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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, 2024

or

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

For the transition period from _____ to

Commission File 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, 2024)**:** $314,835,036.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 24, 2025: 74,800,131 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 2025 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, 2024. 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, 2024, (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, and reference to "Sherlock" mean Sherlock Biosciences, Inc. and its wholly owned subsidiaries. References in this Annual Report to "we", "us", "our", "OTI" or the "Company" mean OraSure and its consolidated subsidiaries, DNAG, Diversigen, Novosanis, and Sherlock, 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;*
- *Failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for the Company's products;*
- *Significant customer concentrations that exist or may develop in the future;*
- *The Company's ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements;*
- *The Company's ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements;*
- *The Company's ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (or the "FDA”), or other regulators;*
- *Changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements;*
- *The Company's ability to meet increased demand for its products;*
- *The impact of replacing distributors on the Company's business;*
- *Inventory levels at distributors and other customers;*
- *The Company's ability to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales;*
- *The impact of competitors, competing products and technology changes on the Company's business;*
- *Reduction or deferral of public funding available to customers;*
- *Competition from new or better technology or lower cost products;*
- *The Company's ability to develop, commercialize and market new products;*

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

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

Investors should also be aware that while the Company does, from time to time, communicate with securities analysts, it is against the Company's policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that the Company agrees with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, the Company has a policy against issuing

or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

Trademarks, Trade Names and Service Marks

This Annual Report contains certain trademarks, which are protected under applicable intellectual property laws and are the Company's property. Solely for convenience, the Company's trademarks and trade names referred to in this Annual Report may appear without the ® or ™ symbol, but such references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. The Company owns rights to trademarks and service marks that it believes are necessary to conduct its business as currently operated. In the United States, the Company owns a number of trademarks, including the OraSure®, Intercept®, Intercept i2®*he,* Intercept i2*he*®, OraQuick®, OraQuick ADVANCE®, ORASURE QUICKFLU®, SUREQUICK®, Q.E.D.®, InteliSwab®, Oragene®, DNA Genotek®, OMNImet®, ORAcollect®, OMNIgene®, Diversigen®, CoreBiome®, Boostershot®, MetaGene®, Benchmark®, Novosanis®, Colli-Pee®, UCM®, UAS™, THINK OUTSIDE THE CUP®, AUTO-LYTE®, prepIT®, and HEMAgene® trademarks. The Company also 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 by powering the shift that connects 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 January 2024, the Company completed an equity investment in KKR Sapphiros L.P. ("Sapphiros"), leading its Series B financing and entering into a wide-ranging strategic distribution relationship with Sapphiros, which secures exclusive distribution rights to certain products in Sapphiros' development pipeline, including self-collected blood test and diagnostic tests. Sapphiros is a privately held consumer diagnostics portfolio company based in Boston.

In December 2024, the Company acquired Sherlock Biosciences, Inc. and its subsidiaries ("Sherlock"). Sherlock is a global health company focused on next generation diagnostics. Sherlock's molecular diagnostics platform aims to provide rapid results with strong sensitivity and specificity in a disposable format. Sherlock's first test for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) is currently in Phase 3 clinical studies and is expected to be submitted to the FDA for approval by the end of 2025. Subject to regulatory approvals, this test is expected to expand the Company's portfolio for rapid diagnostics for sexually transmitted infections.

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. Our diagnostic products include tests for diseases including HIV, Hepatitis C, Syphilis 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, HCV 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.

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 and environmental market segments. The Company has also developed collection devices for the emerging microbiome market, which focuses on studying microbiomes and their effect on human and animal health. The Company also has a urine collection device which allows for the volumetric collection of first void urine. This product is in its early stages, and initial sales are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets.

In 2020, the Company expanded its market focus by selling existing collection products for use with COVID-19 tests. Beginning in 2022 and continuing through 2024, demand for COVID-19 PCR testing declined significantly, which was primarily driven by the availability of antigen tests, the reduction in the number of COVID-19 cases, and the wider availability of vaccines that negatively impacted the sales of the collection products.

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. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of developer solution and allowed to develop. When blood-based specimens are to be tested, a loop collection device is used to collect a drop of the specimen and mix it in the developer solution, after which the collection pad is inserted into the solution and the test is allowed to develop. The specimen and developer solution then flow through the testing device where test results are observable between 20 and 40 minutes. The OraQuick® device is a screening test and requires a confirmation test where an initial positive result is obtained. This test is available for use by laboratories located in the United States certified under CLIA, to perform moderately complex tests. The Company has also received a CLIA waiver for use of the test with oral fluid and finger-stick and venous whole blood. As a result, the test can be used by numerous additional sites in the United States not certified under CLIA to perform moderately complex tests, such as outreach clinics, community-based organizations and physicians' offices.

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

OraQuick® In-Home HIV Test

The OraQuick® In-Home HIV test is an OTC oral-fluid only version of the Company's OraQuick *ADVANCE*® HIV 1/2 Antibody Test. The Company received PMA approval to sell this test in the U.S. OTC market. The In-Home test is performed in the same manner as the OraQuick *ADVANCE*® test, except that it has product labeling and instructions designed for consumers. In addition, the Company has established toll-free, 365-day per year customer telephone support to provide additional information and referral services for consumers that use this product. On January 7, 2025, the Company announced that the FDA had approved a premarket approval application supplement for a labeling change to include individuals 14 years of age and older. The previous approval was available for individuals 17 years of age and older.

OraQuick® HIV Self-Test

The OraQuick® HIV Self-Test 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 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.

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. The OraQuick® HCV test has received a CE mark for use with oral fluid, venous whole blood, finger-stick whole blood, plasma and serum and is sold in Europe. This CE-marked product is also registered and sold in other foreign countries and has received WHO pre-qualification.

Additionally, the OraQuick® HCV Self-Test is an over the counter self-test 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™

In February 2024, the Company entered into a strategic agreement with Diagnostics Direct to distribute its *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 a 2nd generation Ebola test on the OraQuick® testing platform with the objective of developing increased sensitivity, utilizing sustainable raw materials and increasing shelf life, with new chemistry and higher degrees of automation in the test's manufacturing process. In September 2023, the agreement was modified to add an additional $6.8 million in funding to be used to obtain the appropriate regulatory approvals for the product.

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 2024, 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.

Intercept® Drug Testing System

A collection device that is substantially similar to the OraSure® collection device is sold under the name Intercept®, and is used to collect oral mucosal transudate for oral fluid drug testing. The Company has received FDA 510(k) clearance to use the Intercept® collection device with laboratory-based EIAs to test for drugs-of-abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 (i.e., tetrahydrocannabinol ("THC" or marijuana), cocaine, opiates, amphetamines/methamphetamines and phencyclidine ("PCP")), and for barbiturates, methadone and benzodiazepines.

Each of these EIAs is also FDA 510(k) cleared for use with the Intercept® device. The Intercept® device and oral fluid assays are sold in the U.S. primarily through laboratory distributors.

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

In November 2024, the Company announced that it intended to exit the substance abuse testing business. Though the Company will continue to fulfill final orders for certain of its *Intercept® Drug Testing System* products through the first half of 2025, it substantially ceased the production and sale of substance abuse testing products as of the end of 2024.

Immunoassay Tests and Reagents

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

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

In November 2024, the Company announced that it intended to exit the substance abuse testing business. Though the Company will continue to fulfill final orders for certain of its immunoassay products through the first half of 2025, it substantially ceased the production and sale of substance abuse testing products as of the end of 2024.

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.

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 does not have FDA clearance and is labeled “For Research Use Only” in the U.S.

Microbiome Products

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

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

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

Laboratory and Data Analytical Services

During the third quarter of 2024, the Company exited its microbiome laboratory testing and data analytical services, with the Company continuing to close out limited and modest final service orders. These services focused on accelerating microbiome discovery for customers in the pharmaceutical, agriculture, and research communities.

Other Products

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

OraSure® Collection Device

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

Q.E.D.® Saliva Alcohol Test

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

In November 2024, the Company announced that it intended to exit the substance abuse testing business. Though the Company will continue to fulfill final orders for certain of its Q.E.D.® saliva alcohol test through the first half of 2025, it substantially ceased the production and sale of substance abuse testing products as of the end of 2024.

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 a 2nd generation 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 molecular self-test for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG), which is currently in clinical studies. The Company acquired this program in connection with its acquisition of Sherlock.

Through its Sherlock subsidiary, the Company is also developing of 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 both the genomics and microbiome areas. Genomic customers are demonstrating an increasing demand for collection and stabilization of cell-free nucleic acids, exosomes, DNA and RNA. On the microbiome front, the Company continues to focus research and development work on collecting and stabilizing microbial DNA, RNA and metabolites from multiple sample types including gut, skin, vagina and saliva.

The Company is working to develop a blood proteomics product, which, if approved, the Company expects will be used in emerging applications, like liquid biopsy, oncology and neurology, and in connection with chronic illnesses like Alzheimer's and diabetes.

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

The Company's OraQuick® HIV Self-Test is the only oral fluid HIV test prequalified by the WHO 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.

Substance Abuse Testing

On November 6, 2024, the Company announced that it intended to exit the substance abuse testing business. Though the Company will continue to fulfill final orders for certain of its substance abuse testing products, it substantially ceased the production and sale of such products as of the end of 2024. The Company's substance abuse testing products are marketed to laboratories serving the workplace testing, forensic toxicology, criminal justice and drug rehabilitation markets in the U.S. and certain international markets.

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.

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,		
	2024	2023	2022
OraQuick® HIV	$ 60,804	$ 60,823	$ 38,812
InteliSwab®	45,136	257,493	233,666
Genomics	44,861	47,005	54,335

One non-commercial customer accounted for approximately 24% of the Company's consolidated net revenues for the year ended December 31, 2024 and 63% and 58% for the years ended December 31, 2023 and 2022, respectively. The Company had no other customers that accounted for more than 10% of consolidated net revenues for the years ended December 31, 2024, 2023 and 2022.

Supply and Manufacturing

The Company manufactures its InteliSwab® COVID-19 Rapid Test, OraQuick *ADVANCE*® Rapid HIV test, OraQuick® In-Home HIV test, OraQuick® HCV test, OraQuick® Ebola test, OraSure®, Intercept® and Intercept i2® *he* collection devices, AUTO-LYTE® and MICRO-PLATE assays and Q.E.D.® saliva alcohol test in its Bethlehem, Pennsylvania facilities. With the exception of its substance abuse testing products, 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 2024, 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's MICRO-PLATE and AUTO-LYTE® assays require the production of highly specific and sensitive antibodies corresponding to the analyte of interest. Substantially all the Company's antibody raw materials are provided by

contract suppliers. The Company believes that it has adequate reserves of antibody supplies and that it has access to sufficient raw materials for these products.

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

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

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, 2024, the Company had 501 full-time employees, which compares to 638 employees as of December 31, 2023. The decrease in employees during 2024 was the result of the need to reduce manufacturing capacity for the Company's InteliSwab® COVID-19 Rapid Test, transition away from the microbiome molecular sequencing services business and close its Belgian operations. In addition, the Company exited its risk assessment business. 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® In-Home HIV oral fluid test is the only rapid HIV test approved by the FDA for sale in the U.S. OTC market.

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

The Company's OraQuick® HIV Self-Test is CE marked, which enables it to participate in the European OTC market for HIV.

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

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.

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

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

Patents and Proprietary Information

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

The Company has patents throughout its product lines. Its patent portfolio includes pending applications and issued 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 November 2038, 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 December 2042. Two related design patents issued in 2022 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 two international families of patent applications filed in the United States and in numerous countries worldwide. These applications are directed to novel nucleoside reverse transcriptase inhibitor-specific antibodies for use in assays to detect the presence of nucleoside reverse transcriptase inhibitor drug derivatives, including tenofovir, in fluid samples. Patents issuing from these applications will expire in October 2038 and December 2040.

The Company holds, through its subsidiary, DNAG, nineteen granted United States patents and numerous foreign patents issued for compositions, methods and apparatuses for the collection, stabilization, transportation, and storage of nucleic acids (DNA and RNA) from oral fluid and other bodily fluids and tissues. Certain patents expired in June 2023, and others will expire through 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®, Intercept®, Intercept i2®*he,* Intercept i2*he*®, OraQuick®, OraQuick ADVANCE®, ORASURE QUICKFLU®, SUREQUICK®, Q.E.D.®, InteliSwab®, Oragene®, DNA Genotek®, OMNImet®, ORAcollect®, OMNIgene®, Diversigen®, CoreBiome®, Boostershot®, MetaGene®, Benchmark®, Novosanis®, Colli-Pee®, UCM®, UAS™, THINK OUTSIDE THE CUP®, AUTO-LYTE®, prepIT®, and HEMAgene® trademarks. The Company also 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 System Regulations ("QSRs"), including current good manufacturing practices. These regulations govern the entire life cycle of a medical device, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing as well as complaint handling, corrective and preventative actions, and internal auditing. In complying with the QSRs, manufacturers must continue to expend time, money and effort in the area of production, quality, and post-market surveillance to ensure full compliance.

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

In February 2024, the FDA issued the Quality Management System Regulation ("QMSR") Final Rule to amend the QSR, incorporating by reference the international standard for medical device quality management systems set by the International Organization for Standardization ("ISO"), ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required to comply with the QSR. The Company believes that its facilities and procedures are in material compliance with the FDA's QSR requirements, 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 QSR regulations at the time of the last FDA inspection. If the FDA determines that the Company's facilities or procedures do not comply with the QSR regulations, it may refuse to provide such certificates until the Company resolves the issues to the FDA's satisfaction. Failure to obtain a CFG could inhibit the Company's ability to export its products to countries that require such certificates.

International

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

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

The EU Medical Devices Regulation (EU) 2017/745 (the "EU MDR") and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (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 products do not benefit from such transitional provisions and have been required to be EU IVDR compliant since May 26, 2022. The transition deadline for other classes of devices ranges between December 21, 2027 and 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 boy 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 regulatory authority is not required to obtain CE certification, but, depending on the class of product, conformity assessment by a notified body may be required. Notified bodies are accredited and supervised by national regulatory authorities to conduct conformity assessment procedures of medical devices or other products. The conformity assessment procedure for medical devices and in vitro diagnostic devices is to assess whether the device is compliant with the general safety and performance requirements set forth in the EU MDR or EU IVDR (as applicable), and includes an examination of the product's technical dossier and the manufacturer's quality system. ISO certification of the quality system in accordance with the relevant standard for medical devices or in vitro diagnostic devices creates a rebuttable presumption that the product satisfies the applicable requirements of the EU MDR or EU IVDR (as applicable)

with respect to the quality management system. Compliance with these general safety and performance requirements allows the Company to complete the applicable conformity assessment procedure, involving a notified body where necessary, and to affix the CE mark to its products, without which they may not be placed on the market in the EU. The Company also notes that from January 1, 2021, the United Kingdom ("UK") has introduced a UK-specific route to market for medical devices. Compliance with these requirements may add further complexities to the Company's international strategy.

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

The Company has obtained WHO pre-qualification for its OraQuick® HIV-1/2 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.
- The Company may not realize revenue levels from its InteliSwab® COVID-19 Rapid Test consistent with prior years.
- Marketing of the Company's COVID-19 tests and collection kits under EUAs from the FDA is subject to certain limitations and it is required to maintain compliance with the terms of the EUA, among other things, and the continuance of the EUAs is subject to government discretion.
- If acceptance and adoption of oral fluid testing and collection products does not continue, the Company's future results may suffer.
- The Company expects to face increasing competition from other providers of diagnostic tests, 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

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

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

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

Risks Relating to the Company's Common Stock

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

General Risk Factors

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

Risk Factors

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

Risks Relating to Products, Marketing and Sales

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

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

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

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

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

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

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

The Company 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 expects revenues to continue to decline in 2025. 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 the COVID-19 pandemic becomes a seasonal virus or experiences fluctuations in prevalence, the Company could experience fluctuations in its revenues associated with its InteliSwab® COVID-19 Rapid Tests. While there is still 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. A significant decline in demand for the InteliSwab® COVID-19 Rapid Test without a corresponding increase in the Company's other businesses could have a material, adverse effect on the Company's results of operations, cash flow and financial position.

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 QSR under 21 CFR Part 820. It is possible that the Company may not be able to obtain those clearances or approvals in a timely manner, or at all, and that one or more of OraSure's competitors may obtain the necessary clearances or approvals for their products before the Company does.

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

The Company has made significant progress in gaining acceptance of oral fluid testing products, particularly for 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.

However, clinical reference laboratories and hospital-based laboratories currently provide the majority of diagnostic tests used by physicians and other healthcare providers in the U.S. In certain international markets such as Europe, diagnostic testing is performed primarily by centralized laboratories. The Company's future sales will depend, in part, on the Company's ability to expand market acceptance of rapid point-of-care testing by physicians, other healthcare providers and consumers and successfully compete against laboratory testing methods and products. Even if the Company can

demonstrate that its products are more cost effective, save time, or have better performance or other benefits, physicians, other healthcare providers and consumers may resist changing to rapid point-of-care tests and instead may choose to obtain diagnostic results through laboratory tests. The Company's failure to achieve and expand market acceptance of its rapid point-of-care diagnostic tests with customers would have a negative effect on its future sales growth.

The Company Expects to Face Increasing Competition From Other Providers of Diagnostic Tests 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.

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

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

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

The sales cycles for certain of the Company's products can be lengthy and unpredictable, which makes it more difficult to accurately forecast revenues in a given period and may cause revenues and operating results to vary from period to period. Sales of the Company's products often involve purchasing decisions by large public and private institutions, may require many levels of approval and may be dependent on economic or political conditions and the availability of grants or funding from governmental or public health agencies which can vary from period to period in both amount and timing. For example, in past years the Company's OraQuick *ADVANCE*® HIV-1/2 test has been purchased through bulk procurement or other funding provided by governmental agencies. The Company's OraQuick® HCV test has been purchased by customers who receive government funding, and the Company believes increased funding from 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, the order has been temporarily stayed, there can be no assurance that it will not take effect or that other 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.

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 $13.9 million, or 7% of consolidated revenues in 2024, $14.6 million, or 4% of consolidated revenues in 2023, and $19.1 million, or 5% of consolidated net revenues in 2022. In addition, the Company's subsidiary DNAG, which accounted for $52.5 million or 28% of consolidated net revenues in 2024, 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 a second generation 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® In-Home HIV tests in support of the CDC "Together Take me Home," HIV self-test program. Under the program, the CDC is expected to provide $41.5 million over a five-year period to support community testing. During the third quarter of 2022, the Company entered into a contract with the Defense Logistics Agency ("DLA") for the second procurement of the Company's InteliSwab® COVID-19 Rapid Test for OTC use. During the same quarter, the Company entered into a contract with the BARDA to provide it with up to $13.6 million in funding to obtain an FDA 510(k) clearance and CLIA waiver for the Company's InteliSwab® test. The Company continued development work and analytical testing on this test throughout 2023. However, in early 2024, the Company has communicated to BARDA that it does not intend to pursue further development of this product. In September 2021, the Company entered into a contract with the U.S. DOD in coordination with the HHS for $109 million in funding to build additional manufacturing capacity in the United States for the Company's InteliSwab® test.

As a result of the Company's U.S. government funding and product sales to the U.S. government, it must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to the Company as compared to competitors that do not rely on government contracts. For example, the government has the right to terminate one or more of these contracts at its convenience even if the Company has not defaulted in any of its obligations.

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

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

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

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

In February 2024, the FDA issued the Quality Management System Regulation (QMSR) Final Rule to amend the QSR, incorporating by reference the international standard for medical device quality management systems set by the

International Organization for Standardization (ISO), ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required to comply with the QSR. We believe that our facilities and procedures are in material compliance with the FDA's QSR 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 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.

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 24% of its net consolidated revenues for the year ended December 31, 2024. Certain parts of the Company's business may continue to have a high customer concentration and depend disproportionately on a few large customers. To the extent that such a large customers fail to meet their purchase commitments, change their ordering patterns or business strategies, or otherwise reduce their purchases or stop purchasing the Company's products, or if it experiences difficulty in meeting the high demand by these larger customers for its products, the Company's revenues and results of operations could be adversely affected.

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. 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.

In recent months, the U.S. government has implemented funding freezes and delays that have directly affected healthcare and life sciences procurement. For example, on January 22, 2025, the Office of Management and Budget (“OMB”) issued a directive halting the disbursement of certain federal funds, pending review of budgetary priorities. Similarly, on February 10, 2025, the U.S. Department of State and USAID announced a 90-day suspension of new foreign assistance obligations, affecting global health initiatives and domestic procurement of essential healthcare supplies.

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.

Since the beginning of 2019, the Company has acquired or made investments in several companies through which it has gained access to new technologies, products and services which are complementary to its existing business and aligned with its long-term business strategy. For example, in January 2024, the Company announced its investment and entry into wide ranging strategic distribution agreements with KKR Sapphiros L.P. ("Sapphiros"), and in December 2024, the Company acquired Sherlock Biosciences, Inc. ("Sherlock"), expanding the Company's product pipeline with the addition of

Sherlock's molecular diagnostics platform. 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.

We May Fail to Realize the Anticipated Benefits of the Acquisition of Sherlock.

The success of the acquisition of Sherlock will depend on, among other things, our ability to combine our business with Sherlock in a manner that allows us to achieve developmental and operational synergies. The integration process could result in the loss of key employees, the disruption of our ongoing business or the ongoing business of Sherlock, or inconsistencies in standards, controls, procedures, or policies, in each case, that could adversely affect our ability to achieve the anticipated benefits of the acquisition. Integration efforts between the two companies will also divert management's attention from our core business and other opportunities that could have been beneficial to our stockholders. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of our common stock. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer or cost more to realize than expected.

