File No. 333-176315, File No. 333-151077, File No. 333-138814, File No. 333-118385, File No. 333-102235, File No. 333-50340, and File No. 333-48662).

/s/ GRANT THORNTON LLP

Philadelphia, Pennsylvania
March 9, 2026

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, 2025, 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 20, 2026.

/s/ Steven K. Boyd
Signature

Steven K. Boyd
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, 2025, 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 20, 2026.

/s/ John P. Kenny
Signature

John P. Kenny
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, 2025, 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 20, 2026.

/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, 2025, 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 20, 2026.

/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, 2025, 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 20, 2026.

/s/ Robert W. McMahon
Signature

Robert W. McMahon
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 9, 2026

/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 9, 2026

/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, 2025 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 9, 2026

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, 2025 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 9, 2026