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, the order has been temporarily stayed, there can be no assurance that it will not take effect or that other 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 products that are to be sold in the EU must bear the CE mark indicating conformance with the requirements of the relevant EU in vitro diagnostic medical devices legislation. The 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 QSR and FDA regulatory requirements in the United States and other applicable regulations worldwide, including but not limited to ISO standards. The Company believes that its facilities and procedures are in material compliance with the FDA requirements and ISO standards, but the regulations may be unclear and are subject to change, and the Company cannot be sure that the FDA or other regulators will agree with its compliance with these requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved or cleared products or impose conditions on any product clearances or approvals that could restrict the distribution or commercial applications of those products. Regulatory agencies may impose restrictions on the Company or its distributors' advertising and promotional activities or preclude these activities altogether if a noncompliance is believed to exist. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product or additional regulatory actions, including withdrawal of the product from the market.

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

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

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

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

The Company believes that its products and procedures are in material compliance with all applicable FDA regulations, ISO requirements, and other applicable regulatory requirements, but the regulations regarding the manufacture and sale of

its products, the QSR and ISO requirements, and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to the Company's products, necessitate additional clinical trials or procedures, or make it impractical or impossible for it to market its products for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to change the requirements for obtaining product approval or clearance and/or impose new or additional requirements as part of the approval or clearance process. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and could delay or make it more difficult or complicated to obtain approvals and sell the Company's products.

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.

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 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 to the United States in compliance with data protection laws may impede the Company's ability to conduct trials and may adversely affect its business and financial position. Complying with the enhanced obligations imposed by the GDPR imposes additional obligations and risk upon the Company's business, and may result in significant costs to its business and require it to amend certain of its business practices. Further, the Company has no assurances that violations will not occur, particularly given the complexity of the GDPR.

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.

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.

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 build and integrate AI into our business practices, and the evolving nature of AI technologies and the surrounding legal and regulatory environment presents risks and uncertainties that could affect our business. The use of AI technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, in the U.S., a number of states have proposed and passed laws regulating various uses of AI. In Europe, the EU's Artificial Intelligence Act ("AI Act") — 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 dedicate AI laws and regulations, we may be subject to novel legal and business risks relating to our adoption of these new technologies. 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.

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

In mid-2010, the FDA announced that it would begin regulating LDTs, including laboratory developed molecular tests, and in October 2014 issued proposed guidance on the regulation of LDTs for public comment. On January 13, 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. The 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.

- In Phase 1 (effective May 6, 2025), clinical laboratories would be required to comply with medical device reporting, correction/removal reporting, and certain quality systems complaint handling requirements.
- In Phase 2 (effective May 6, 2026), clinical laboratories would be required to comply with all other device requirements (e.g., establishment registration and device listing, labeling, investigational use requirements), except for remaining quality systems requirements and premarket review requirements.
- In Phase 3 (effective May 6, 2027), clinical laboratories would be required to comply with all remaining quality systems requirements.
- In Phase 4 (effective November 6, 2027), clinical laboratories would be required to comply with premarket submission requirements for high-risk tests (i.e., tests subject to FDA's premarket approval (PMA) requirement).
- In Phase 5 (effective May 6, 2028), clinical laboratories would be required to comply with premarket submission requirements for moderate- and low- risk tests (i.e., tests subject to de novo classification or the 510(k) requirement).

On May 29, 2024, the American Clinical Laboratory Association filed a lawsuit challenging the FDA's authority to regulate LDTs as medical devices under the FDCA. Subsequently, on August 19, 2024, the Association for Molecular Pathology filed a lawsuit similarly challenging FDA's final rule on LDTs. The outcomes of these lawsuits is uncertain at this time.
The Company's subsidiary, DNAG, sells its DNA collection systems to certain laboratories and other customers for use with LDTs. The FDA’s increased regulation of LDTs could make it more difficult for laboratories and other customers to continue offering LDTs that involve genetic or molecular testing. This, in turn, could increase costs, delay the introduction of new LDTs and reduce demand for DNAG’s products and adversely impact the Company's revenues.

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

laboratories to either stop offering such services or restricting the use of such services. Such a reduction in testing could result in decreased sales of the Company's DNA collection devices.

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

The Company has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the FCPA and similar foreign laws. In 2024, approximately $13.9 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 year ended December 31, 2024. In addition, as of December 31, 2024, the Company had an accumulated deficit of $103.4 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

The imposition of tariffs, non-tariff barriers, and other import and export restrictions have contributed to increased global economic uncertainty. The rise of economic nationalism could 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. 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.

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

At December 31, 2024, the Company's consolidated balance sheet reflected approximately $40.3 million of goodwill and approximately $17.4 million of intangible assets. Goodwill is recorded when the purchase price of a business exceeds the fair value of the tangible and separately measurable intangible net assets. U.S. generally accepted accounting principles (“U.S. GAAP”) require the Company to test goodwill for impairment on an annual basis or when events or circumstances occur indicating that goodwill might be impaired. Long-lived assets, such as intangible assets with finite useful lives, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment review often cannot be done at the level of the individual asset and it must instead be applied to a group of assets. For the purpose of the Company's annual goodwill impairment testing based on the current circumstances of how the Company manages or business, this group of assets is the Company as a whole. If the Company determines that any of its goodwill or intangible assets were impaired, it will be required to take an immediate charge to earnings and its results of operations could be adversely affected. The Company recognized a pre-tax impairment charge of $8.5 million related to intangible assets during the year ended December 31, 2023, which is reported in loss on impairments in the Company's consolidated statement of operations.

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

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

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

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

Risks Relating to the Company's Common Stock

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

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

- The performance of the Company's business, including its efforts to increase sales of OraQuick® HIV, HCV and sample management solutions and its OraQuick® In-Home HIV test and 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; and
- Terrorist attacks, civil unrest, war and national disasters, including pandemics.

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

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

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

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

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

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

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

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

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

General Risk Factors

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

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

- Decreased demand for the Company's products;
- Lost revenues;
- Damage to the Company's image or reputation;
- Costs related to litigation;
- Increased product liability insurance costs;

- Diversion of management time and attention; and
- Incurrence of damages payable to plaintiffs.

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

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

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

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

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

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

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

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

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

efforts are unsuccessful or delayed. Furthermore, the Company's failure to successfully introduce new or enhanced products and services and develop new markets could have a material adverse effect on its business and prospects.

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

Ensuring that the Company has adequate internal financial and accounting controls and procedures in place so that it can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. The Company is required to comply with the requirements of the Sarbanes-Oxley Act of 2002, or SOX, which requires that it maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, the Company must perform system and process evaluation, document its controls and perform testing of its key controls over financial reporting to allow management and its independent public accounting firm to report on the effectiveness of its internal control over financial reporting, as required by Section 404 of SOX. The Company's testing, or the subsequent testing by its independent public accounting firm, may reveal deficiencies in its internal control over financial reporting that are deemed to be material weaknesses. For instance, management identified a material weakness in the Company's internal control over financial reporting related to customer pricing in the revenue recognition process and concluded that its disclosure controls and procedures were not effective due to the existence of the material weakness as of September 30, 2023, 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 in the past and may in the future experience cybersecurity incidents. If successful, these attacks could lead to service interruptions, extortion, theft of confidential, personal or proprietary information, the compromise of data integrity or unauthorized information disclosure. Any technology service interruption or breach of the Company's systems could adversely affect its business operations and/or result in the loss or compromise of personal, sensitive, or confidential information or intellectual property. The Company maintains cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of the Company's systems.

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

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

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

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

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

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

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

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

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

The Company May Require Future Additional Capital.

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

- The costs, scope and timing of strategic acquisitions;
- The costs and timing of expansion of sales and marketing activities;
- The timing and success of the commercial launch of new products or services;
- The extent to which the Company gains or expands market acceptance for existing, new or enhanced products and services;
- The costs and timing of the expansion of the Company's manufacturing and laboratory capacity;
- The success of the Company's research and product development efforts;
- The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with distributors and other business partners;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and liability associated with patent infringement or other types of litigation; and
- Competing technological and market developments.

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

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in early 2023, several financial institutions closed and were taken in receivership by the Federal Deposit Insurance Corporation. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future.

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

Economic Volatility and Disruption Resulting from the COVID-19 Pandemic and any Future Pandemic and Health Crises Could Adversely Affect the Company’s Business, Financial Performance, Results of Operations, Cash Flow and Financial Condition or Those of Its Customers and Suppliers.

Global and U.S. markets and economies have experienced extreme volatility and disruption following the COVID-19 pandemic. Volatile economic conditions may occur again or continue in the future. Impacts of the COVID-19 pandemic that the Company has or may experience in the future include, but are not limited to:

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

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

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 Israel-Hamas war, 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 Israel, or of the sanctions imposed to date, which could include embargoes, regional instability, geopolitical shifts, exchange rate fluctuations, financial market disruptions and economic recession. Further, the conflict in Ukraine or Israel could exacerbate supply chain challenges, lead to an increase in cyberattacks, affect the global price and availability of key commodities, reduce the Company's sales and earnings or otherwise have an adverse effect on its business and results of operations.

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

The Increasing Prevalence of AI-based Software Presents New Risks and Could Adversely Affect Our Business and Reputation.

AI-based software and software making use of AI functionality, which the Company uses in certain parts of its business, is increasingly being used in the healthcare industry, such as for research, marketing, and commercialization, and we expect to use technology that uses AI in the future. As with many developing technologies, AI-based software presents risks and challenges. For example, algorithms may be flawed; data sets may be insufficient, of poor quality or contain biased information; and inappropriate or controversial data practices could impair results. If the analyses that AI-based software assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Use of AI-based software may also lead to cybersecurity risks or the release of confidential proprietary information, including personal data, which may impact our ability to realize the benefit of our intellectual property or violate our internal policies, data protection laws or contractual requirements. The use of AI-based software may also result in unauthorized access of personal data or the intellectual property of third parties. Since the use of AI is

subject to new or evolving laws and regulations, compliance may impose operational costs and limit our ability to use AI-based software, and failure to comply may result in potential government actions, litigation, fines, penalties or adverse publicity.

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 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.

We own a 31,700 square foot facility that houses our primary corporate office, our sales and marketing, research and development, human resources, and regulatory and quality offices. We also own a 48,000 square foot facility and a 33,500 square foot facility which are used for manufacturing activities. We lease a 23,000 square foot storage facility as well as an additional 139,000 square foot manufacturing facility. Each of these facilities is located in Bethlehem, Pennsylvania. Our 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. Our 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 its corporate offices, production, and research and development activities. Our other subsidiary, Diversigen, also leases facilities for its remaining operations. Novosanis's facility lease terminated on December 31, 2024.

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 15, 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 24, 2025, there were 253 holders of record and approximately 22,476 holders in street name of the Company's Common Stock, and the closing price of its Common Stock was $3.99 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, 2]
October 1, 2024 - October 31, 2024	669 [3]	$ 4.21	—	$11,984,720
November 1, 2024 - November 30, 2024	2,654 [3]	$ 4.25	—	$11,984,720
December 1, 2024 - December 31, 2024	0 [3]	$ —	—	$11,984,720
	3,323		—	

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

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

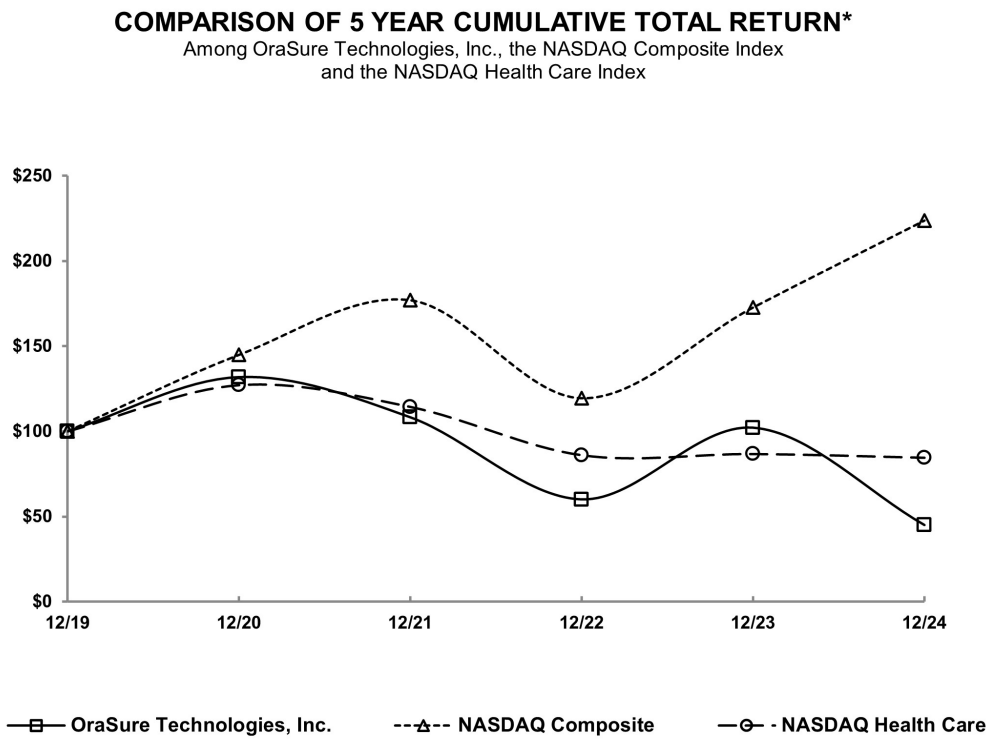
(3) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted and performance shares, these shares were retired to satisfy minimum tax withholdings.

Performance Graph

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

The following graph compares the cumulative total returns to investors in the Company's Common Stock, the Nasdaq Composite Index, and the Nasdaq Health Care Index for the period from December 31, 2019 through December 31, 2024. The graph assumes that $100 was invested on December 31, 2019 in the Company's Common Stock and in each of the above-mentioned indices, and that all dividends, if any, were reinvested.

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



*$100 invested on 12/31/19 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	Fiscal Year Ending December 31,					
	2019	2020	2021	2022	2023	2024
OraSure Technologies, Inc.	**100.00**	**131.82**	**108.22**	**60.02**	**102.12**	**44.96**
NASDAQ Composite	**100.00**	**144.92**	**177.06**	**119.45**	**172.77**	**223.87**
NASDAQ Health Care	**100.00**	**127.18**	**114.41**	**86.04**	**86.74**	**84.53**

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, 2024 (this "Annual Report") generally discusses 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Discussion of 2022 items and year-to-year comparisons between 2023 and 2022 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, 2023.

Business Overview

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

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

Recent Developments

Diversigen

During the first quarter of 2024, the Company initiated steps to wind down and exit the molecular services business offered by its Diversigen subsidiary. This strategic action was largely completed in June 2024. Diversigen contributed $1.7 million and $4.5 million, to revenues during the years ended December 31, 2024 and 2023, respectively.

Novosanis

During the first quarter of 2024, the Company also made a strategic decision to commence wind-down of its operations at it Novosanis subsidiary located in Belgium. The Company intends to continue to sell and manufacture its Colli-Pee® product under the DNAG product line of collection devices. As of December 31, 2024, this strategic plan was largely completed.

Sapphiros

In January 2024, the Company announced that it led the Series B financing and entered into wide-ranging strategic distribution agreements with Sapphiros, a privately held consumer diagnostic portfolio company based in Boston, and certain of its related entities. Through this strategic relationship, the Company expects to be able to offer a more comprehensive range of low-cost diagnostic test and sample management solutions to the Company's customers globally. The Company has funded $30.0 million for its interest in Sapphiros.

Risk Assessment Testing

In October 2024, the Company announced the discontinuance of the sales of its risk assessment product line which is expected to be completed in the first half of 2025. Sales of its risk assessment products contributed $8.4 million and $9.7 million to revenues during the years ended December 31, 2024, and 2023, respectively.

Sherlock Acquisition

In December 2024, the Company acquired Sherlock and its subsidiaries. The Sherlock acquisition expands the Company's innovation pipeline with the addition of Sherlock's molecular diagnostics platform, which is in Phase 3 clinical trials and is expected to provide rapid results with strong sensitivity and specificity in a disposable format that is well-suited for OTC usage. Sherlock has operations in the United States and the United Kingdom.

Results of Operations

The Company's consolidated net loss for the year ended December 31, 2024 was $19.5 million, or $0.26 per share on a fully diluted basis, compared to consolidated net income of $53.7 million, or $0.72 per share on a fully diluted basis, for the year ended December 31, 2023.

Year ended December 31, 2024 compared to December 31, 2023.

CONSOLIDATED NET REVENUES

The table below shows a summary of total consolidated net revenues (dollars in thousands) for the years ended December 31, 2024 and 2023.

	For the Years Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2024	2023	% Change	2024	2023
Diagnostics [1]	$ 75,917	$ 73,694	3 %	41 %	18 %
Sample Management Solutions [2]	51,046	54,274	(6)	28	13
COVID-19 Diagnostics	45,136	257,493	(82)	24	64
Risk Assessment Testing [3]	8,354	9,736	(14)	4	2
Other products and services	2,417	2,265	7	1	1
Molecular Services	1,705	4,474	(62)	1	1
COVID-19 Molecular Products	36	286	(87)	—	—
Net product and services revenues	184,611	402,222	(54)	99	99
Non-product and services revenues [4]	1,216	3,250	(63)	1	1
Net revenues	$ 185,827	$ 405,472	(54)%	100 %	100 %

[1] Includes HIV, HCV and Syphilis product revenues.
[2] Includes Genomics, Microbiome and Colli-Pee product revenues.
[3] Includes substance abuse testing product revenues.
[4] Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues decreased 54% to $185.8 million for the year ended December 31, 2024 from $405.5 million for the year ended December 31, 2023.

Sales of the Company's Diagnostics products increased 3% to $75.9 million for the year ended December 31, 2024 from $73.7 million for the year ended December 31, 2023. This increase in revenues is largely due to higher international HIV revenues primarily driven by customer ordering patterns in Africa offset by lower sales into Asia. Also contributing to the diagnostic revenue increase is an increase in sales of the Company's HCV domestic product and higher Syphilis revenues. Offsetting these increases in revenues is a decline in HIV domestic revenue resulting from funding delays or reductions in funding for HIV products and customer ordering patterns.

Sample Management Solutions revenues decreased by 6% to $51.0 million for the year ended December 31, 2024 compared to $54.3 million for the year ended December 31, 2023. Sales of the Company's Sample Management Solutions are being impacted by reduced consumer demand for products in which the Company's genomics collection devices are used, economic pressures, and the overall decline in the microbiome market.

COVID-19 Diagnostics revenues decreased 82% to $45.1 million for the year ended December 31, 2024 from $257.5 million for the year ended December 31, 2023 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 expects further declines in 2025.

Risk assessment testing revenues decreased 14% to $8.4 million for the year ended December 31, 2024 from $9.7 million for the year ended December 31, 2023 due to the loss of customers to competing products. The Company has announced the discontinuance this product line and expects minimal sales through the first half of 2025 as it fulfills existing customer orders.

Molecular Services revenues, which are largely derived from the Company's microbiome molecular sequencing services, decreased 62% to $1.7 million for the year ended December 31, 2024 from $4.5 million for the year ended December 31, 2023. 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 decreased 63% to $1.2 million for the year ended December 31, 2024 from $3.3 million for the year ended December 31, 2023 as a result lower funding for research and development activities and lower royalty income.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 43% for the year ended December 31, 2024 from 42% for the year ended December 31, 2023. Gross margins increased in 2024 despite the significant decrease in revenues due to following factors. Results for the year ended December 31, 2024 included lower depreciation expense as a result of the inclusion in 2023 results of $6.9 million of accelerated depreciation associated with the wind-down of InteliSwab® manual assembly in Thailand as the Company on-shored and automated the manufacturing of this product at its Pennsylvania facilities and $0.5 million from the exit from one of its leased warehouse in an effort to consolidate facilities and further lower costs. Results for the year ended December 31, 2024 also included improved manufacturing overhead absorption largely resulting from reduced salary and benefits due to the reduction of workforce put in place in 2024 and 2023. 2024 also included lower product scrap expense as compared to the prior year. Offsetting these improvement to margins was lower gross margins generated from product mix primarily driven by the decline in InteliSwab® revenues and the mix of higher international sales of the Company's HIV products. Other non-product revenues which contribute 100% to gross margins also declined for the year ended December 31, 2024.

Consolidated operating loss for the year ended December 31, 2024 was $28.3 million, a $60.9 million decline from the $32.7 million operating income reported for the year ended December 31, 2023. Results for the year ended December 31, 2024 were negatively impacted by the decrease in revenues and were positively impacted by reduced operating expenses. Results for the year ended December 31, 2024 included $4.4 million of impairment losses compared to $10.8 million for the year ended December 31, 2023.

Operating expenses for the year ended December 31, 2024, excluding the impairment charges, decreased by $25.0 million to $103.2 million compared to $128.2 million the year ended December 31, 2023, reflecting the impact of the Company's cost saving measures and headcount reductions.

Research and development expenses decreased 23% to $26.0 million for the year ended December 31, 2024 from $33.7 million for the year ended December 31, 2023 largely due to lower staffing costs due to a decrease in headcount and no related project management fees for our $109 million manufacturing expansion contract which ended during the fourth quarter of 2023, and a decrease in spend on COVID-19 product development. This overall decrease in spend is partially offset by an increase in severance costs for those employees impacted by the Company's decisions to exit the molecular services business offered by its Diversigen subsidiary and wind-down of operations located in Belgium. The Company expects research and development expense to increase in 2025 as we invest in the development of Sherlock's test for CT/NG and other innovative projects.

Sales and marketing expenses decreased 15% to $31.0 million for the year ended December 31, 2024 from $36.3 million for the year ended December 31, 2023 primarily due to decreased employee costs associated with a reduction in headcount, and lower advertising and consulting spend. Amortization also decreased as $6.2 million of intangibles were impaired in 2023. These decreases are partially offset by increases in bad debt expense and severance charges related to the discontinuance of the risk assessment product line.

General and administrative expenses decreased 21% to $46.2 million for the year ended December 31, 2024 from $58.2 million for the year ended December 31, 2023 largely due to lower legal fees relating to the Spectrum litigation (discussed further in Note 15, Commitments and Contingencies, to the consolidated financial statements included herein) and lower employee costs associated with reduced headcount partially offset by increase in non-cash stock compensation expense and transaction expenses associated with the Company's acquisition of Sherlock in December.

All of the above contributed to the Company's operating loss of $28.3 million for the year ended December 31, 2024, which included non-cash impairment charges of $4.4 million, non-cash charges of $10.9 million for depreciation and amortization, and $11.9 million for stock-based compensation. The Company's operating income of $32.7 million for the year ended December 31, 2023 included a non-cash impairment charge of $10.8 million, non-cash charges of $20.9 million for depreciation and amortization, and $10.7 million for stock-based compensation.

CONSOLIDATED OTHER INCOME

Other income for the year ended December 31, 2024 was $12.2 million compared to $23.6 million for the year ended December 31, 2023. This decrease is largely due to the inclusion in 2023 results of $12.8 million of additional profit earned above the guaranteed profit earned under the $109 million DOD manufacturing expansion contract that was completed in the fourth quarter of 2023. This additional profit resulted from lower spend under the fixed firm contract than originally budgeted. Other income in 2023 also included $2.8 million of guaranteed profit which covered project management costs recognized straight-line over the term of the contract. These amounts included in 2023 other income, which were not repeated in 2024, were partially offset by higher interest income and foreign currency gains for the year ended December 31, 2024 as compared to 2023.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. Although the Company has achieved U.S. cumulative pre-tax earnings based on a rolling three year window the Company has not achieved a level of sustained profitability that would, in its judgement, support the release of the valuation allowance. For the year ended December 31, 2024, the Company recorded income tax expense of $1.8 million. 2024 income tax expense is comprised of $0.4 million of U.S. federal and state income tax expense, and foreign income tax expense of $1.4 million. For the year ended December 31, 2023, the Company recorded income tax expense of $2.6 million. 2023 income tax expense is comprised of U.S. state income tax expense of $1.9 million, and foreign income tax expense of $0.7 million.

Liquidity and Capital Resources

	December 31, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	$ 267,763	$ 290,407
Working capital	299,737	346,923

The Company's cash and cash equivalents decreased to $267.8 million at December 31, 2024 from $290.4 million at December 31, 2023. $82.0 million, or 31%, of the Company's $267.8 million in cash, cash equivalents and available-for-sale securities is held by DNAG, the Company's Canadian subsidiary.

The Company's working capital decreased to $299.7 million at December 31, 2024 from $346.9 million at December 31, 2023. The decrease in cash and cash equivalents and working capital is primarily due to the investment in Sapphiros of $30.0 million and the initial payment for the acquisition of Sherlock for $5.0 million. 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, 2024, net cash provided by operating activities was $27.4 million. Cash flows from operations can be significantly impacted by factors such as timing of receipt from customers, inventory purchases, and payments to vendors. The Company's net loss of $19.5 million included non-cash charges of depreciation and amortization expense of $10.9 million, stock-based compensation expense of $11.9 million, impairment charges taken for idle equipment and right-of-use assets associated with Diversigen and Novosanis of $4.4 million, a loss on equity investment of 1.7 million and other non-cash charges aggregating to $0.8 million.

Cash provided by the Company's working capital accounts included a decrease in accounts receivable of $15.9 million largely associated with lower overall sales and collections of balances due, a decrease in inventory of $13.1 million as the Company fulfilled demand for its InteliSwab® product, and a decrease in prepaid and other assets of $4.1 million. Offsetting these increases in cash was a $7.6 million decrease in accounts payable due to the timing of invoices received and payments made and a decrease in accrued expenses and other liabilities of $6.4 million.

Investing Activities

Net cash used in investing activities was $39.0 million for the year ended December 31, 2024, which reflects proceeds from the maturities and redemptions of investments of $53.1 million, offset by $53.2 million used to purchase investments and $30.0 million used to purchase an equity stake in Sapphiros. Investing activities also included $3.8 million to acquire property and equipment to support normal operations of the business and the acquisition of Sherlock of $5.0 million.

Financing Activities

Net cash used in financing activities was $4.2 million for the year ended December 31, 2024, which reflects $3.5 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted awarded to the Company's employees and payments for lease liabilities of $0.8 million.

Resources

The Company's contractual obligations are included in Note 15 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® In-Home HIV test to the retail trade, and InteliSwab® products to the retail trade and certain customers.

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

Service Revenues

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

Arrangements with multiple-performance obligations

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

Inventories

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

Goodwill

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

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

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, 2024, 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 3% of the Company's total revenues for the year ended December 31, 2024. The Company does have foreign currency exchange risk related to its operating subsidiaries in Canada and Belgium. The principal foreign currencies in which it conducts business are the Canadian dollar and the Euro. Fluctuations in the exchange rate between the U.S. dollar and these foreign currencies could affect year-to-year comparability of operating results and cash flows. The Company's foreign subsidiaries had net assets, subject to translation, of $113.4 million in U.S. Dollars, which are included in the Company’s consolidated balance sheet as of December 31, 2024. A 10% unfavorable change in the Canadian-to-U.S. dollar and Euro-to-U.S. dollar exchange rates would have increased the Company's comprehensive loss by approximately $11.3 million as of December 31, 2024.

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, 2024. Based on that evaluation, the Company's management, including such officers, concluded that as of December 31, 2024 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, 2024.

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 Company acquired Sherlock Biosciences, Inc. and its wholly owned subsidiaries om December 19, 2024, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2024, the acquired company representing approximately 4% of total assets, excluding intangible assets and goodwill related to the acquisition and 0% of total revenue of the Company as of and for the year ended December 31,2024. Management plans to fully integrate the operations of these businesses into the assessment of the effectiveness of the Company's internal control over financial reporting in 2025.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2024 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, 2024 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 OraSure Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2024, 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, 2024, 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, 2024, and our report dated March 7, 2025 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.

Our audit of, and opinion on, the Company's internal control over financial reporting does not include the internal control over financial reporting of Sherlock Biosciences, Inc., a wholly-owned subsidiary, whose financial statements reflect total assets, excluding intangible assets and goodwill related to the acquisition, and revenues constituting 4 percent and 0 percent, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2024. As indicated in Management's Report, Sherlock Biosciences, Inc. was acquired during 2024. Management's assertion on the effectiveness of the Company's internal control over financial reporting excluded internal control over financial reporting of Sherlock Biosciences, Inc.

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 7, 2025

ITEM 9B. Other Information.

a. None.

b. During the fourth quarter of the fiscal year ended December 31, 2024, no director of "officer" as defined in Rule 16a-1(f) under the Exchange Act 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.

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 2025 Annual Meeting of Stockholders (the "2025 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 2025 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 2025 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 2025 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 2025 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 2025 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.
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	Second Amended and Restated Bylaws of OraSure Technologies, as of May 9, 2023, is incorporated by referenced to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.
4.1	Description of Securities is incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year-ended December 31, 2019.
10.1	Employment Agreement, dated as of January 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	Form of Restricted Share Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015.*
10.14	Form of Restricted Unit Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016. *
10.15	Form of Restricted Unit Award Agreement (Executive Officers-Employment Agreements) for 2021 awards is incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.*
10.16	Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.17	Nonqualified Stock Option Award General Terms and Conditions (Executive Officers) is incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.18	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
10.19	OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed December 21, 2011.*
10.20	Adoption Agreement related to OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed December 21, 2011.*
10.21	$109 Million Capital Funding Agreement with the U.S. Department of Defense, in coordination with the Department of Health and Human Services is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on From 10-Q for the period ended September 30, 2021, filed November 4, 2021.
10.22	Industrial Lease between Core5 at Laughman Farms Phase 1, LLC as Landlord and OraSure Technologies, Inc. as Tenant, dated January 3, 2022 is incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.
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

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 7, 2025.

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 7, 2025, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ Carrie Eglinton Manner Carrie Eglinton Manner	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Kenneth J. McGrath Kenneth J. McGrath	Chief Financial Officer (Principal Financial Officer)
/s/ Michele Anthony Michele Anthony	Senior Vice President, Controller & Chief Accounting Officer (Principal Accounting Officer)
*MARA G. ASPINALL Mara G. Aspinall	Director
*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
*DAVID J. SHULKIN, M.D. David J. Shulkin, M.D.	Director

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

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
OraSure Technologies, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheet of OraSure Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2024, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for the year ended December 31, 2024, 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, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, 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, 2024, 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 7, 2025 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 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 the 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 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 audit 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 audit provides 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 acquired in-process and research developed intangible asset and royalty contingent consideration in the Sherlock Biosciences, Inc. acquisition

As further described in Note 14 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 contingent consideration, as defined under the merger agreement, related to, 1) achievement of a regulatory milestone associated with the acquired in-process research and development technology ("IPR&D technology") intangible asset, and 2) royalty payments through December 31, 2034, representing a mid-single digit percentage of future revenues associated with the IPR&D technology intangible asset. Approximately $17.0 million of the initial purchase consideration was allocated to the IPR&D technology intangible asset. The estimated fair value of the royalty based contingent consideration was $7.0 million. We identified the fair value determinations of the IPR&D technology intangible asset and royalty based contingent consideration as a critical audit matter.

The principal consideration for our determination that the fair value of the IPR&D technology intangible asset and 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 cash flows and (ii) discount rates. Further, changes in these assumptions and judgments could have a significant impact on the recorded fair values.

Our audit procedures related to the fair value of the IPR&D technology and 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 and cash flows 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 7, 2025

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of OraSure Technologies, Inc. and subsidiaries (the Company) as of December 31, 2023, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for each of the years in the two-year period 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 audits. We are a public accounting firm registered with the Public Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

/s/ KPMG LLP

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

Philadelphia, Pennsylvania
March 11, 2024, except for Note 13, 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, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 267,763	$ 290,407
Accounts receivable, net of allowance for doubtful accounts of $774 and $1,216	23,816	40,171
Inventories	34,197	47,614
Prepaid expenses	3,956	6,041
Other current assets	3,488	2,226
Total current assets	333,220	386,459
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation	45,105	45,420
Operating right-of-use assets, net	13,442	12,270
Finance right-of-use assets, net	145	576
Intangible assets, net of accumulated amortization	17,435	1,206
Goodwill	40,330	35,696
Investment in equity method investee	28,300	—
Deferred tax asset	156	—
Other noncurrent assets	1,526	1,218
Total noncurrent assets	146,439	96,386
TOTAL ASSETS	**$ 479,659**	**$ 482,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 8,173	$ 13,151
Deferred revenue	2,961	1,559
Accrued expenses and other current liabilities	20,179	22,710
Finance lease liability	41	539
Operating lease liability	2,129	1,577
Total current liabilities	33,483	39,536
Noncurrent Liabilities:		
Finance lease liability	113	226
Operating lease liability	12,321	11,162
Acquisition-related contingent consideration obligation	22,910	—
Other noncurrent liabilities	494	696
Deferred income taxes	—	554
Total noncurrent liabilities	35,838	12,638
TOTAL LIABILITIES	69,321	52,174
Commitments and contingencies (Note 15)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 74,598 and 73,528 shares issued and outstanding	—	—
Additional paid-in capital	538,129	529,543
Accumulated other comprehensive loss	(24,360)	(14,941)
Accumulated deficit	(103,431)	(83,931)
Total stockholders' equity	410,338	430,671
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 479,659**	**$ 482,845**

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,		
	2024	2023	2022
NET REVENUES:			
Products and services	$ 184,611	$ 402,222	$ 378,047
Other	1,216	3,250	9,432
	185,827	405,472	387,479
COST OF PRODUCTS AND SERVICES SOLD	106,437	233,820	239,041
Gross profit	79,390	171,652	148,438
OPERATING EXPENSES:			
Research and development	26,047	33,728	36,237
Sales and marketing	30,986	36,319	49,238
General and administrative	46,215	58,191	68,206
Loss on impairments	4,392	10,829	17,101
Change in the estimated fair value of acquisition-related contingent consideration	—	(99)	(188)
	107,640	138,968	170,594
Operating (loss) income	(28,250)	32,684	(22,156)
OTHER INCOME	12,249	23,574	6,481
(Loss) Income before income taxes	(16,001)	56,258	(15,675)
INCOME TAX EXPENSE	1,799	2,603	1,458
LOSS ON EQUITY INVESTMENT	(1,700)	—	—
NET (LOSS) INCOME	$ (19,500)	$ 53,655	$ (17,133)
(LOSS) INCOME PER SHARE:			
BASIC	$ (0.26)	$ 0.73	$ (0.24)
DILUTED	$ (0.26)	$ 0.72	$ (0.24)
SHARES USED IN COMPUTING (LOSS) INCOME PER SHARE:			
BASIC	74,434	73,348	72,505
DILUTED	74,434	74,389	72,505

See accompanying notes to the consolidated financial statements.

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

	For the Years Ended December 31,		
	2024	2023	2022
NET (LOSS) INCOME	$ (19,500)	$ 53,655	$ (17,133)
OTHER COMPREHENSIVE (LOSS) INCOME			
Currency translation adjustments	(9,419)	3,274	(8,572)
Unrealized gain on marketable securities	—	220	214
COMPREHENSIVE (LOSS) INCOME	$ (28,919)	$ 57,149	$ (25,491)

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2024, 2023 and 2022
(in thousands)

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

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,		
	2024	**2023**	**2022**
OPERATING ACTIVITIES:			
Net (loss) income	$ (19,500)	$ 53,655	$ (17,133)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities			
Stock-based compensation	11,920	10,729	11,622
Depreciation and amortization	10,872	20,936	15,308
Loss on impairments	4,392	10,829	17,101
Other non-cash amortization	(564)	3	228
Provision for credit losses	71	(462)	(1,032)
Unrealized foreign currency (gain) loss	(263)	103	(161)
Interest expense on finance leases	22	51	94
Loss on equity investment	1,700	—	—
Deferred income taxes	(657)	102	(1,651)
Loss on sale of fixed assets	563	—	729
Change in the estimated fair value of acquisition-related contingent consideration	—	(99)	(188)
Payment of acquisition-related contingent consideration	—	(19)	—
Changes in assets and liabilities:			
Accounts receivable	15,872	31,116	(25,162)
Inventories	13,096	48,228	(43,274)
Prepaid expenses and other assets	4,089	(2,499)	(7,091)
Accounts payable	(7,577)	(26,976)	2,634
Deferred revenue	(219)	(730)	(596)
Accrued expenses and other liabilities	(6,443)	(3,384)	1,370
Net cash provided by (used in) operating activities	27,374	141,583	(47,202)
INVESTING ACTIVITIES:			
Purchases of short-term investments	(53,244)	(74,652)	(22,873)
Purchase of equity method investee	(30,000)	—	—
Proceeds from maturities and redemptions of short-term investments	53,052	102,440	47,415
Acquisition of business, net of cash acquired	(5,037)	—	—
Proceeds from sale of assets	—	—	121
Purchases of property and equipment	(3,797)	(5,802)	(6,774)
Purchase of property and equipment under government contracts	—	(4,501)	(57,135)
Proceeds from funding under government contract	—	48,669	60,331
Net cash (used in) provided by investing activities	(39,026)	66,154	21,085
FINANCING ACTIVITIES:			
Cash payments for lease liabilities	(842)	(1,345)	(1,381)
Proceeds from exercise of stock options	214	269	15
Payment of acquisition-related contingent consideration	—	(46)	(208)
Repurchase of common stock	(3,548)	(1,901)	(2,254)
Net cash used in financing activities	(4,176)	(3,023)	(3,828)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(6,816)	1,713	(2,837)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(22,644)	206,427	(32,782)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	290,407	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 267,763	$ 290,407	$ 83,980

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

1. THE COMPANY:

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

The Company's product portfolio is broadly divided into diagnostics products and 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 COVID-19, HIV and Hepatitis C, and Syphilis 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 is expected to be 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"), and Sherlock Biosciences, Inc. ("Sherlock"). All intercompany transactions and balances have been eliminated. References herein to “we”, “us”, “our”, or the “Company” mean OraSure and its consolidated subsidiaries, unless otherwise indicated.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the 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 tax of $1.8 million in 2024, and received income tax refunds of $4.9 million in 2023 and paid income tax of $9.4 million in 2022.

The Company had account receivable write-offs of $0.5 million, $0.7 million, and $2.3 million in 2024, 2023, and 2022, respectively.

As of December 31, 2024, 2023 and 2022, the Company had accruals for purchases of property and equipment of $0.5 million, $0.2 million and $0.2 million, respectively.

The Company acquired Sherlock in exchange for contingent consideration of $22,910 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 gain and losses, if any, reported in stockholders' equity as a component of 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, 2024 and 2023.

The Company maintains cash balances in the United States in excess of the federally insured limits

Fair Value of Financial Instruments

As of December 31, 2024 and 2023, 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.

		December 31,	
	Level	2024	2023
Guaranteed investment certificates	1	$ 66,584	$ 71,698
Contingent consideration	3	$ 22,910	$ —

Included in cash and cash equivalents at December 31, 2024 and 2023 was $66.6 million and $71.7 million, respectively, invested in guaranteed investment certificates.

Included in cash and cash equivalents at December 31, 2024 and 2023, was $118.5 million and $112.7 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, 2024 and 2023 was $0.7 million and $0.8 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 further discussed in Note 14, 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 two different tranches: milestone payments and royalty 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 are 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 developed intangible asset.

There were no changes in fair value from date of acquisition to December 31, 2024.

Equity Method Investee

In January 2024, the Company lead 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 sample management solutions to the Company's customers globally. As of December 31, 2024, 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, which coincides with the availability of its financial information. The investment in Sapphiros of $28.3 million as of December 31, 2024 is included in the investment in equity method investee line of the Company's balance sheet and is measured as a Level 3 investment. 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, 2024 financial statements, the Company considered whether the carrying value of the investment in Sapphiros was impaired and concluded that no such impairment existed. There was no similar investment as of December 31, 2023.

Accounts Receivable

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

	December 31,		
	2024	2023	2022
Accounts receivable	$ 23,816	$ 40,171	$ 70,797
Allowance for doubtful accounts	$ 774	$ 1,216	$ 2,365

Inventories

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

Property, Plant and Equipment

Property, plant and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets 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 Notes 5 and 6 for discussion of property, plant and equipment and intangible asset impairments, respectively, recorded for the years ended December 31, 2024 and 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 its the annual impairment assessment to November 30, to better align with the Company's annual forecasting process. On November 30, 2024, the Company performed a quantitative goodwill impairment test which concluded that the carrying value of the Company's goodwill was below its fair value indicating there was no impairment.

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

Revenue

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

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

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

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

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

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

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

Deferred revenue. The Company records deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of December 31, 2024 and 2023 included customer prepayments of $3.0 million and $1.2 million, respectively. 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, 2024. Revenue recognized during the years ended December 31, 2024 and 2023 was $3.7 million and $2.6 million, respectively, which was included in the beginning period deferred revenue.

	December 31,		
	2024	2023	2022
Deferred revenue	$ 2,961	$ 1,559	$ 2,273

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

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

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

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

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

	For the Years Ended December 31,		
	2024	2023	2022
HIV	$ 60,804	$ 60,823	$ 38,812
Sample Management Solutions [1]	51,046	54,274	63,342
COVID-19 [2]	45,172	257,779	243,325
HCV	14,024	12,871	13,369
Risk Assessment Testing [3]	8,354	9,736	10,269
Other product and services revenues [4]	3,506	2,265	1,634
Molecular Services	1,705	4,474	7,296
Net product and services revenues	184,611	402,222	378,047
Non-product and services revenues [5]	1,216	3,250	9,432
Net revenues	$ 185,827	$ 405,472	$ 387,479

[1] Includes Genomics, Microbiome and Colli-Pee product revenues.
[2] Includes COVID-19 Diagnostics and COVID-19 Molecular Products revenues.
[3] Includes substance abuse testing product revenues.
[4] Includes Syphilis 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,		
	2024	2023	2022
United States	$ 139,161	$ 361,660	$ 350,206
Africa	32,745	29,254	18,152
Europe	8,424	8,111	11,536
Other regions	5,497	6,447	7,585
	$ 185,827	$ 405,472	$ 387,479

Customer concentrations. The following table represents customer concentration risk:

	For the Years Ended December 31,	
	2024	2023
Revenue Concentration		
Non-commercial customer [1]	24%	63%

	December 31,	
Accounts Receivable	2024	2023
Commercial customer	10%	N/A
Non-commercial customer [1]	N/A	40%

[1] Same non-commercial customer.

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.

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 2024, 2023, and 2022, the Company incurred $0.5 million, $1.6 million, and $4.8 million, respectively, in advertising expenses.

Stock-Based Compensation

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

Income Taxes

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

The Company assesses the realizability of its net deferred tax assets on a quarterly basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, the Company reduces its net deferred tax assets by a valuation allowance. The realization of the net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the Company's net operating loss carryforwards.

Foreign Currency Translation

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in the Company's consolidated statements of operations in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions included in other income in the Company's consolidated statements of operations were $1.2 million, $(0.1) million, and $1.6 million for the years ended December 31, 2024, 2023, and 2022, 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,		
	2024	2023	2022
Net income (loss)	$ (19,500)	$ 53,655	$ (17,133)
Weighted average shares of common stock outstanding:			
Basic	74,434	73,348	72,505
Dilutive effect of stock options, restricted stock, and performance stock units	—	1,041	—
Diluted	74,434	74,389	72,505
Earnings per share:			
Basic	$ (0.26)	$ 0.73	$ (0.24)
Diluted	$ (0.26)	$ 0.72	$ (0.24)

For the year ended December 31, 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 896 shares 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. For the year ended December 31, 2022, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 436 shares were excluded from the computation of diluted loss per share.

Accumulated Other Comprehensive Loss

The Company classifies items of other comprehensive income (loss) by their nature and discloses the accumulated balance of other comprehensive 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. Changes in accumulated other comprehensive loss by component is listed below:

	Foreign Currency	Total
Balance at December 31, 2023	$ (14,941)	$ (14,941)
Other comprehensive loss	(9,419)	(9,419)
Balance at December 31, 2024	$ (24,360)	$ (24,360)

Recent Accounting Pronouncements

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), Scope Application of Profits Interest and Similar Awards*. 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 is evaluating the impact on the Company's consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures*. The purpose of the update was to improve financial reporting by requiring disclosures of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The amendments in this ASU are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted and require retrospective application to all periods presented in the consolidated financial statements. The Company has adopted the amendments for the year ended December 31, 2024.

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

Immaterial Correction of Errors

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

3. GOVERNMENT CAPITAL CONTRACTS:

In September 2021, the Company entered into an agreement for $109.0 million in funding from the 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 year ended December 31, 2024. The Company recognized $2.8 million and $2.2 million of such income during the years ended December 31, 2023 and 2022, respectively. Additionally, in connection with the completion of the contract, the Company recognized $12.8 million in excess of the guaranteed profit in other income in the Company's consolidated statement of operations 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 year ended December 31, 2024. The Company recognized $2.0 million and $1.4 million of such costs during the years ended December 31, 2023 and 2022, respectively.

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, 2024	December 31, 2023
Raw materials	$ 17,001	$ 20,727
Work in process	420	1,900
Finished goods	16,775	24,987
	$ 34,197	$ 47,614

During the years ended December 31, 2024, 2023, and 2022, the Company recorded adjustments to inventory which had a cost of $2.6 million, $8.9 million, and $15.6 million, respectively. Adjustments for the year ended December 31, 2024 were primarily driven by the write down of inventory based on an estimated amount of inventory that may not be sold as the Company exits 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. Additionally, a significant portion of the Company's 2022 adjustments were related to production and tech-transfer issues associated with the Company's COVID-19 rapid test.

5. PROPERTY, PLANT AND EQUIPMENT:

	December 31, 2024	December 31, 2023
Land	$ 1,118	$ 1,118
Buildings and improvements	36,152	34,606
Machinery and equipment	51,015	64,156
Computer equipment and software	11,502	17,739
Furniture and fixtures	1,621	3,748
Construction in progress	9,615	9,196
	111,023	130,563
Accumulated depreciation	(65,918)	(85,143)
	$ 45,105	$ 45,420

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

During the 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 2024, 2023, and 2022 was $9.8 million, $17.9 million, and $11.7 million, respectively.

6. GOODWILL AND OTHER INTANGIBLE ASSETS:

Changes in goodwill are as follows:

	December 31,	
Collection Device Reporting Unit	**2024**	**2023**
Balance as of January 1	$ 35,696	$ 35,104
Change related to foreign currency translation	(1,754)	592
Balance as of December 31	33,942	35,696
Diagnostics Reporting Unit		
Balance as of January 1	—	—
Acquisition	6,388	—
Balance as of December 31	6,388	—
	$ 40,330	$ 35,696

On November 30, 2024, 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.

During 2022, the Company determined that a triggering event occurred in relation to the depressed market price of the Company's common stock and corresponding decline in the Company's market capitalization. As a result, the Company performed an interim quantitative goodwill impairment test and concluded that the carrying value of the Company's Diagnostics reporting unit exceeded its estimated fair value and the goodwill balance for that segment was fully impaired. The Company recognized a pre-tax impairment charge of $3.6 million during the year ended December 31, 2022, which is reported in loss on impairments in the Company's consolidated statement of operations.

Intangible assets consist of the following:

	Amortization Period (Years)	December 31, 2024		
		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 14)	N/A	17,000	—	17,000
		$ 49,848	(32,413)	17,435

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

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 2024, 2023, and 2022 was $0.7 million, $2.0 million, and $2.3 million, respectively.

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

2025	$ 290
2026	145
2027	—
2028	—
2029	—
Beyond	—
	$ 435

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	December 31,	
	2024	2023
Payroll and related benefits	$ 11,147	$ 14,654
Professional fees	2,469	2,827
Sales tax payable	1,339	1,245
Other	5,224	3,984
	$ 20,179	$ 22,710

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 (in thousands):

	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. No additional expense associated with the 2023 reduction in workforce was incurred during the year ended December 31, 2024. 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. This was accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*. The charges for termination benefits included in the Company's consolidated statement of operations are as follows (in thousands):

	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. 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 (in thousands):

	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, 2024 the Company had $0.5 million accrued and had paid $1.2 million related to the reduction in workforce. The Company expects this reduction in workforce to be completed by September 2025.

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. 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 (in thousands):

	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, 2024 the Company had $1.1 million accrued and had paid $0.1 million related to the reduction in workforce. The Company expects this reduction in workforce to be completed by January 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, 2024, the Company is the lessee in all lease agreements. The Company's leases have remaining lease terms of one to ten 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 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,		
	2024	2023	2022
Operating lease cost	$ 1,729	$ 2,407	$ 2,910
Variable and short-term lease cost	549	381	521
Finance lease cost:			
Amortization of right-of use assets	331	1,091	1,299
Interest on lease liabilities	22	51	94
Total finance lease cost	353	1,142	1,393
Total lease cost	$ 2,631	$ 3,930	$ 4,824

Supplemental cash flow information related to leases is as follows:

	For the Years Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 1,901	$ 1,863	$ 2,209
Operating cash flows from financing leases	22	51	94
Financing cash flows from financing leases	842	1,345	1,381
Non-cash activity:			
Right-of-use assets obtained in exchange for operating lease obligations	4,086	4,363	3,963
Right-of-use assets obtained in exchange for finance lease obligations	193	334	117

Supplemental balance sheet information related to leases is as follows:

	December 31,	
	2024	2023
Weighted Average Remaining Lease Term		
Weighted-average remaining lease term — operating leases	7.57 years	8.51 years
Weighted-average remaining lease term — finance leases	3.74 years	1.71 years
Weighted Average Discount Rate		
Weighted-average discount rate — operating leases	4.44 %	3.71 %
Weighted-average discount rate — finance leases	4.82 %	3.45 %

As of December 31, 2024, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2025	$ 48	$ 2,559
2026	48	2,373
2027	42	2,141
2028	25	2,081
2029	6	2,020
Thereafter	—	5,722
Total minimum lease payments	169	16,896
Less: imputed interest	(15)	(2,446)
Present value of lease liabilities	$ 154	$ 14,450

10. INCOME TAXES:

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

	For the Years Ended December 31,		
	2024	2023	2022
United States	$ (21,523)	$ 61,671	$ (7,111)
Foreign	5,522	(5,413)	(8,564)
	$ (16,001)	$ 56,258	$ (15,675)

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

	For the Years Ended December 31,		
	2024	2023	2022
Current			
Federal	$ 229	$ —	$ —
State	111	1,896	955
Foreign	2,116	605	2,154
	2,456	2,501	3,109
Deferred			
Federal	(2,962)	13,570	(2,250)
State	1,368	(382)	(633)
Foreign	4,365	(1,867)	(2,617)
	2,771	11,321	(5,500)
Increase (decrease) in valuation allowance	(3,428)	(11,219)	3,849
	(657)	102	(1,651)
Total income tax expense	$ 1,799	$ 2,603	$ 1,458

For the years ended December 31, 2024, 2023, and 2022 the Company recorded net foreign income tax expense of $1.4 million, $0.7 million, and $0.5 million, respectively. The Company's 2022 foreign income tax expense included $1.7 million of Canadian withholding taxes paid on the repatriation of Canadian earnings offset by a foreign income tax benefit of $1.2 million associated with the Company's Canadian subsidiary. For the years ended December 31, 2024, 2023, and 2022 the Company recorded U.S. federal tax expense of $0.2 million and state tax expense of $0.1 million, $1.9 million, and $1.0 million respectively.

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

	For the Years Ended December 31,		
	2024	2023	2022
Statutory U.S. federal income tax rate	21.0 %	21.0 %	21.0 %
Nondeductible executive compensation	(8.5)	0.5	(5.8)
Impact of stock-based payment awards	(2.3)	(0.3)	(5.1)
Tax effect of foreign items	(1.9)	(0.4)	(6.0)
State income taxes, net of federal benefit	(9.1)	2.0	(0.8)
U.S. and foreign tax credits	1.2	1.3	3.7
Nondeductible expenses and other	(2.4)	0.9	8.7
Nondeductible transaction costs	(2.1)	—	—
NOL adjustment, foreign	(31.4)	—	—
Non-controlling interests	2.2	—	—
Change in valuation allowance, federal and state	(10.0)	—	—
Change in valuation allowance, foreign	32.1	(20.4)	(25.0)
Effective tax rate	(11.2) %	4.6 %	(9.3) %

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,	
	2024	2023
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 55,583	$ 28,014
Inventories	2,344	2,654
Capitalized research and development costs	12,946	3,897
Accruals and reserves currently not deductible	2,754	3,324
Acquired intangible assets	(3,981)	(164)
Depreciation and amortization	(2,017)	(3,567)
Right-of-use assets	(2,266)	(3,010)
Lease liabilities	2,497	3,173
Stock-based compensation	3,303	3,467
Tax credit carryforwards	4,184	3,326
Net deferred tax asset	75,347	41,114
Valuation allowance	(75,191)	(41,668)
Net deferred tax asset (liability)	$ 156	$ (554)

In assessing the realizability of the Company's deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent upon several factors, including the generation of sufficient taxable income, to realize the NOL carryforwards. In 2008, the Company established a full valuation allowance against the Company's U.S. deferred tax asset, and although the Company has achieved cumulative of U.S. pre-tax earnings based on a rolling three year window the Company has not achieved a level of sustained profitability that would, in the Company's judgement, support the release of the valuation allowance. Management believes the full valuation allowance is still appropriate as of December 31, 2024 and 2023. As a result, no U.S. federal income tax benefit was recorded for the years ended December 31, 2024, 2023, and 2022.

The Company's federal NOL carryforwards consist of $108.6 million from existing business along with $71.5 million of acquired NOL carryforwards. None of these NOL carryforwards have an expiration date. The Company's foreign NOL carryforwards consist of $63.0 million of acquired NOL carryforwards. These foreign NOL carryforwards do not have an expiration date. The Company's state NOL carryforwards consist of $33.9 million from existing business along with $4.0 million of acquired NOL carryforwards. The state NOL carryforwards have expirations as follows:

Year of Expiration	NOLs
2026 - 2040	$ 14,122
2041 - 2046	13,442
Non-Expiring	10,294
	$ 37,858

The Tax Reform Act of 1986 contains provisions under Internal Revenue Code ("IRC") Section 382 that limit the annual amount of federal and state NOL carryforwards that can be used in any given year in the event a significant change in ownership. The Company does not believe that there is a Section 382 limitation that will impair the Company's future ability to utilize NOLs to offset the Company's future taxable income. The Company continues to review ownership changes on an annual basis and the Company does not believe it has had a subsequent ownership change that would impact the NOLs. The Company acquired 382 limited NOL carryforwards as part of its acquisition of Sherlock. These NOL carryforwards have no expiration date.

In January 2022, approximately $65.0 million was repatriated from the Company's Canadian subsidiary as a one-time event. Associated with this repatriation the Company paid $1.7 million in Canadian withholding tax which is included in the Company's foreign income tax expense within the table further above. It is still the Company's intention to continue to permanently reinvest the historical undistributed earnings of the Company's foreign subsidiary to the extent that the Company will not incur any additional tax expense associated with foreign withholding or other local tax expense on the future cash transfers. As such, deferred taxes have not been recorded on the unremitted earnings of the foreign subsidiary as of December 31, 2024.

As of December 31, 2024, the Company's gross unrecognized tax benefits totaled $0.3 million, and based upon the valuation allowance for the Company's U.S. operations, the recognition of any tax benefit would not impact the Company's effective tax rate. The Company records interest and penalties related to unrecognized tax benefits as a component of income tax expense. Interest and penalties were immaterial in 2024, 2023, and 2022. 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, 2024.

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

	2024	2023	2022
Balance at January 1	$ 304	$ 373	$ 805
Additions for tax positions of prior periods	29	—	1
Reductions for tax positions of prior periods	—	(69)	(433)
Balance at December 31	$ 333	$ 304	$ 373

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, 2024, 5,412 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	**2024**	**2023**	**2022**
Risk-free interest rate [1]	4.14 %	4.23 %	1.65 %
Expected dividend yield	—	—	—
Expected stock price volatility [2]	53 %	51 %	50 %
Expected life of stock options (in years) [2]	5	5	5

[1] Based on the constant maturity interest rate of U.S. Treasury securities whose term is consistent with the expected life of the Company's stock options.
[2] Based upon historical experience.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2024, 2023, and 2022 was $3.68, $3.24 and $4.15, respectively.

Compensation expense recognized in the financial statements related to stock options was $1.4 million, $1.3 million, and $1.5 million for the years ended December 31, 2024, 2023, and 2022, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2024, 2023, and 2022 (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) was $38.4 thousand, $43.0 thousand, and $4.0 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, 2024	2,070	$ 9.27		
Granted	595	6.99		
Exercised	(32)	6.70		
Expired	(188)	11.19		
Forfeited	(208)	7.20		
Outstanding on December 31, 2024	2,237	$ 8.73	6.33	$ —
Vested or expected to vest as of December 31, 2024	2,198	$ 8.72	6.44	$ —
Exercisable on December 31, 2024	1,389	$ 9.79	4.91	$ —

As of December 31, 2024, there was $2.6 million of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 2.6 years.

Net cash proceeds from the exercise of stock options were $0.2 million, $0.3 million and $0.02 million for the years ended December 31, 2024, 2023, and 2022, 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, 2024:

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
$4.26 - $6.82	578	7.35	$ 5.98	285	$ 6.02
$7.13 - $10.69	1,277	6.51	7.89	728	8.21
$12.90 - $19.34	334	4.33	14.87	329	14.86
$21.64 - $32.46	48	2.78	$ 21.65	47	$ 21.65
	2,237	6.33	$ 8.73	1,389	$ 9.79

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 $6.9 million, $7.6 million and $9.2 million related to restricted shares was recognized during the years ended December 31, 2024, 2023, and 2022, 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, 2024	2,521	$ 6.04
Granted	875	6.84
Vested	(1,604)	5.81
Forfeited	(98)	7.37
Issued and unvested, December 31, 2024	1,694	$ 6.60
Issued and expected to vest, December 31, 2024	1,694	$ 6.60

As of December 31, 2024, there was $6.0 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, 2024, 2023, and 2022, the Company purchased and immediately retired 617, 262 and 241 shares with aggregate values of $3.4 million, $1.4 million and $1.6 million, respectively, in satisfaction of minimum tax withholding and exercise obligations.

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

Compensation cost of $3.6 million, $1.8 million and $0.9 million related to the PSUs was recognized during the years ended December 31, 2024, 2023, and 2022, respectively.

The following table summarizes PSU activity under the Stock Plan:

	Units	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2024	991	$ 6.52
Granted [1]	519	8.87
Performance adjustment [2]	18	N/A
Vested	(74)	10.99
Forfeited	—	—
Issued and unvested, December 31, 2024	1,454	$ 7.19
Issued and expected to vest, December 31, 2024	1,454	$ 7.19

[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, 2024, there was $5.3 million of unrecognized compensation expense related to unvested performance stock units that is expected to be recognized over a weighted average period of 1.7 years.

In connection with the vesting of performance stock units during the year ended December 31, 2024, 2023 and 2022, the Company purchased and immediately retired 23, 86, and 88 shares with aggregate values of $0.2 million, $0.5 million and $0.6 million, respectively.

Share Repurchase Program

On August 5, 2008, the Company's Board of Directors approved a share repurchase program pursuant to which the Company is permitted to acquire up to $25.0 million of the Company's outstanding common shares. No shares were purchased and retired during the years ended December 31, 2024, 2023, and 2022.

12. TRANSITION COSTS

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

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

13. BUSINESS SEGMENT INFORMATION:

The Company is organized on the basis of products and services into a single reportable segment. All products and services reside under the same reporting hierarchy. Historically, there was separate management leading the Company's Diagnostics and Molecular Solutions businesses. In February 2023, the Company announced a corporate restructuring to combine the commercial and innovation teams across the Diagnostics and Molecular Solutions businesses into one operating segment with sales, marketing, product development and research teams covering all product lines and reporting to a Chief Product Officer ("CPO").

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,	
	2024	2023
United States	$ 40,286	$ 48,311
United Kingdom	12,849	—
Canada	5,468	8,777
Other regions	89	1,178
	$ 58,692	$ 58,266

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

	For the Years Ended December 31,		
	2024	2023	2022
Net revenues	$ 185,827	$ 405,472	387,479
Cost of products and services sold [3]	106,437	233,820	239,041
Gross profit	79,390	171,652	148,438
Research and development [3]	26,047	33,728	36,237
Sales and marketing [3]	30,986	36,319	49,238
General and administrative [3]	46,215	58,191	68,206
Loss on impairments	4,392	10,829	17,101
Change in the estimated fair value of acquisition-related contingent consideration	—	(99)	(188)
Operating (loss) income	(28,250)	32,684	(22,156)
Other (expense) income [1]	(380)	17,836	3,453
Interest revenue	11,469	5,862	1,569
Other segment items [2]	1,160	(124)	1,459
(Loss) income before income taxes	(16,001)	56,258	(15,675)
Income tax expense	1,799	2,603	1,458
Loss on equity investment	(1,700)	—	—
Net (loss) income	$ (19,500)	$ 53,655	$ (17,133)

[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,		
	2024	2023	2022
Stock-based Compensation			
Cost of products and services sold	$ 734	$ 564	$ 334
Research and development	839	1,159	1,128
Sales and marketing	1,129	1,181	1,702
General and administrative	9,219	7,826	8,458
	$ 11,920	$ 10,729	$ 11,622

	For the Years Ended December 31,		
	2024	2023	2022
Depreciation and Amortization			
Cost of products and services sold	$ 6,343	$ 15,311	$ 9,230
Research and development	1,029	1,208	1,098
Sales and marketing	189	571	630
General and administrative	3,311	3,846	4,350
	$ 10,872	$ 20,936	$ 15,308

14. BUSINESS COMBINATIONS:

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 is Sherlock's first test for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) is in clinical studies and is expected to be submitted to the FDA for approval by the end of 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 had as shown 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 fair value of this milestone metric contingent consideration was $15.9 million. The range of outcome for the milestone contingent consideration is $0.0 million to $20.0 million. Also, there is a mid-single digits quarterly royalty fee based on future sales until 2034 as defined in the Merger Agreement, which was fair valued as part of 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 its 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, 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 fair value of contingent payments approach was used to value the royalty based contingent consideration, were primarily based on significant unobservable inputs and are considered Level 3 fair value measurements. The fair value of contingent payments approach were 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 continues to evaluate the fair value of certain 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 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. For the year ended December 31, 2024, consolidated net revenues include revenues associated with Sherlock of $78.0 thousand and consolidated results from operations include a net loss of $255.4 thousand generated since the acquisition date.

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

15. COMMITMENTS AND CONTINGENCIES:

Purchase Commitments

As of December 31, 2024, the Company had a manufacturing agreement with a third party vendor requiring a minimum purchase commitment. If the minimum commitment is not achieved, the Company will be required to make annual penalty payments over the next year. Based on current forecasts, these penalties aggregate to approximately $0.3 million and are accrued for in the consolidated balance sheet. These estimated penalties can fluctuate based on changes in forecasted demand.

The table below represents an estimate of future purchases under the agreement (in thousands):

2025	$	1,443
2026		—
2027		—
2028		—
2029		—
	$	1,443

Collaborations

Sherlock has an active third-party license agreement entered into in order to advance and obtain technologies and services related to the business. Under this license, the Company is required to make up to $2.3 million of cash payments upon the achievement of certain scientific and commercial milestones as well as low single digit royalty payments on product sales. No milestone payments have been made as of December 31, 2024. The Company has the right to terminate the license for any reason. Unless otherwise terminated, the license terminates upon the expiration of the last to expire valid claim.

Litigation

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

Spectrum Patent Litigation

In March 2021, the Company filed a complaint against Spectrum Solutions, LLC (“Spectrum”) in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum filed an answer asserting that its device does not infringe the Company’s patent and that the Company’s patent is invalid. In August 2021, the Company amended its complaint to add a second patent to this litigation. Spectrum responded to the Company's amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation and subsequently filed a request for review of the second patent at the Patent and Trademark Office (“PTO”), which was granted by the PTO. The District Court issued multiple pretrial orders, resolving the infringement, antitrust, and inequitable conduct claims without trial. First, the District Court granted Spectrum’s motion for summary judgment of noninfringement. Second, the Court denied Spectrum’s motion to supplement its allegations of alleged antitrust violations, finding that if such an amendment were allowed, Spectrum’s claims would not survive a motion for summary judgment. Spectrum thereafter withdrew its antitrust and inequitable conduct counterclaims. Spectrum did not appeal the District Court's denial of its motion to amend. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. On February 14, 2025, the Court of Appeal affirmed the District Court’s judgment. The Company is considering its appellate options. On February 7, 2024, the PTO issued a Final Written Decision regarding the second patent in the litigation, holding that claims 1, 3–8, 11, and 12 of U.S. Patent No. 11,002,646 B2 are unpatentable. On March 8, 2024, the Company filed a Request for Rehearing by the Director of the PTO of the Final Written Decision. On March 27, 2024, the Company’s Request for Rehearing was denied. On September 15, 2023, Spectrum filed a separate petition for *inter partes* review of a third patent, which DNAG did not assert in the District Court. On March 26, 2024, the PTO issued a Decision Granting Institution of *Inter Partes* Review. On July 2, 2024, the Company filed a Motion to Amend the claims of the third patent and oral argument in this IPR took place on January 24, 2025. On February 19, 2025, the PTO issued a Final Written Decision regarding the third patent in the litigation, granting the Company's Motion to Amend as to cancelling the original claims,

but denying the Company's Motion to Amend as to adding proposed substitute claims. The Company is considering its appellate options.

NowDiagnostics Litigation

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.

16. 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 $1.2 million, $1.6 million and $1.8 million to the 401(k) Plan, net of forfeitures, in 2024, 2023, and 2022, 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, 2024 and 2023, the value of the assets associated with this plan was $0.7 million and $0.8 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, 2024 and 2023, the Company's total obligation under this plan was $0.7 million and $0.8 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 $0.4 million, $0.4 million and $0.5 million to the RRSP in 2024, 2023, and 2022, respectively.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

Agreement and Plan of Merger

by and among

OraSure Technologies, Inc.,

Project Watson Merger Sub, Inc.,

Sherlock Biosciences, Inc.

and

Mr. Paul Meister, as the Securityholder Representative

December 19, 2024

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ANNEXES AND EXHIBITS

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AGREEMENT AND PLAN OF MERGER

This Agreement and Plan of Merger (this "**Agreement**") is made and entered into as of December 19, 2024 (the "**Agreement Date**"), by and among OraSure Technologies, Inc., a Delaware corporation ("**Parent**"), Project Watson Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Parent ("**Merger Sub**"), Sherlock Biosciences, Inc., a Delaware corporation (the "**Company**"), and Mr. Paul Meister, solely in its capacity as representative of the securityholders of the Company for certain purposes described in this Agreement (the "**Securityholder Representative**"). Unless the context otherwise requires, references herein to the "**parties**" means Parent, Merger Sub, the Company and the Securityholder Representative. Certain capitalized terms used herein have the meanings set forth in Article 1 or elsewhere in this Agreement as identified in Article 1.

Recitals

A. The parties intend to effect a business combination through the merger of Merger Sub with and into the Company (the "**Merger**"), with the Company continuing as the surviving corporation in the Merger (the "**Surviving Corporation**") upon the terms and subject to the conditions set forth in this Agreement and in accordance with the General Corporation Law of the State of Delaware (the "**DGCL**").

B. The boards of directors of Parent, Merger Sub and the Company have determined that the Merger is in the best interests of their respective companies and stockholders and have unanimously approved and declared advisable the Merger on the terms and subject to the conditions set forth in this Agreement, and the board of directors of the Company has unanimously recommended the adoption of this Agreement by the stockholders of the Company.

C. Concurrently with the execution and delivery of this Agreement, and as a condition and inducement to Parent's willingness to enter into this Agreement, the Persons identified on Schedule 1.1(a) (the "**Major Stakeholders**") are executing and delivering to Parent joinder agreements in substantially the form attached hereto as Exhibit A (the "**Joinder Agreement**").

D. Concurrently with the execution of this Agreement, and as a condition and inducement to Parent's and Merger Sub's willingness to enter into this Agreement, (i) the Company's stockholders sufficient to deliver the Stockholder Approval, including all Major Stakeholders, are delivering to the Company a duly executed irrevocable written consent in the form attached hereto as Exhibit B (the "**Written Consent**") which written consent (x) is conditioned upon, and shall become effective immediately following, the execution and delivery of this Agreement and, (y) when effective, shall constitute, collectively, the receipt of Stockholder Approval.

Agreement

Now, Therefore, in consideration of the foregoing and the representations, warranties, covenants and agreements contained herein, and intending to be legally bound hereby, the parties hereby agree as follows:

Article 1
DEFINITIONS

1.1 Certain Definitions. For the purposes of this Agreement, the following capitalized terms shall have the meanings set forth below (which shall apply equally to both the singular and plural forms of such terms):

"**Accounting Principles**" means GAAP, and to the extent consistent therewith, the accounting principles and policies as adjusted on Schedule 1.1(b).

"**Action**" means any action, order, writ, injunction, demand, claim, suit, litigation, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, arbitration, mediation, audit, inquiry, dispute, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Authority or any arbitrator or arbitration panel.

"**Affiliate**" means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Person, and the term "**control**" (including the terms "**controlled by**" and "**under common control with**") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of voting securities, by Contract or otherwise. References herein to Affiliates of Parent shall be deemed to include the Surviving Corporation and its Subsidiaries following the Effective Time.

"**Affordable Care Act**" means the Patient Protection and Affordable Care Act (Pub. L. 111−148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111−152), and the regulations promulgated pursuant to each of the foregoing laws.

"**Balance Sheet Date**" means November 30, 2024.

"**Base Consideration Value**" means an amount equal to Five Million Dollars ($5,000,000).

"**Books and Records**" means all files, documents, instruments, papers, books and records relating to the Company and its Subsidiaries, the business, operations or condition of the Company and its Subsidiaries, or each of the Company's and its Subsidiaries' respective properties and assets, including financial statements, internal reports, Tax Returns and related work papers and letters from accountants, budgets, pricing guidelines, ledgers, journals, deeds, title policies, minute books, share certificates and books, share transfer ledgers, Contracts, licenses, customer lists, computer files and programs (including data processing files and records), retrieval programs, operating data and plans, and environmental studies and plans.

"**Business Day**" means any day that is not a Saturday, Sunday or other day on which banks are required or authorized by Law to be closed in New York, New York.

"CARES Act" means the Coronavirus Aid, Relief, and Economic Security Act of 2020 (Pub. L. 116–136), as amended and in effect from time to time, and any successor statute(s), together with any rules and regulations promulgated in connection therewith, any rulings or orders issued by any applicable Governmental Authority (including, without limitation, the Small Business Administration) thereunder, or the application or official interpretation of any of the foregoing.

"**Cash**" means, as of a given time, the aggregate amount of all cash and cash equivalents required or permitted to be reflected as cash and cash equivalents on a consolidated balance sheet of the Company and its Subsidiaries as of such time prepared in accordance with GAAP, including cash, checks and wires received by the Company, its Subsidiaries or its banks prior to such date, whether or not cleared and less any checks written by, or wires issued by or on behalf of, the Company or its Subsidiaries prior to such date but not yet cleared, but excluding all restricted cash, including security deposits, cash held pursuant

to escrow arrangements, collateral for letters of credit, bonds and similar arrangements and the cash payable as Taxes to repatriate any cash held in any jurisdiction outside the United States.

"**CE Certificate**" means the certification that a product meets all relevant European Union medical device or in vitro diagnostic medical device (IVD) regulations and guidance, including Regulation (EU) 2017/745, Regulation (EU) 2017/746 and guidance from the Medical Device Coordination Group, and is a legal requirement to place a device on the market in the European Union.

"**Change of Control Payment**" means (i) any payment, benefit or other obligation triggered by or that becomes due as a result of the Merger or the other transactions contemplated by this Agreement (either alone or in connection with any other event, contingent or otherwise, or the passage of time), whether due prior to, at or after the Closing (whether or not subject to vesting or other conditions), arising out of any management, incentive or phantom equity, employment, retention, bonus, change in control, paid time-off, severance, or other similar arrangement with any current or former director, officer, employee, independent contractor or any other service provider of the Company or any of its Subsidiaries (including any separation payment, contractual or otherwise, or statutory severance payments or payments in lieu of notice, including but not limited to payments in lieu of notice required under the federal WARN Act and state equivalents) and (ii) the employer portion of any payroll, employment, or similar Tax related to any of the foregoing.

"**Charter Documents**" means, with respect to an entity, the (i) articles of association, certificate of association, certificate of incorporation, certificate of formation, articles of organization, or certificate of limited partnership, (ii) bylaws, limited liability company agreement, or limited partnership agreement, and (ii) other equivalent or similar organizational documents.

"**Choate Transaction Expenses**" means all amounts due and payable to Choate, Hall & Stewart LLP incurred by the Company in connection with the transactions contemplated by this Agreement; provided, however, in no event shall such amount exceed $[***] unless consented to in writing by Parent.

"**Claim**" means a claim for indemnification, compensation or reimbursement for Losses under Article 6.

"**Closing Cash**" means the total amount of the Cash of the Company and its Subsidiaries as of the Measurement Time (as reduced by any Cash used after the Measurement Time and before the Effective Time to pay off any Indebtedness or Transaction Expenses or to make any dividends or other payments to Company Securityholders, their respective Affiliates or any other Person other than in the Ordinary Course of Business).

"**Closing Indebtedness**" means the total amount of the Indebtedness of the Company and its Subsidiaries as of the Measurement Time.

"**Closing Net Working Capital**" means, as of the Measurement Time, (i) the consolidated current assets of the Company and its Subsidiaries, excluding all Tax assets, less (ii) the consolidated current liabilities of the Company and its Subsidiaries, excluding any Tax liabilities and any items included in the calculation of Closing Indebtedness or Unpaid Transaction Expenses, in each case determined in accordance with the Accounting Principles. An illustrative example of the calculation of the Closing Net Working Capital calculated as of November 30, 2024 using the Accounting Principles set forth on Schedule 1.1(b) attached hereto.

"**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**Company Ancillary Agreement**" means each agreement or document (other than this Agreement) that the Company is to enter into as a party thereto pursuant to this Agreement.

"**Company Balance Sheet**" means the unaudited consolidated balance sheet of the Company as of the Balance Sheet Date that is included in the Company Financial Statements.

"**Company Business**" means the business of the Company and its Subsidiaries as presently conducted and as proposed by the Company and its Subsidiaries to be conducted, including the design, development, manufacturing, distribution, sale, marketing, licensing, supply, and provision of any of the Company Offerings.

"**Company Capital Stock**" means the Company Common Stock and the Company Preferred Stock.

"**Company Common Stock**" means the Company's common stock, $0.0001 par value per share.

"**Company Data**" means all data, meta-data, or information (i) transmitted to the Company or any of its Subsidiaries by users or customers of any products of the Company or any of its Subsidiaries or Company Web Site, or (ii) contained in any IT Systems or other databases of the Company (including any and all Proprietary Information, User Data, listings and other content displayed or distributed on or through any Company Offering or Company Software) and all other information, data and compilations thereof used by, or necessary to the business of, the Company or any of its Subsidiaries.

"**Company Disclosure Schedule**" means the disclosure schedule of the Company dated as of the Agreement Date and delivered to Parent concurrently with the parties' execution of this Agreement.

"**Company Employee Plan**" means each: (A) an employee benefit plan within the meaning of Section 3(3) of ERISA whether or not subject to ERISA; (B) stock option plans, stock purchase plans, bonus or incentive plans, severance pay plans, programs or arrangements, deferred compensation arrangements or agreements, employment agreements, compensation plans, programs, agreements or arrangements, change in control plans, programs or arrangements, supplemental income arrangements, vacation plans, and all other employee benefit plans, agreements, and arrangements, not described in (A) above; and (C) plans or arrangements providing compensation to employee and non-employee directors, in each case in which the Company or any ERISA Affiliate sponsors, contributes to, or provides benefits under or through such plan, or has any obligation to contribute to or provide benefits under or through such plan, or if such plan provides benefits to or otherwise covers any current or former employee, officer or director of the Company or any ERISA Affiliate (or their spouses, dependents, or beneficiaries). In the case of a Company Employee Plan funded through a trust described in Section 401(a) of the Code or an organization described in Section 501(c)(9) of the Code, or any other funding vehicle, each reference to such Company Employee Plan shall include a reference to such trust, organization or other vehicle.

"**Company Financial Statements**" means (i) the unaudited consolidated balance sheets of the Company for the eleven-month period ended November 30, 2024, (ii) the unaudited consolidated statements of operations, stockholders' equity (deficit) and cash flows of the Company for the eleven-month period ended November 30, 2024, (iii) the audited consolidated balance sheets of the Company dated as of December 31, 2022 and December 31, 2023 and (iv) the audited consolidated statements of operations, stockholders' equity (deficit) and cash flows of the Company for the years ended December 31, 2022 and December 31, 2023.

"**Company Intellectual Property Right**" means any Intellectual Property Right that is owned, purported to be owned, used, held for use, or practiced by, or exclusively licensed to, the Company or any of its Subsidiaries, including any Intellectual Property Right incorporated into or otherwise used, held for use or practiced in connection with (or planned by the Company or any of its Subsidiaries to be incorporated into or otherwise used, held for use or practiced in connection with) any Company Offering or Company Data.

"**Company Legal Expenses**" means all amounts due and payable to Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP incurred by the Company in connection with the transactions contemplated by this Agreement; provided, however, in no event shall such amount exceed $[***] unless consented to in writing by Parent.

"**Company Material Contract**" means any Contract required to be listed on the Company Disclosure Schedule pursuant to Section 3.11 (whether or not so listed).

"**Company Note Holder**" means the holder of a Company Note.

"**Company Notes**" means, collectively, (i) the Company Unsecured Notes, and (ii) the Company Secured Notes.

"**Company Note Payout Amount**" means, in respect of each Company Note, as applicable, the Company Secured Note Payout Amount or the Company Unsecured Note Payout Amount.

"**Company Offering**" means any medical, exercise, diagnostic or therapeutics device or equipment or other product that the Company or any of its Subsidiaries is currently or at any time has been manufacturing, distributing, marketing or selling and any products currently under development by the Company or its Subsidiaries.

"**Company Option**" means an option to purchase Company Common Stock issued pursuant to the Company Stock Plan.

"**Company Preferred Stock**" means, collectively, the Company Series A Preferred Stock and Company Series B Preferred Stock.

"**Company Secured Notes**" means each secured convertible promissory note of the Company that is issued and outstanding as of the Agreement Date, as amended, in such principal amount (together with all accrued but unpaid interest as of the Agreement Date), as set forth on Schedule 1.1(c) attached hereto.

"**Company Secured Note Payout Amount**" means, for each Company Secured Note, an amount equal to (i) the principal amount (together with all accrued but unpaid interest as of the Agreement Date), as set forth on Schedule 1.1(c) attached hereto, multiplied by (ii) [***]. For the avoidance of doubt, the Company Secured Note Payout Amount for each Company Secured Note is set forth on Schedule 1.1(c)

"**Company Securities**" means (i) shares of capital stock or voting securities of the Company, (ii) securities of the Company convertible into or exchangeable for shares of capital stock or voting securities of the Company, including the Company Notes, and (iii) options or other rights to acquire from the Company, or other obligation of the Company to issue, any capital stock, voting securities or securities convertible into or exchangeable for capital stock or voting securities of the Company.

"**Company Securityholders**" means each holder of Company Securities, including each Company Note Holder and each Company Stockholder.

"**Company Series A Preferred Stock**" means the Company's Series A Preferred Stock, $0.0001 par value per share.

"**Company Series B Preferred Stock**" means the Company's Series B Preferred Stock, $0.0001 par value per share.

"**Company Software**" means all Software owned by or developed by or for the Company or any of its Subsidiaries.

"**Company Stock Plan**" means the 2018 Stock Plan of the Company, as amended from time to time.

"**Company Stockholder**" means any holder of shares of Company Capital Stock.

"**Company Technology**" means any and all Technology owned, used, exclusively licensed to, held for use or practiced by the Company or any of its Subsidiaries, including any Technology incorporated into or otherwise used, held for use or practiced in connection with (or planned by the Company or any of its Subsidiaries to be incorporated into or otherwise used, held for use or practiced in connection with) any Company Offering.

"**Company Unsecured Notes**" means each unsecured convertible promissory note of the Company that is issued and outstanding as of the Agreement Date, as amended, in such principal amount (together with all accrued but unpaid interest as of the Agreement Date), as set forth on Schedule 1.1(d) attached hereto.

"**Company Unsecured Note Payout Amount**" means, for each Company Unsecured Note, an amount equal to (i) the principal amount (together with all accrued but unpaid interest as of the Agreement Date), as set forth on Schedule 1.1(d) attached hereto, multiplied by (ii) three (3). For the avoidance of doubt, the Company Unsecured Note Payout Amount for each Company Unsecured Note is set forth on Schedule 1.1(d).

"**Company Web Site**" means any public or private web site or online service owned, maintained, or operated at any time by or on behalf of the Company or any of its Subsidiaries, including the web site at www.alterg.com and any online service made available by the Company or any of its Subsidiaries.

"**Confidentiality Agreement**" means that certain Mutual Nondisclosure Agreement, by and between Parent and the Company, dated as of [***].

"**Contingent Consideration**" means, collectively, the First Milestone Payment, the Second Milestone Payment and each Royalty Payment, if any, that becomes due and payable pursuant to the terms of this Agreement.

"**Contract**" means any contract, agreement, instrument, arrangement, commitment, understanding or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts, purchase orders and sale orders), whether written or oral.

"**Copyleft License**" means any license of Technology or Intellectual Property Rights that provides, as a condition to the use, modification, or distribution of such licensed Technology or Intellectual Property Rights, that such licensed Technology or Intellectual Property Rights or any other Technology or Intellectual Property Rights that are incorporated into, derived from, based on, linked to, or used or distributed or made available with such licensed Intellectual Property Rights or Technology, be licensed, distributed, or otherwise made available (i) in a form other than binary or object code (e.g., in source code form), (ii) under terms that permit or require redistribution, reverse engineering or creation of derivative works or other modification or (iii) without a license fee. "Copyleft License" includes the GNU General Public License, the GNU Library General Public License, the GNU Lesser General Public License, the Affero General Public License, the Mozilla Public License, the Common Development and Distribution License, the Eclipse Public License, and any Creative Commons "sharealike" license.

"**Copyright**" means any copyright, mask work right, exclusive exploitation right, or similar or equivalent right with respect to Works of Authorship and Mask Works and any registration of the foregoing or application for the foregoing (including any moral or economic right, however denominated).

"**COVID-19**" means SARS-CoV-2 or COVID-19 (novel coronavirus), and any evolutions or mutations thereof or related or associated epidemics, pandemics or disease outbreaks.

"**COVID-19 Measures**" means any quarantine, "shelter in place," "stay at home," workforce reduction, shut down, closure, sequester or any other Law or Order by any Governmental Authority in connection with or in response to COVID-19, including, but not limited to, CARES Act.

"**Credentials**" means any logins, passwords, IDs, user IDs, account IDs, tokens, entitlements, certificates, authorization codes or any other assigned data or code for access to or use of any Third-Party Platform.

"**CT/NG Test**" means the Company's In Vitro Diagnostic (IVD) test that is the subject of the PROMISE Study.

"**Disregarded Shares**" means (i) the Cancelled Shares and (ii) the Dissenting Shares.

"**Dissenting Share**" means any share of Company Capital Stock (other than Cancelled Shares) that is issued and outstanding immediately prior to the Effective Time and in respect of which appraisal rights have been perfected in accordance with Section 262 of the DGCL in connection with the Merger.

"**Encumbrance**" means, with respect to any asset, any mortgage, deed of trust, lien, pledge, charge, security interest, title retention device, collateral assignment, adverse claim, exclusive license or covenant, option to obtain an exclusive license or covenant, restriction or other encumbrance of any kind in respect of such asset (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any legally permissible income or proceeds derived from any asset, any restriction on the legally permissible use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"**Enforceability Exceptions**" means, with respect to any Contract, limitations on enforcement and other remedies imposed by or arising under or in connection with (i) applicable bankruptcy, insolvency, reorganization, moratorium or other similar Laws now or hereafter in effect relating to or affecting rights of creditors generally, and (ii) rules of law and general principles of equity, including those governing specific performance, injunctive relief and other equitable remedies.

"**Environmental Law**" means any Law relating to pollution or protection of human health or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any Law or regulation relating to any emission, discharge, release or threatened release of Materials of Environmental Concern or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Materials of Environmental Concern.

"**Equity-Related Agreement**" means any stockholder agreement, investors' rights agreement, voting agreement, voting trust, preemptive right, right of first offer, right of first refusal and co-sale agreement, right of first negotiation, right to notice of the Merger, management rights agreement, and any other similar Contract to which the Company is a party or by which it is bound, relating to, affecting, or restricting the transfer of, voting of, registration of, giving of notice or consent with respect to, or dividend right of, any Company Security.

"**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended.

"**ERISA Affiliate**" means any entity, trade or business that is, or at any applicable time was, a member of a group described in Section 414(b), (c), (m) or (o) of the Code or Section 4001(b)(1) of ERISA that includes the Company.

"**FDA Approval**" means the receipt of Regulatory Approval from the FDA for the CT/NG Test pursuant to the submission of applications described in clause (i), (ii) or (iv) in the definition of Regulatory Filings.

"**First Milestone Payment**" means $15,000,000.

"**Foreign Government Official**" means any officer or employee of a Governmental Authority or an Affiliate thereof (including any sovereign wealth fund) or of a public international organization, or any Person acting in an official capacity for or on behalf of any such Governmental Authority or an Affiliate thereof, or for or on behalf of any such public international organization, or any political party, party official, or candidate thereof.

"**Fraud**" means actual and intentional common law fraud under the Laws of the State of Delaware (and not any fraud premised on recklessness or negligence).

"**Fundamental Representation Claim**" means any Claim under Section 6.2(a) with respect to any of the Fundamental Representations, other than any such Claim involving Fraud.

"**Fundamental Representations**" means the representations and warranties of the Company set forth in Sections 3.1 (Organization and Good Standing), 3.3 (Power, Authorization and Validity), 3.4 (Capitalization of the Company), 3.5(a) (No Conflict; Required Consents), 3.7 (Taxes), 3.13 (Intellectual Property) and 3.26 (Brokers' Fees).

"**Future Payments**" means, if and to the extent required to be paid pursuant to this Agreement, (i) the payment of any Contingent Consideration pursuant to Section 2.12; and (ii) the payment of any Royalty Payments pursuant to Section 2.12.

"**GAAP**" means United States generally accepted accounting principles as in effect for the applicable period or date.

"**General Representation Claim**" means any Claim under Section 6.2(a) or under Section 6.3(a), in each case with respect to any of the General Representations, other than any such Claim involving Fraud.

"**General Representations**" means the representations and warranties of the Company set forth in Article 3, other than Fundamental Representations.

"**Governmental Authority**" means any (i) multinational or supranational body exercising legislative, judicial, taxing or regulatory powers, (ii) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature, (iii) federal, state, local, municipal, foreign or other government or (iv) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, bureau, commission, instrumentality, official, organization, unit, body, subdivision, court, arbitrator or other tribunal and any authority with responsibility for overseeing and/or enforcing Privacy Laws).

"**Healthcare Laws**" means all applicable Laws to which the Company and its Subsidiaries are subject (i) relating to healthcare, healthcare providers and facilities, participation in federal health care programs, the practice of medicine, institutional and professional licensure, medical documentation and physician orders, medical record retention, laboratory services, unprofessional conduct, fee-splitting, referrals, billing and submission of false or fraudulent claims, corporate practice of medicine, claims processing, medical necessity, medical information privacy and security, patient confidentiality and informed consent, hiring of employees or health care providers or acquisition of services from Persons excluded from participation in federal health care programs, standards of care, quality assurance, risk management, utilization review, peer review, mandated reporting of incidents, occurrences, diseases and events, advertising or marketing of healthcare services, or the enforceability of restrictive covenants on health care providers; or (ii) governing or relating to the design, manufacturing, testing, distribution, sale, marketing, advertising, ordering or referring of, or the billing, coding or payment for medical devices, biological products, human cells, tissues, and cellular or tissue-based products ("**HCT/Ps**"), or other products or services pertaining to health care. Healthcare Laws includes, but is not limited to, the FDCA, the Medical Devices Regulation, the Medical Devices Directive, the In Vitro Diagnostic Regulation, the In Vitro Diagnostic Directive, Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Social Security Act), TRICARE (10 U.S.C. § 1071 *et seq.*), the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), state anti-kickback statutes, the federal self-referral law (42 U.S.C. § 1395nn), state self-referral laws, criminal false claims statutes (*e.g.*, 18 U.S.C. §§ 287 and 1001), the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. § 3801 *et seq.*), the Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a(a)(5)), the Clinical Laboratory Improvement Act (42 U.S.C. § 263a *et seq.*), the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108-173, 117 Stat. 2066), the No Surprises Act (Title XXVII of the Public Health Service Act), the Civil Monetary Penalty Law (42 U.S.C. § 1320a-7a), the civil False Claims Act (31 U.S.C. §§ 3729 *et seq.*), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d *et seq.*), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 *et seq.*) and the exclusion laws (42 U.S.C. § 1320a-7), the Prescription Drug Marketing Act of 1987, the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the Comprehensive Drug Abuse Prevention and Control Act of 1970 and any amendments thereto, the Controlled Substances Act and any amendments thereto, Pricing Reporting Laws, all regulations or guidance promulgated pursuant to such Laws and any comparable non-U.S. Law, and any other similar federal, state or non-U.S. Law that regulates the provision of healthcare or the design, development, testing, studying, manufacturing, processing, storing, importing or exporting, licensing, labeling or packaging, advertising, distributing, selling, pricing or marketing of biological products, HCT/Ps, or

medical devices, or that is related to remuneration (including ownership) to or by physicians or other health care providers (including kickbacks).

"**Indebtedness**" means, without duplication, (i) all obligations (including the principal amount thereof or, if applicable, the accreted amount thereof and the amount of accrued and unpaid interest thereon) of the Company or any of its Subsidiaries, whether or not represented by bonds, debentures, notes or other securities (whether or not convertible into any other security), for the repayment of money borrowed, whether owing to banks, financial institutions, on equipment leases or otherwise, (ii) all deferred obligations of the Company or any of its Subsidiaries for the payment of the purchase price of property or assets purchased (including any other "earn outs" or contingent payments or "seller notes" related to business acquisitions), (iii) all obligations of the Company or any of its Subsidiaries to pay rent or other payment amounts under a lease which is required to be classified as a capital lease or a liability on the face of a balance sheet prepared in accordance with GAAP, (iv) all outstanding reimbursement obligations of the Company or any of its Subsidiaries with respect to letters of credit, bankers' acceptances or similar facilities, (v) all obligations of the Company or any of its Subsidiaries under any interest rate swap agreement, forward rate agreement, interest rate cap or collar agreement or other financial agreement or arrangement entered into for the purpose of limiting or managing interest rate risks, (vi) all obligations secured by any Encumbrance existing on property owned by the Company or any of its Subsidiaries, (vii) unpaid and accrued Pre-Closing Taxes; *provided* that the sum of such amounts shall be calculated taking into account Tax assets that are deductible in a Pre-Closing Tax Period at a "more likely than not" or higher level of comfort (including deductions arising by virtue of the transactions contemplated by this Agreement) and any estimated payments and overpayments of Taxes to the extent such estimated payments or overpayments may be utilized to reduce such unpaid Taxes and shall be without duplication of any amounts included in Transaction Expenses or Closing Net Working Capital, (viii) all premiums, penalties, fees, expenses, breakage costs and change of control payments required to be paid or offered in respect of any of the foregoing on payment or prepayment (regardless if any of such are actually paid), as a result of the consummation of the Merger or any of the other transactions contemplated hereby or in connection with any consent of any counterparty with respect to any such Indebtedness, (ix) all defined benefit or defined contribution pension, multiemployer pension, post-retirement health and welfare benefit, accrued annual or other bonus obligations, any unpaid severance, vacation or "paid time off" (PTO) liabilities currently being paid or payable in respect of employees and service providers of the Company or any of its Subsidiaries who terminated employment or whose services to the Company or any of its Subsidiaries have ceased (as applicable) prior to the Closing and deferred compensation Liabilities of the Company or any of its Subsidiaries, together, in each case, with any associated employer payroll taxes (x) any obligations or Liabilities existing as of the Closing Date (whether payable to any current or former Related Party of the Company or any of its Subsidiaries or any third party, pursuant to a contract or otherwise, but shall be without duplication of any amounts included in Transaction Expenses or Net Working Capital); (xi) any deferred revenue; and (xii) all guaranties, endorsements, assumptions and other contingent obligations of the Company or any of its Subsidiaries in respect of, or to purchase or to otherwise acquire, any of the obligations and other matters of the kind described in any of the clauses (i) through (xi) appertaining to third parties.

"**Indemnified Parties**" means the Parent Indemnified Parties or Stockholder Indemnified Parties, as applicable.

"**Indemnifying Securityholders**" means each of the Company Note Holders.

"**Initial Merger Consideration**" means an amount in cash that is equal to (i) the Base Consideration Value, plus (ii) Company Legal Expenses, plus (iii) the Tail Policy Costs.

"**Intellectual Property License**" means any license, sublicense, right, covenant, non-assertion or similar covenant, permission, immunity, consent, release or waiver under or with respect to any Intellectual Property Rights or Technology.

"**Intellectual Property Right**" means any right in Technology and/or industrial property (anywhere in the world, whether statutory, common law or otherwise) including any (i) Patent, (ii) Copyright, (iii) Software, including any right with respect to Software along with registration of such right or any application to register such right, (iv) industrial design right or registration of such right and any application to register such right, (v) any Mark, and any right with respect to such Mark, registration for any Mark, and any application to register any Mark, along with all goodwill associated with each of the foregoing, (vi) any Domain Name, including any right with respect to such Domain Name and registration for any Domain Name, along with all goodwill associated with each of the foregoing, (vii) any Proprietary Information, including any right to such Proprietary Information along with any right to limit the use or disclosure of Proprietary Information by any Person, (viii) any Database, including any right with respect to any Database along with registration of such right and any application to register such right, (ix) right of publicity and personality, including any right with respect to use of a Person's name, signature, likeness, image, photograph, voice, identity, personality, and biographical and personal information and materials, (x) moral right, (xi) renewal, reissue, reversion, reexamination, or extension of any of the foregoing, and (xii) any right equivalent or similar to any of the foregoing.

"**IRS**" means the United States Internal Revenue Service.

"**IT System**" means any information technology and computer or software system (including Software, information technology and telecommunication hardware, hardware, middleware network and other equipment) relating to the transmission, storage, maintenance, organization, presentation, generation, processing or analysis of data and information and any support, disaster recovery and online service whether or not in electronic format, used in, held for use, or necessary to the conduct of the Company Business.

"**Knowledge of the Company**" or "**Company's Knowledge**" means the actual knowledge or deemed knowledge, as determined pursuant to this definition, of a particular fact, circumstance, event or other matter in question of any of [***] which such persons will be deemed to have knowledge of a particular fact, circumstance, event or other matter if such person should reasonably be expected to have knowledge of the fact, circumstance, event or other matter after conducting reasonable inquiry by such person of the Company's books and records in their control or possession and their respective direct reports (excluding, for the avoidance of doubt, external legal counsel).

"**Law**" means any foreign, federal, state, local or municipal law, statute, ordinance, directive, edict, regulation, standard, or rule, any order, ruling, writ, injunction, award, judgment or decree (and any regulations promulgated thereunder), and any other legislative measure or decision having the force of law, treaty, convention or other agreement between states, or between states and supranational bodies, rule of common law, customary law and equity and any civil or other code.

"**Lease Termination Agreement**" means [***] as landlord.

"**Liability**" means any debt, duty, Tax, obligation or liability of any kind or nature (including any unknown, undisclosed, unmatured, unaccrued, unasserted, contingent, conditional, implied, vicarious, derivative, joint, several or secondary liability), regardless of whether such debt, duty, Tax, obligation or

liability would be required to be disclosed on a balance sheet prepared in accordance with GAAP and regardless of whether such debt, duty, liability, Tax or obligation is immediately due and payable.

"**Losses**" means any and all deficiencies, judgments, settlements, assessments, Liabilities, losses, damages, interest, fines, penalties, costs, Taxes, and expenses of any kind or nature, including lost profits, diminution in value, "multiple of profits" or "multiple of cash flow," reasonable legal, accounting and other costs and expenses of professionals incurred in connection with investigating, defending, settling or otherwise satisfying any of the foregoing or matters arising out of or relating to the foregoing, and in seeking and enforcing rights to indemnification, compensation and reimbursement hereunder.

"**Mark**" means any trademark, service mark, logo and design mark, trade dress, trade name, fictitious or other business name, and brand name, together with all goodwill, registrations and applications associated with any of the foregoing.

"**Material Adverse Effect**" when used in connection with an entity means any effect, event, change, fact, occurrence, circumstance or development, that individually or in the aggregate has had or would reasonably be expected to have a material adverse effect on (i) the prospects, condition (financial or otherwise), results of operations, assets, liabilities, or Company Business, taken as a whole, or (ii) the ability of the Company to timely perform its obligations under this Agreement or to consummate the transactions contemplated hereby; provided, however, that solely in the case of clause (i), "Material Adverse Effect" shall not include any effect, event, change, fact, occurrence, circumstance or development, to the extent resulting from or attributable to: (a) general economic, business, financial, market or political conditions; (b) conditions generally affecting the industries or industry sectors in which the Company operates; (c) any changes in financial, banking, or securities markets in general, including any disruption thereof and any decline in the price of any security or any market index or any change in prevailing interest rates; (d) acts of war (whether or not declared), armed hostilities, or terrorism, or the escalation or worsening thereof; (e) any changes in applicable Laws or accounting rules (including GAAP) or the enforcement, implementation or interpretation thereof; (f) any natural or man-made disasters, epidemics and pandemics or acts of God, including, but not limited to, COVID-19; or (g) any action required by this Agreement or any action taken (or omitted to be taken) with the written consent of or at the written request of Parent or Merger Sub, in each case, after the date hereof, except in the case of the foregoing clauses (a) through (f), to the extent such effect, event, change, fact, occurrence, change, circumstance or development has had or would be reasonably expected to have, individually or in the aggregate, a disproportionate impact on the Company compared to other participants engaged in the industry in which the Company operates.

"**Materials of Environmental Concern**" means any chemical, pollutant, contaminant, waste, toxic substance, petroleum or petroleum product or any other substance that is currently regulated by an Environmental Law or that is otherwise a danger to health, reproduction or the environment.

"**Measurement Time**" means 12:01 a.m. local time in New York, New York on the Closing Date.

"**Merger Sub Ancillary Agreements**" means each agreement or document (other than this Agreement) that Merger Sub is to enter into as a party thereto pursuant to this Agreement.

"**Merger Sub Common Stock**" means the common stock, $0.0001 par value per share, of Merger Sub.

"**Multiemployer Plan**" has the meaning set forth in Section 3(37) of ERISA.

"**Net Sales**" means, following Regulatory Approval of the CT/NG Test in such country, jurisdiction or market in the Territory, the aggregate gross amount invoiced by Parent or its Affiliates, including to its agents and distributors, for the sale of the CT/NG Test in the Territory on the basis of such Regulatory Approval, less the following discounts [***].

"**Net Working Capital Deficit**" means the amount by which the Target Net Working Capital exceeds the Closing Net Working Capital (reflected as a positive number), as determined by Parent following the Closing.

"**Order**" means any decree, order, judgment, writ, award, injunction, stipulation or consent of or by a Governmental Authority.

"**Ordinary Course of Business**" means a course of business that is in the ordinary course of the business of the Company and its Subsidiaries and consistent with its past practices, including with respect to frequency and amounts.

"**Parent Ancillary Agreements**" means each agreement or document (other than this Agreement) that Parent is to enter into as a party thereto pursuant to this Agreement.

"**Patent**" means any patent or patent application, industrial designs and design patent rights, utility model or application for any utility model, inventor's certificate or application for any inventor's certificate, or invention disclosure statement, including any nonprovisionals, substitutions, continuations, divisionals, continuations-in-part and provisional applications and any patents issuing on any of the foregoing and any reissues, supplementary protection certificates, reexaminations, substitutes, term extensions, certificates of invention and extensions of any of the foregoing and the equivalents of any of the foregoing.

"**[***] Milestone**" means [***] on or before December 31, 2026 [***].

"**Per Note Initial Merger Consideration**" means the portion of the Initial Merger Consideration payable at the Closing in respect of the applicable Company Note, as in effect at the Closing, and as set forth on the Initial Payment Allocation Schedule.

"**Per Note Future Payment**" means the portion of each Future Payment, if any, payable in respect of the applicable Company Note, as set forth on the applicable Future Payment Allocation Schedule.

"**Per Share Future Payment**" means the portion of each Future Payment, if any, payable in respect of the applicable share of Company Capital Stock, in accordance with the liquidation waterfall set forth in the Company's Amended and Restated Certificate of Incorporation, as in effect at the Closing, and as set forth on the applicable Future Payment Allocation Schedule.

"**Permitted Encumbrance**" means (i) any statutory lien for Taxes (a) not yet due or delinquent or (b) the validity or amount of which is being contested in good faith by appropriate proceedings; *provided* that in the case of clause (b), adequate reserves in accordance with GAAP have been established therefor on a basis consistent with prior periods and are reflected on the Company Financial Statements; (ii) any mechanics', carriers', workers', repairers' or other similar lien arising or incurred in the Ordinary Course of Business relating to obligations as to which there is no default on the part of the Company or any of its Subsidiaries or the validity or amount of which is being contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP have been established therefor on

a basis consistent with prior periods and are reflected on the Company Financial Statements; (iii) any pledge, deposit or other lien securing the performance of bids, trade contracts, leases or statutory obligations (including workers' compensation, unemployment insurance or other social security legislation); and (iv) with respect to any real property leased by the Company or any of its Subsidiaries (a) any Encumbrance on leases, subleases, easements, licenses, rights of use, rights to access and rights of way arising therefrom or benefiting or created by any superior estate, right or interest, (b) any Encumbrance that would be set forth in any title policies, endorsements, title commitments, title certificates and/or title reports and any zoning, entitlement, conservation restriction and other land use and environmental regulations by Governmental Authorities, and (c) any minor encroachment; *provided*, *however*, that none of the foregoing Encumbrances or encroachments described in clause (iv) could, individually or in the aggregate, impair, in any material respect, the continued use and operation of the property to which they relate in the Company Business.

"**Person**" means any individual, corporation, company, limited liability company, partnership, limited partnership, limited liability partnership, trust, estate, proprietorship, joint venture, association, organization, or other entity of any kind or nature or any Governmental Authority.

"**Personal Information**" means, in addition to all information defined or described by the Company or its Subsidiaries as "personal data," "personal information," "personally identifiable information," "PII," or any similar term in the Company's or its Subsidiaries' privacy policies or other public-facing statement, any information that is subject to any Privacy Law or regarding or capable of being associated with an individual consumer or device, including: (i) information that identifies, could be used to identify (alone or in combination with other information) or is otherwise identifiable with an individual or a device, including name, physical address, telephone number, email address, financial account number, government-issued identifier (including Social Security number and driver's license number), medical, health or insurance information, gender, date of birth, educational or employment information, any religious or political view or affiliation, marital or other status, photograph, face geometry, or biometric information, and any other data used or intended to be used to identify, contact or precisely locate an individual, (ii) any data regarding any activity of an individual online or on a mobile device or other application (*e.g.*, any search conducted, web page or content visited or viewed), whether or not such information is associated with an identifiable individual, and (iii) any Internet Protocol address or other persistent identifier, in each case collected by or on behalf of, or controlled by, the Company or its Subsidiaries. Personal Information may relate to any individual, including any user of any Internet or device application who views or interacts with any Company Offering, or a current, prospective or former customer, employee or vendor of any Person. Personal Information includes information in any form, including paper, electronic and other forms.

"**PHI**" means "protected health information" as defined in 45 C.F.R. § 160.103.

"**PMA**" means (a) in the U.S., a premarket approval application (including any supplement thereto) made to the FDA for a medical device in accordance with section 515 of the FDCA and the applicable regulations including 21 C.F.R. Part 814, or (b) any analogous application to those set forth in the foregoing clause (a) that is filed with the relevant Governmental Authority in a country or region, including any supplemental applications including any supplemental applications thereto.

"**Pre-Closing Taxes**" means (i) any Tax imposed on the Company or any of its Subsidiaries in respect of any Pre-Closing Tax Period, (determined, with respect to any Straddle Period, in accordance with Section 9.4), (ii) any Tax of any Company Securityholder or any of its Affiliates for which any of the Company, any of its Subsidiaries or any Indemnified Party is or may be liable, whether by reason of

any requirement to withhold or otherwise, and incurred in connection with the Merger or this Agreement, (iii) any Tax for which the Company or any of its Subsidiaries is held liable under Treasury Regulations Section 1.1502-6 (or any corresponding or similar provision of state, local or foreign Tax Law) by reason of the Company or any of its Subsidiaries being included in any consolidated, affiliated, combined or unitary group in any Pre-Closing Tax Period, (iv) any Tax of another Person for which the Company or any of its Subsidiaries is held liable as a result of being a successor or transferee of such Person on or prior to the Closing Date or as a result of any express or implied obligation existing on or prior to the Closing Date to indemnify, compensate or reimburse any such Person, by Contract or otherwise, (v) any Taxes due with respect to income that was, or would be, recognized in a Pre-Closing Tax Period under Sections 951, 951A or 952 of the Code under a "closing of the books" if the Closing Date were the last day of the taxable year for the Company or such Subsidiary, (vi) any deferred payments to be made in future taxable periods pursuant to Section 965(h) of the Code as though such amounts were due as of the Closing Date, (vii) any Tax incurred as a result of the transactions contemplated by this Agreement, including the employer portion of any payroll or employment Taxes with respect to any payments arising as a result of the transactions contemplated by this Agreement and (viii) any Transfer Taxes for which the Company Stockholders are liable pursuant to Section 7.5; provided, that, Pre-Closing Taxes shall be without duplication of any amounts included in Transaction Expenses, Closing Net Working Capital or otherwise included in the calculation of Total Merger Consideration.

"**Pre-Closing Tax Period**" means any Tax period ending on or before the Closing Date and that portion of any Straddle Period ending on and including the Closing Date.

"**Pricing Reporting Laws**" means, collectively, the applicable rules and regulations relating to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126), the Medicare Part D Coverage Gap Discount Program, or any state pharmaceutical assistance program or U.S. Department of Veterans Affairs agreement, and any successor government programs, or any equivalent non-U.S. Laws, rules or regulations by a comparable foreign Governmental Authority.

"**Privacy Law**" means any Law that governs the receipt, collection, compilation, use, storage, processing, sharing, safeguarding, security, disposal, destruction, disclosure or transfer of Personal Information or User Data and any such Law governing breach notification, any penalties and compliance with any order, including the Children's Online Privacy Protection Act, the Telephone Consumer Protection Act, the California Online Privacy Protection Act, the California Consumer Privacy Act, the Video Privacy Protection Act, the Communications Decency Act, the CAN-SPAM Act and Canada's Anti-Spam Legislation, the Payment Card Industry – Data Security Standards or other requirements of the payment card brands, HIPAA, and the UK Data Protection Act 2018, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation or "**GDPR**"), EU Directive 2002/58/EC and any laws or regulations implementing either or both of the GDPR and EU Directive 2002/58/EC (each as amended from time to time) and any analogous legislation in any jurisdiction in which the Company carries on its business and / or from which the Company and its Subsidiaries collects Personal Information, as well as applicable industry standards.

"**PROMISE Study**" means the Company's clinical study to evaluate the performance of its Chlamydia Trachomatis and Neisseria Gonorrhoeae (CT/NG) over-the-counter disposable molecular test to enable a submission for a De Novo 510(k).

"**Pro Rata Share**" means, as to each Indemnifying Securityholder, the quotient (expressed as a percentage) obtained by dividing (i) the amount of Total Merger Consideration actually received by such Indemnifying Securityholder pursuant to this Agreement as of the applicable time of distribution by (ii) the aggregate amount of the Total Merger Consideration actually received by all Indemnifying Securityholders pursuant to this Agreement. The aggregate Pro Rata Shares of all Indemnifying Securityholders shall equal 100%.

"**Proprietary Information**" means any information or material not generally known to the public, including any trade secret, know-how or other confidential and proprietary information.

"**Registered Company Intellectual Property Right**" means (i) any issued Patent, Patent application, Mark registration, application for Mark registration, Copyright registration, application for Copyright registration and Domain Name registration owned, purported to be owned, filed or applied for by or on behalf of the Company or any of its Subsidiaries, and (ii) any other application, registration, recording and filing filed by or on behalf of the Company or any of its Subsidiaries (or otherwise authorized by or in the name of the Company or any of its Subsidiaries) with respect to any Company Intellectual Property Right.

"**Regulatory Approval**" means all authorizations, registrations, approvals or clearances with or by the appropriate Regulatory Authorities which are required for the use of a product in any country or regulatory jurisdiction, including obtaining approval or clearance pursuant to any Regulatory Filings, as well as the marketing, promotion and sale of such product.

"**Regulatory Filings**" means (i) a *de novo* classification request made to the FDA pursuant to Section 513(f)(2) of the FDCA, (ii) a 510(k) premarket notification made to the FDA pursuant to 21 C.F.R. Part 807, Subpart E, (iii) an investigational device exemption for a medical device as described in 21 C.F.R. Part 812, (iv) a PMA, (v) a conformity assessment to obtain a CE Certificate, (vi) conformity assessment to obtain a UKCA Certificate, or (vii) any analogous applications or equivalent filings in any country or regulatory jurisdiction other than the U.S., or any additional filings with any Governmental Authority relating to a Regulatory Approval of a product.

"**Related Party**" means (i) any Affiliate of the Company or any of its Subsidiaries, or any director, executive officer, general partner or managing member of such Affiliate, (ii) any officer or director of the Company or any of its Subsidiaries, (iii) any Immediate Family member of a Person described in clause (b), or (iv) any other Person who holds, individually or together with any Affiliate of such other Person and any member(s) of such Person's Immediate Family, any outstanding Company Securities.

"**Representatives**" means, with respect to any Person, such Person's officers, directors, employees, agents, advisors (including any attorneys, financial advisors, investment bankers or accountants) and other representatives.

"**Royalty Term**" means the period beginning as of the Closing Date and ending on December 31, 2034.

"**Second Milestone Payment**" means $5,000,000.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Software**" means any (i) computer program, including any API or SDK, software implementation of any algorithm, model or methodology, whether in source code, object or executable code, or other form, (ii) Database, (iii) descriptions, flow-charts and other work product used to design, plan, organize and develop any of the foregoing, screens, subroutines, user interfaces, report formats, firmware, development tools, templates, menus, buttons and icons and (iv) documentation, including user manuals and other training documentation, related to any of the foregoing.

"**Special Matter**" means (i) any Fundamental Representation Claim or (ii) any Claim under any of clauses (b) through (f) of Section 6.2.

"**Stakeholder Claim**" means any claim (i) asserted by any current, former or alleged holder of Company Securities or any Person who has any right or claim with respect to ownership of any Company Securities (whether against the Company, Parent, any Affiliate of the Company or Parent, or any officer, director, employee, agent or representative of any of the foregoing) (A) relating to this Agreement, any other agreement entered into in connection with this Agreement, the Merger or any of the other transactions contemplated hereby or thereby, (B) alleging any ownership of or interest in any Company Securities that is not specifically disclosed in the Closing Statement, (C) relating to any rights of a securityholder of the Company (or any Subsidiary of the Company), including any rights to Company Securities, anti-dilution protection, preemptive rights, rights of first offer or first refusal, or rights to notice or to vote and any claim that any formulas, definitions or provisions related to the payment of the Initial Merger Consideration or the Future Payments or application thereof are incorrect, (D) relating to any rights under the Charter Documents or any other Equity-Related Agreement, (E) that such Person's securities were wrongfully issued, cancelled or repurchased by the Company, (F) relating to any actual or alleged breach of fiduciary duties, and (G) related to the Initial Payment Allocation Schedule or any Future Payment Allocation Schedule; or (ii) any current or former officer, director or employee for indemnification or advancement of expenses in respect of claims made against them arising out of or in connection with their employment with or service to the Company or any of its Subsidiaries on or prior to the Effective Time, whether or not asserted prior to the Effective Time or (B) relating the exercise by any Company Stockholder of appraisal rights or dissenters' rights under applicable Law, including any payment made with respect to any Dissenting Share to the extent that such payment exceeds the value of the amount that otherwise would have been payable pursuant to Section 2.4 for such Dissenting Share.

"**Stockholder Approval**" means the affirmative vote of (i) the holders of a majority of all outstanding shares of Company Common Stock and Company Preferred Stock (on an as-converted basis), voting together as a single class, (ii) the holders of a majority of all outstanding shares of Company Preferred Stock (including any Company Common Stock issued upon conversion of shares of Company Preferred Stock), voting together as a single class, (iii) the holders of a majority of all outstanding shares of Company Series A Preferred Stock, voting as a single class, and (iv) the holders of a majority of all outstanding shares of Company Series B Preferred Stock, voting as a single class.

"**Straddle Period**" means any Tax period beginning before or on the Closing Date and ending after the Closing Date.

"**Subsidiary**" means, with respect to any Person, any entity (whether or not incorporated) of which (i) such Person or any other Subsidiary of such Person is a general partner (excluding partnerships, the general partnership interests of which held by such Person or any Subsidiary of such Person do not have a majority of the voting interest in such partnership) or (ii) at least a majority of the securities or other interests having by their terms ordinary voting power to elect a majority of the board of directors or others performing similar functions with respect to such entity or a majority of the profit interests in such

entity is directly or indirectly owned or controlled by such Person or by any one or more of its Subsidiaries, or by such Person and one or more of its Subsidiaries.

"**Tail Policy Costs**" means all amounts due and payable to [***] in connection with the binding of the Tail Policy.

"**Target Net Working Capital**" means $[***].

"**Tax**" (and, with correlative meaning, "**Taxes**") means (i) any federal, state, local or foreign income, alternative or add-on minimum, gross income, gross receipts, sales, use, VAT, transfer, franchise, profits, license, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, environmental, escheat, unclaimed property, estimated or windfall profit tax, custom duty, national insurance tax, health tax or other tax or other like assessment or charge in the nature of a tax, together with any interest or any penalty, addition to tax or additional amount imposed by any Governmental Authority responsible for the imposition of any such tax (domestic or foreign), whether disputed or not, (ii) any Liability for the payment of any amount of the type described in clause (i) as a result of being a member of an affiliated, consolidated, combined, unitary or aggregate group for any Tax period, and (iii) any Liability for the payment of any of the type described in clause (i) or (ii) as a result of being a transferee of or successor to any Person or as a result of any express or implied obligation to indemnify any other Person, by Contract or otherwise.

"**Tax Authority**" means any Governmental Authority or political subdivision thereof having jurisdiction over the reporting, withholding, assessment, determination, collection or other imposition in respect of Taxes.

"**Tax Return**" means any return, amended return, election declaration, report, voluntary disclosure, claim for refund, information return or statement filed or required to be filed in respect of Taxes, including any schedule or attachment thereto, and including any amendment thereof.

"**Technology**" means any: (i) technology, formulae, algorithm, procedure, process, method, technique, idea, know-how, creations, inventions, discoveries and improvement (whether patentable or unpatentable and whether or not reduced to practice); (ii) technical, engineering, manufacturing, product, marketing, servicing, business, financial, supplier, personnel or other information and materials; (iii) customer list, customer contact and registration information, customer correspondence and customer purchasing history; (iv) specification, design, industrial design, model, device, prototype, schematic, configuration and development tool; (v) Software, website, content, image, logo, graphic, text, photographs, artwork, audiovisual works, sound recording, graph, drawing, reports, analysis, writing, of any other work of authorship and copyrightable subject matter ("**Work of Authorship**"); (vi) database or other compilation or collection of data or information ("**Database**"); (vii) mask work, layout, topography or other design feature with respect to any integrated circuit ("**Mask Work**"); (viii) Mark; (ix) domain name, uniform resource locator or other name or locator associated with the Internet ("**Domain Name**") or social media identifier; and (x) tangible embodiments of any of the foregoing, in any form or media whether or not specifically listed in this definition.

"**Territory**" means worldwide.

"**Third-Party Platform**" means any other Person's device, platform, server, application, operating system, website, networked physical object (including Internet of Things (IoT)), software as a service, platform as a service, infrastructure as a service, cloud service or similar service.

"**Total Merger Consideration**" means the Initial Merger Consideration and all Future Payments that actually become payable pursuant to this Agreement.

"**Transaction Expense**" means any cost or expense of any kind or nature incurred by, paid by, or to be paid by, the Company or any of its Subsidiaries in connection with the Merger and this Agreement and the transactions contemplated by this Agreement, as well as any related sale or financing process, including, without duplication, (i) any fee or expense of any investment banker, financial advisor, legal counsel, accountant or other professional advisor, (ii) any Change of Control Payment, (iii) the employer portion of any employment, payroll or similar Tax based on any compensation payments made pursuant to this Agreement (excluding, for the avoidance of doubt, any such Taxes related to any other compensatory payments for services performed after the Closing or any compensatory payments that vest after the Closing Date in connection with the Merger)), (iv) any liabilities incurred in connection with the termination of agreements between or among the Company or any of its Subsidiaries and a Related Party, (v) the Choate Transaction Expenses, (vi) the Tail Policy Costs and (vii) the Paying Agent's fees in connection with the transactions contemplated by this Agreement.

Treasury Regulations" means the United States Treasury Regulations promulgated under the Code.

"**UKCA Certificate**" means the certification that a product meets all relevant United Kingdom medical device or IVD regulations and guidance, including the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) and guidance MEDDEVs, and is a legal requirement to place a device on the market in the United Kingdom.

"**Unpaid Transaction Expenses**" means all Transaction Expenses, in each case whether due prior to, on or after the Closing, that are unpaid as of the Measurement Time.

"**User Data**" means any Personal Information or other data or information collected by or on behalf of the Company or any of its Subsidiaries from any user of any website or any Company Offering or Company Software.

"**[***] Milestone**" means [***] on or before December 31, 2026 [***].

"**VAT**" means any ad valorem, value added, goods and services or similar Tax.

"**Virtual Data Room**" means the electronic data site maintained by the Company in connection with the Merger with Sherlock Fileshare.

"**WARN Act**" means the Worker Adjustment and Retraining Notification Act, as amended, and all state and local statutory equivalents.

1.2 Other Definitions. Other capitalized terms used in the Agreement and not defined in this Annex A shall have the meanings assigned to such terms in this Agreement in the sections referenced below.

Defined Term	***Section***
Agreement	Preamble
Agreement Date	Preamble
Basket	6.4(a)
Board Approval	3.3(c)

Bribery Act	3.22(a)
Cancelled Shares	2.4(b)
Certificate of Merger	2.2
Certificates	2.6(d)(i)
Claim Notice	6.5
Closing	2.1
Closing Date	2.1
Company	Preamble
Company Employee Plan	3.16(n)
Company Service Providers	3.14(b)
Contingent Workers	3.16(a)
DGCL	Recitals
Effective Time	2.2
Exchange Agent	2.6(a)
Expiration Date	6.1
FCPA	3.22(a)
FDCA	3.24(a)
General Representation Cap	6.4(b)
Governmental Permits	3.15(b)
Inbound License	3.11(a)(iii)
Information Security Reviews	3.14(l)
Information Statement	5.1(a)
Insurance Policies	3.18
Invention Assignment Agreement	3.13(m)
Joinder Agreement	Recitals
Letter of Transmittal	2.6(d)(i)
Licensed IP	3.13(c)
Major Stakeholders	Recitals
Merger	Recitals
Merger Sub	Recitals
Non-Core Company Offering	0
Owned Company IP	3.13(c)
Parent	Preamble
Parent Prepared Return	7.1
Payment Condition	2.6(d)(i)
PIIAA	Recitals
[***]	5.9(e)
Privacy Requirements	3.14(b)
Securityholder Representative	Preamble
Significant Supplier	3.20
Standard EULAs	3.11(a)(iii)
Standard Form Agreements	3.13(h)
Stockholder Approval	3.3(d)
Surviving Corporation	Recitals
Tail Policy	5.6

Takeover Statute	3.3(e)
Tax Contest	7.2
Terminated Agreements	5.7
Third-Party Claim	6.6
Trade Approvals	3.23(a)
Trade Laws	3.23(a)
Transfer Taxes	7.5
Union	3.16(d)
Unused Product Assets	5.8
Unused Product Asset Determination	5.8
Written Consent	Recitals

Article 2
THE MERGER

2.1 The Closing. The closing of the Merger (the "**Closing**") shall take place through the electronic exchange of documentation on the date hereof immediately following the Effective Time. The date on which the Closing occurs is referred to herein as the "**Closing Date**."

2.2 The Merger. On the Closing Date, the Company and Merger Sub shall cause the Merger to be consummated by filing a certificate of merger (the "**Certificate of Merger**"), with the Secretary of State of the State of Delaware in accordance with the DGCL. The time of such filing and acceptance by the Secretary of State of the State of Delaware shall be referred to herein as the "**Effective Time**." At the Effective Time, Merger Sub shall be merged with and into the Company, the separate existence of Merger Sub shall cease and the Company shall continue as the Surviving Corporation. The effects of the Merger shall be as provided in this Agreement and the applicable provisions of the DGCL.

2.3 Charter Documents; Directors and Officers. Unless otherwise agreed in writing by Parent and the Company prior to the Effective Time:

(a) at the Effective Time, the certificate of incorporation and the bylaws of the Surviving Corporation shall be amended to be identical to the certificate of incorporation and the bylaws of Merger Sub, respectively, (except that the name of the Surviving Corporation shall not be changed), as in effect immediately prior to the Effective Time; and

(b) the directors and officers, respectively, of Merger Sub serving in such positions immediately prior to the Effective Time shall become, as of the Effective Time, the directors and officers, respectively, of the Surviving Corporation, to hold office until their respective successors are duly appointed or elected and qualified, as applicable, or their earlier death, resignation or removal.

2.4 Effect of the Merger on Company Securities and Merger Sub Capital Stock. At the Effective Time, by virtue of the Merger, subject to the terms and conditions of this Agreement, and without any further action on the part of the parties, any Company Securityholder or any other Person:

(a) each share of Merger Sub Common Stock that is issued and outstanding immediately prior to the Effective Time shall be converted into one newly and validly issued, fully paid and nonassessable share of common stock, $0.0001 par value per share, of the Surviving Corporation, and the shares of the Surviving Corporation into which the shares of Merger Sub Common Stock are so converted shall be the only shares of capital stock of the Surviving Corporation that are issued and outstanding immediately after the Effective Time;

(b) each share of Company Capital Stock held in the Company's treasury or owned by the Company immediately prior to the Effective Time shall be cancelled and extinguished without consideration or conversion (the "**Cancelled Shares**");

(c) subject to the terms and conditions of this Agreement and the applicable Note Cancellation Agreement, each Company Note that is issued and outstanding immediately prior to the Effective Time shall be cancelled and extinguished and shall cease to represent any rights other than the right of each Company Note Holder as of immediately prior to the Effective Time to receive, in respect of each Company Note held by such Company Note Holder, an amount in cash, without interest, equal to (i) the applicable Per Note Initial Merger Consideration payable in respect of such Company Note and (ii) in respect of each Future Payment to be made to the Indemnifying Securityholders (if, as and when payable in accordance with the terms of this Agreement), if any, the applicable Per Note Future Payment applicable to such Future Payment payable in respect of such Company Note; provided, however, that the amounts payable pursuant to this Section 2.4(c) in respect of any Company Note shall in no event exceed the applicable Company Note Payout Amount;

(d) subject to the terms and conditions of this Agreement, each share of Company Capital Stock that is issued and outstanding immediately prior to the Effective Time shall be cancelled and extinguished and, other than Disregarded Shares, automatically converted into the right to receive an amount in cash, without interest in respect of each Future Payment to be made to the Company Stockholders (if, as and when payable in accordance with the terms of this Agreement), that is in excess of the maximum aggregate Company Note Payout Amount, if any, the applicable Per Share Future Payment applicable to such Future Payment payable in respect of such share of Company Capital Stock; and

(e) each Company Option shall be terminated, cancelled and extinguished without the payment of any consideration at the Effective Time or thereafter. Prior to the Effective Time, the Company and the Company Board (or, if appropriate, any committee thereof administering the Company Stock Plan) shall adopt such resolutions and take such other actions as may be required or necessary to (i) provide for the treatment of Company Options as contemplated in this Section 2.4(e), (ii) provide that, from and after the Effective Time, neither Parent nor the Surviving Corporation will be required to deliver any shares of Capital Stock to any Person pursuant to any Company Options, and (iii) terminate the Company Stock Plan effective as of and contingent upon the Effective Time.

2.5 [Intentionally Omitted].

2.6 Allocation of Payments; Surrender of Certificates; Mechanics for Payment and Exchange.

(a) Initial Payment Allocation Schedule. Not less than two (2) Business Days prior to the Closing, the Company shall deliver to Parent a schedule regarding the distribution of the Initial Merger Consideration to the holders of the Company Secured Notes (the "Initial Payment Allocation Schedule"). The Initial Payment Allocation Schedule shall also include a schedule of the Company Legal Expenses requested by Parent to be paid on the Closing Date, which schedule shall include the applicable payee thereof and the applicable wire instructions for such payment. Parent and the Paying Agent shall be permitted to rely, without further inquiry, on the Initial Payment Allocation Schedule (and any update thereof) in making payment of the Initial Merger Consideration to the Indemnifying Securityholders without any Liability to any Indemnifying Securityholder or purported Indemnifying Securityholder or other Person in connection therewith.

(b) Future Payment Allocation Schedules. In connection with the making of any Future Payment required by this Agreement (if, when and to the extent any such Future Payment becomes payable pursuant to the terms hereof), the Securityholders' Representative shall prepare a schedule, substantially similar in form to the Initial Payment Allocation Schedule (the "Future Payment Allocation Schedule"), which sets forth the allocation of each Future Payment (including the Per Note Future Payment for each Company Note and/or the Per Share Future Payment for each applicable class and series of Company Capital Stock and the aggregate amount of such Future Payment allocable to each such Indemnifying Securityholder or Company Stockholder in respect of all Company Securities held by such Indemnifying Securityholder or Company Stockholder). The allocation of each such Future Payment set

forth on such Future Payment Allocation Schedule shall be made in accordance with Schedule 2.6(b). The Securityholders' Representative shall deliver to Parent each applicable Future Payment Allocation Schedule not less than three (3) Business Days prior to the scheduled release or payment of any such Future Payment pursuant to the terms of this Agreement. Parent and the Paying Agent shall be permitted to rely, without further inquiry, on the applicable Future Payment Allocation Schedule in making payment of any Future Payments without any Liability to any Indemnifying Securityholder or Company Stockholder or purported Indemnifying Securityholder or Company Stockholder or other Person in connection therewith.

(c) Distribution Procedures. The Initial Payment Allocation Schedule and any Future Payment Allocation Schedule shall provide that the Initial Merger Consideration and each Future Payment shall be distributed to the Paying Agent (for further distribution to the Indemnifying Securityholders and Company Stockholders) in the manner set forth in such Initial Payment Allocation Schedule or Future Payment Allocation Schedule and subject to and in accordance with the other provisions of this Article 2.

(d) Paying Agent Procedures.

(i) As promptly as reasonably practicable after the Effective Time and pursuant to the terms of that payments administration agreement substantially in the form of Exhibit C attached hereto (the "**Paying Agent Agreement**"), Parent shall deposit, or cause to be deposited, with Acquiom Financial LLC (the "**Paying Agent**") for the benefit of the Company Note Holders the aggregate Per Note Initial Merger Consideration payable pursuant to Section 2.4(c) in respect of each Company Note, to be held by the Paying Agent in accordance with the terms of the Paying Agent Agreement.

(ii) Parent shall, or shall cause the Paying Agent to, deliver (which may be done electronically) prior to or as promptly as reasonably practicable following the Effective Time, (x) to each Company Stockholder a letter of transmittal substantially in the form of Exhibit D attached hereto (a "**Letter of Transmittal**"), and (y) to each Company Note Holder, a note cancellation agreement substantially in the form attached hereto as Exhibit F attached hereto (a "**Note Cancellation Agreement**" and together with the Letter of Transmittal, and such other customary tax documents as may reasonably be required by Parent or the Paying Agent the "**Payment Documents**"). Upon receipt by Parent or the Paying Agent, of the applicable Payment Documents, duly completed and validly executed in accordance with the instructions (together with all certificate or certificates that, as of immediately prior to the Effective Time, represented shares of Company Capital Stock (the "**Certificates**")) (the "**Payment Condition**"), the record owner of such Company Capital Stock or Company Note, as applicable, shall be entitled to receive in exchange therefor the consideration provided for in this Article II. Parent shall have no obligation to deliver, or cause to be delivered, any such consideration to a particular Company Securityholder until such Person has satisfied the Payment Condition.

(iii) At the Effective Time, holders of shares of Company Capital Stock as of immediately prior to the Effective Time shall cease to have any rights as stockholders of the Company, and the stock transfer books of the Company shall be closed with to all shares of such capital stock outstanding immediately prior to the Effective Time. No further transfer of any such shares of Company Capital Stock shall be made on such stock transfer books after the Effective Time. If, after the Effective Time, a valid Certificate is presented to the Surviving Corporation or Parent in accordance with this Section 2.6, such Certificate shall be canceled and shall be exchanged as provided in this Section 2.6. At the Effective Time, all Company Notes shall no longer be outstanding, shall automatically be cancelled and shall cease to exist and each holder of a Company Note shall cease to have any rights with respect thereto, except the rights set forth in this Article 2.

(iv) Any portion of the Total Merger Consideration that was deposited with the Paying Agent and remains undistributed to Indemnifying Securityholders after one year shall be delivered to Parent upon demand, and Indemnifying Securityholders who have not theretofore satisfied the Payment Condition shall thereafter (if Parent has made such demand) look only to

Parent for satisfaction of their claims for any portion of the Total Merger Consideration payable with respect to the Company Securities previously held by such Indemnifying Securityholder without any interest thereon. Notwithstanding anything to the contrary contained herein, none of Parent, Merger Sub, the Company, the Surviving Corporation or the Paying Agent shall be liable to any Indemnifying Securityholder for any portion of the Total Merger Consideration delivered to a public official pursuant to any applicable abandoned property, escheat or similar Law. Any portion of the Total Merger Consideration remaining undistributed to Indemnifying Securityholders immediately prior to such time as such portion of the Total Merger Consideration would otherwise escheat to or become the property of any Governmental Authority shall, to the extent permitted by applicable Law, become the property of the Parent free and clear of all claims or interest of any Person previously entitled thereto.

2.7 Other Closing Payments. Immediately following the Effective Time, Parent shall deposit, or cause to be deposited, with the Paying Agent for the benefit of and for further distribution to the relevant Persons as set forth on the Initial Payment Allocation Schedule, an amount of cash equal to the sum of the Company Legal Expenses, and the Tail Policy Costs to be paid on the Closing Date in accordance with the Initial Payment Allocation Schedule. The Paying Agent shall distribute such amounts of the Company Legal Expenses and the Tail Policy Costs in accordance with the terms of the Paying Agent Agreement and in the manner set forth in the Initial Payment Allocation Schedule.

2.8 Total Merger Consideration. Notwithstanding anything to the contrary contained in this Agreement, in no event shall the aggregate consideration payable by Parent hereunder exceed the Total Merger Consideration.

2.9 Dissenting Shares. If, in connection with the Merger, any holders of Company Capital Stock shall have demanded and perfected their appraisal rights in accordance with Section 262 of the DGCL, none of such Dissenting Shares shall be converted into a right to receive the Merger Consideration otherwise payable to the holder of such Dissenting Shares as provided in Sections 2.4(d), but shall instead be converted into the right to receive such consideration as may be determined to be due with respect to such Dissenting Shares pursuant to the DGCL. Each holder of Dissenting Shares who, pursuant to the provisions of the, becomes entitled to payment of the fair value of such shares shall receive payment therefor in accordance with the DGCL (but only after the value therefor shall have been agreed upon or finally determined pursuant to the DGCL. In the event that any Company Stockholder fails to make an effective demand for payment or fails to perfect its appraisal rights as to its shares of Company Capital Stock or any Dissenting Shares shall otherwise lose their status as Dissenting Shares, then any such shares shall immediately be converted into the right to receive the consideration payable pursuant to Section 2.4(c) in respect of such shares as if such shares had never been Dissenting Shares, and Parent shall deliver to the holder thereof, at (or as promptly as reasonably practicable after) the applicable time or times specified in Section 2.6, following the satisfaction of the Payment Condition, the Merger Consideration to which such Company Stockholder would have been entitled under Section 2.4(d) with respect to such shares. The Company shall give Parent (a) prompt written notice (and in no event to be more than two (2) Business Days) of (i) any demand received by the Company for payment for Dissenting Shares in accordance with the DGCL, and (ii) the withdrawals of such demands and (b) the opportunity to participate in all negotiations and proceedings with respect to demands for appraisal under the DGCL. The Company agrees that, except with Parent's prior written consent, it shall not voluntarily make any payment or offer to make any payment with respect to, or settle or offer to settle, any such demand for payment in connection with the exercise of appraisal rights.

2.10 Tax Withholding. Each of Parent, the Surviving Corporation and the Paying Agent and their Affiliates shall be entitled to deduct and withhold, or cause to be deducted and withheld, from the Merger Consideration or any other payment otherwise payable pursuant to this Agreement, the amounts required to be deducted and withheld under the Code, or any provision of state, local or foreign Tax Law, with respect to the making of such payment and, to the extent that amounts are so deducted and withheld and timely and properly paid over to the applicable Governmental Authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made; provided, however, assuming compliance with Section 5.9(d), if any of Parent, the Surviving Corporation and the Paying Agent or any of their Affiliates determines it is obligated to deduct or withhold any amounts from any non-compensatory amounts payable or otherwise

deliverable pursuant to this Agreement, such person shall (i) use commercially reasonable efforts to provide the applicable recipient with prior written notice of its intent to deduct and withhold (together with information setting forth the basis for such deduction or withholding), and (ii) the parties shall reasonably cooperate to minimize or eliminate any potential deductions and withholdings and such payee shall have the opportunity to reduce or eliminate such withholding. With respect to any compensatory payments, Parent shall effectuate such withholding by paying the applicable amounts for which such withholding is required to the Surviving Corporation and causing the Surviving Corporation to withhold the applicable amounts through the Surviving Corporation's payroll system.

2.11 Closing Statement.

(a) Not less than two (2) Business Days prior to the Closing, the Company shall deliver to Parent a statement (the "**Closing Statement**") duly certified by the chief executive officer and chief financial officer of the Company, setting forth the Company's good faith estimate as of the anticipated Closing Date of (A) the Closing Cash, (B) the Closing Indebtedness, (C) the Closing Net Working Capital and the Net Working Capital Deficit, and (D) the Unpaid Transaction Expenses.

(b) The Closing Statement shall be prepared by the Company in accordance with the Accounting Principles, subject to any appropriate modifications to take into account the definitions of the various items to be included on the Closing Statement as set forth herein. The Company shall deliver to Parent supporting calculations and documentation of such calculations, in reasonable detail, concurrently with the delivery of the Closing Statement. The Company shall consult with Parent and its advisors with respect to the preparation of the Closing Statement and the Closing Statement shall be in form and substance satisfactory to Parent. Parent shall be entitled to rely on the information contained in the Closing Statement for all purposes hereunder and otherwise in connection with the Merger.

2.12 Contingent Consideration.

(a) [***] Milestone. Upon achievement by Parent or a Related Party of the [***] Milestone, subject to Parent's right of set-off provided in Section 2.12(f) and in Section 6.7, the First Milestone Payment shall become due and payable in accordance with the applicable Future Payment Allocation Schedule. Parent shall provide written notice to the Securityholder Representative of the achievement of the [***] Milestone no later than [***] days after the occurrence thereof. For the avoidance of doubt, the First Milestone Payment shall be payable only one (1) time upon the first achievement of the [***] Milestone, and no amounts shall be due for any subsequent or repeated achievements of the [***] Milestone or the receipt of FDA Approval of the CT/NG Test for claims associated with any testing other than vaginal testing. Under no circumstances shall (i) the First Milestone Payment become due or payable after December 31, 2026, or (ii) the aggregate amount payable by Parent pursuant to this Section (a) exceed an amount in cash equal to $15,000,000 in the aggregate, less amounts subject to offset as provided herein.

(b) [***] Milestone. Upon achievement by Parent or a Related Party of the [***] Milestone, subject to Parent's right of set-off provided in Section 2.12(f) and in Section 6.7, the Second Milestone Payment shall become due and payable in accordance with the applicable Future Payment Allocation Schedule. Parent shall provide written notice to the Securityholder Representative of the achievement of the [***] Milestone no later than [***] days after the occurrence thereof. For the avoidance of doubt, the First Milestone Payment shall be payable only one (1) time upon the first achievement of the [***] Milestone, and no amounts shall be due for any subsequent or repeated achievements of the [***] Milestone or the receipt of FDA Approval of the CT/NG Test for claims associated with any testing other than penile testing. Under no circumstances shall (i) the Second Milestone Payment become due or payable after December 31, 2026, or (ii) the aggregate amount payable by Parent pursuant to this Section 2.12(b) exceed an amount in cash equal to $5,000,000 in the aggregate, less amounts subject to offset as provided herein.

(c) Royalties.

(i) On a calendar quarter basis during the Royalty Term, subject to Parent's right of set-off provided in Section 2.12(f) and in Section 6.7, Parent shall pay to the Paying

Agent (for further distribution to the Company Securityholders in accordance with the applicable Future Payment Allocation Schedule) an amount in cash equal to [***] percent [***] of the Net Sales of the CT/NG Test received by Parent or its Related Parties in each jurisdiction where the CT/NG Test has received Regulatory Approval (each such payment, a "**Royalty Payment**").

(ii) Each Royalty Payment shall be made within [***] days of the end of such calendar quarter during the Royalty Term. Each Royalty Payment shall be accompanied by a report setting forth the Net Sales of the CT/NG Test in such calendar quarter and the Royalty Payment due to be paid pursuant to Section 2.12(c)(i) (each, a "**Royalty Report**").

(d) If the Securityholder Representative disagrees with the calculations in any Royalty Report, the Securityholder Representative shall notify Parent of such disagreement in writing (a "**Royalty Dispute Notice**") within thirty (30) days after receipt of such Royalty Report. A Royalty Dispute Notice must set forth in reasonable detail (A) any item on the applicable Royalty Report which the Securityholder Representative in good faith disputes and (B) the Securityholder Representative's alternative calculation of Royalty Report for the applicable calendar quarter. Any item or amount that the Securityholder Representative does not dispute in reasonable detail in a Royalty Dispute Notice within such thirty (30) day period shall be deemed to have been accepted by the Securityholder Representative and shall become final and binding upon the parties hereto and the Indemnifying Securityholders for all purposes under this Agreement. In the event that a Royalty Dispute Notice is timely provided in accordance with the foregoing, Parent and the Securityholder Representative shall for a period of thirty (30) days (or such longer period as they may mutually agree) seek in good faith to resolve any disagreements with respect to the calculations included in such Royalty Report that were disputed in the Royalty Dispute Notice. If, at the end of such period, Parent and the Securityholder Representative remain unable to resolve the dispute in its entirety, Parent and the Securityholder Representative shall submit the dispute to an independent certified public accounting firm in the United States of national recognition mutually agreeable to the Securityholder Representative and Parent (the "**Independent Accountant**"). The parties agree that the procedure set forth in this Section 2.12(d) for resolving disputes with respect to any Royalty Report shall be the sole and exclusive method for resolving any such disputes; *provided that* this provision shall not prohibit any party from instituting litigation to enforce the ruling of the Independent Accountant. The determination of the Independent Accountant shall constitute an arbitration award for purposes of the Federal Arbitration Act and any comparable state Laws.

(e) The parties acknowledge and agree that Parent and the Surviving Corporation shall have the freedom to operate the Surviving Corporation in its sole discretion, and neither Parent, the Surviving Corporation nor their respective Affiliates shall have any duties (fiduciary or otherwise) or obligations to any Company Securityholder in respect of Contingent Consideration. The parties further acknowledge that there is no assurance to any Company Securityholder of any Contingent Consideration and neither Parent nor the Surviving Corporation has promised or projected any Contingent Consideration other than those set forth in this Section 2.12.

(f) Notwithstanding anything to the contrary in this Agreement, (i) any Contingent Consideration to be paid pursuant to this Section 2.12, shall be reduced by (1) any indemnification amounts paid by Parent to the Paying Agent pursuant to section 6 of the Paying Agent Agreement, (2) (w) the Company Legal Expenses, (x) the Closing Indebtedness, (y) the Unpaid Transaction Expenses, and (3)) the Net Working Capital Deficit in an amount equal to $[***], provided however that, in the event the Net Working Capital Deficit exceeds $[***], any Contingent Consideration shall also be reduced by the total amount of the Net Working Capital Deficit in excess of $[***], in each of the foregoing cases (1) though (3), as determined and notified by Parent to the Securityholder Representative within one hundred and twenty (120) days following the Closing Date, and (ii) the obligation of Parent to pay any Contingent Consideration pursuant to this Section 2.12 shall further be qualified in its entirety by the right of Parent to reduce the amount of such Contingent Consideration by the amount of any indemnification claim pursuant to Section 6.2.

(g) For U.S. federal income tax purposes, any Contingent Consideration shall be treated as an adjustment to the Total Merger Consideration (subject to any imputation of interest required under Section 483 or Section 1274 of the Code), unless otherwise required by a Tax Authority in connection with a Tax Contest following a good faith attempt to defend such tax treatment.

2.13 Further Assurances. If, at any time before or after the Effective Time, Parent reasonably believes or is advised that any further instruments, deeds, assignments or assurances are reasonably necessary to consummate the Merger or to carry out the purposes and intent of this Agreement at or after the Effective Time, then the Company, Parent, the Surviving Corporation and their respective officers and directors are hereby authorized to execute and deliver all such proper deeds, assignments, instruments and assurances and do all other things reasonably necessary to consummate the Merger and to carry out the purposes and intent of this Agreement.

Article 3

REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except as set forth in the Company Disclosure Schedule, the Company represents and warrants to Parent as follows as of the date hereof:

3.1 Organization and Good Standing. The Company is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. The Company has all requisite corporate power and authority to own, operate and lease its assets and properties and to carry on the Company Business. The Company is duly qualified or licensed to do business, and is in good standing, in each jurisdiction where the character of the properties owned, leased or operated by it or the character or location of its assets or properties (whether owned, leased or licensed) or nature of its activities makes such qualification or licensing necessary, in each case except where the failure to be so duly qualified, licensed and in good standing would not be expected to be material on the Company. Section 3.1 of the Company Disclosure Schedule sets forth each jurisdiction in which the Company and its Subsidiaries are qualified or licensed to do business. The Company has made available to Parent complete and correct copies of the Charter Documents, each as amended to date, of the Company. The Charter Documents are in full force and effect. The Company is not and has never been in violation of the provisions of any current or past Charter Documents in any material respect.

3.2 Subsidiaries.

(a) Section 3.2(a) of the Company Disclosure Schedule sets forth a true, correct and complete list of each Subsidiary of the Company, indicating the record and beneficial owner of all of such Subsidiary's issued and outstanding shares of capital stock or other equity interests. Other than the Subsidiaries listed on Section 3.2(a) of the Company Disclosure Schedule, the Company does not directly or indirectly own or control any equity interest or similar interest in, or any interest convertible into or exchangeable or exercisable for, any equity interest or similar interest in, any Person, or have any commitment or obligation to invest in, purchase any securities or obligations of, fund, guarantee, contribute or maintain the capital of or otherwise financially support any Person. Each Subsidiary of the Company is a corporation or other appropriate form of local jurisdiction entity duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, as applicable, and has the requisite corporate power and authority to own, operate and lease its assets and properties and to carry on its business as currently conducted. Each Subsidiary of the Company is duly qualified or licensed as a foreign corporation or other appropriate form of local jurisdiction entity to do business, and is in good standing, in each jurisdiction where the character of the properties owned, leased or operated by it or the character or location of its assets or properties (whether owned, leased or licensed) or nature of its activities makes such qualification or licensing necessary, in each case except where the failure to be so duly qualified, licensed and in good standing would not be expected to be material on the Company. All of the outstanding equity interests of each Subsidiary of the Company are duly authorized, validly issued, fully paid and nonassessable (to the extent such concept exists under the Law of the jurisdiction of organization or formation of such Subsidiary of the Company), and are free of any Encumbrance, preemptive rights and put or call rights created by Law, the Charter Documents of such Subsidiary, or any Contract to which the Company or any of its Subsidiaries is a party or by which any of their respective assets are bound. The Company has made available to Parent complete and correct copies of the Charter Documents of each of its Subsidiaries, each as amended to date, such Charter Documents are in full force and effect and no such Subsidiary is or has even been in violation of the provisions of any of its current or past Charter Documents in any material respect. Section 3.2(b) of the Company Disclosure Schedule sets forth a list of all of the current and former officers and directors of each

Subsidiary of the Company (including, for each such individual, the position held with each such Subsidiary).

(b) Except for the Subsidiaries listed on Section 3.2(a) of the Company Disclosure Schedule, the Company does not own, and has never owned, beneficially or otherwise, any shares or other securities of, or any direct or indirect equity interest in, any Person. There is no obligation, contingent or otherwise, of the Company to provide funds to, or make any investment in (in the form of a loan, capital contribution or otherwise), or provide any guarantee with respect to the obligations of, any other Person.

3.3 Power, Authorization and Validity.

(a) Power and Authority. The Company has all requisite corporate power and authority to execute and deliver this Agreement and each of the Company Ancillary Agreements and, subject to receipt of the Stockholder Approval, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery and, subject to receipt of the Stockholder Approval, performance by the Company of this Agreement and each of the Company Ancillary Agreements and the consummation of the transactions contemplated hereby or thereby have been duly and validly approved and authorized by all requisite corporate action on the part of the Company.

(b) Enforceability. This Agreement has been duly executed and delivered by the Company. This Agreement and each of the Company Ancillary Agreements are, or when executed and delivered by the Company shall be, assuming the due authorization, execution and delivery by Parent, Merger Sub and the other Persons party hereto or thereto, valid and binding obligations of the Company, enforceable against the Company in accordance with their respective terms, subject to the Enforceability Exceptions.

(c) Board Approval. The board of directors of the Company has, at a meeting duly called and held, by a unanimous vote of the entire board of directors, or by a unanimous written consent in lieu thereof: (i) approved and declared advisable this Agreement, (ii) determined that the Merger and other transactions contemplated by this Agreement are advisable, fair to, and in the best interests of the Company and the Company Stockholders and approved the same, (iii) approved the Company Ancillary Agreements and the transactions contemplated thereby, (iv) resolved to recommend to the Company Stockholders the adoption of this Agreement, and (v) directed that this Agreement be submitted to the Company Stockholders for adoption (such board approval in clauses (i) through (v), the "**Board Approval**").

(d) Required Vote of Company Stockholders. The Stockholder Approval is the only votes or consents of the holders of any class or series of Company Capital Stock necessary to adopt or approve this Agreement, the Merger and the other matters set forth in the Written Consent, and, to the extent such approval is required, the Company Ancillary Agreements and the other transactions contemplated hereby and thereby.

(e) No Restrictions on the Merger; Takeover Statutes. No "fair price," "moratorium," "control share acquisition" or other similar antitakeover statute or regulation enacted under Law ("**Takeover Statute**") is applicable to the Merger or the other transactions contemplated by this Agreement and the Company Ancillary Agreements.

3.4 Capitalization of the Company.

(a) Authorized and Outstanding Capital Stock of the Company. The authorized capital stock of the Company consists solely of 75,000,000 shares of Company Common Stock and 44,190,602 shares of Company Preferred Stock, of which 10,959,725 shares have been designated Company Series A Preferred Stock, and 33,230,877 shares have been designated Company Series B Preferred Stock. As of the Agreement Date, 17,818,571 shares of Company Common Stock, 10,959,725 shares of Company Series A Preferred Stock, and 33,230,877 shares of Company Series B Preferred Stock are issued and outstanding. As of the Agreement Date, 6,849,599 shares of Company Common Stock are subject to outstanding Company Options. Section 3.4(a) of the Company Disclosure Schedule

sets forth, as of the Agreement Date, a complete and correct list of each record holder of Company Capital Stock, including for each such holder (i) the number of shares of each class and series held by such holder and (ii) whether any shares of Company Capital Stock were eligible for an election under Section 83(b) of the Code, including the date of issuance of such shares, and whether such election under Section 83(b) of the Code was timely made. No shares of Company Capital Stock are issued or outstanding as of the Agreement Date that are not set forth in Section 3.4(a) of the Company Disclosure Schedule. The Company does not hold any treasury stock and does not otherwise own any shares of Company Capital Stock. All issued and outstanding shares of Company Capital Stock (x) have been duly authorized and validly issued, are fully paid and nonassessable, (y) were offered, issued, sold and delivered by the Company in compliance with applicable Law, the Charter Documents, and all requirements set forth in applicable Contracts, and (z) are not subject to right of rescission, right of first refusal or preemptive right under applicable Law, the Charter Documents or any Contract to which the Company is a party. There is no Liability for dividends accrued and unpaid by the Company. Each share of Company Preferred Stock is convertible into one share of Company Common Stock. All of the outstanding shares of Company Capital Stock are represented by electronic certificates issued via Carta.com and the Company has never issued physical stock certificates.

(b) Company Options. The Company Stock Plan is the only equity-based plan or program providing for equity compensation of any Person in respect of the Company Capital Stock, and except for the Company Stock Plan, the Company has never adopted or maintained any stock option plan or other plan, agreement or arrangement providing for equity compensation of any Person. The Company has reserved an aggregate of 11,447,293 shares of Company Common Stock for issuance pursuant to the Company Stock Plan (including shares subject to outstanding Company Options). As of the Agreement Date, a total of 6,849,599 shares of Company Common Stock are subject to outstanding Company Options, 4,908,128 of which were vested and exercisable as of the Agreement Date. The Company has not issued any awards under the Company Stock Plan other than Company Options. Section 3.4(b) of the Company Disclosure Schedule sets forth, as of the Agreement Date, for each Company Option: (i) the name of the holder thereof, (ii) the exercise price per share, (iii) the number of shares of Company Common Stock subject to such Company Option, (iv) the date of grant and vesting schedule (if applicable), (v) the extent such Company Option is vested as of the Agreement Date, and (vi) whether such Company Option is an incentive stock option or non-statutory stock option under the Code. Complete and correct copies of the Company Stock Plan, the standard agreements under the Company Stock Plan and each agreement for awards under the Company Stock Plan that does not conform to the standard agreements under the Company Stock Plan, in each case as are in effect as of the Agreement Date, have been made available to Parent, and there are no agreements, understandings or commitments to amend, modify or supplement the Company Stock Plan or any such agreements. The terms of the Company Stock Plan permit the treatment of Company Options as provided herein, without the consent or approval of any holders of Company Options, the Company Stockholders or any other Person other than the board of directors of the Company, which board approval was obtained prior to the execution and delivery hereof by the Company. No Company Options are subject to any right of rescission, right of first refusal or preemptive right and all Company Options have been issued under the Company Stock Plan in compliance with Law and all requirements set forth in applicable Contracts. All Company Options and shares of Company Common Stock issued upon exercise thereof have been granted and issued, and all exercises of Company Options have been made, in accordance with the terms of the Company Stock Plan and in compliance with applicable Law and all requirements set forth in applicable Contracts and each such grant, exercise and issuance was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company. No Company Option has been granted with an exercise price less than the fair market value of a share of Company Common Stock on the date on which the grant of such Company Option was by its terms to be effective. All Company Options that were ever issued by the Company ceased to vest on the date on which the holder thereof ceased to be an employee, consultant or director of the Company.

(c) No Other Rights. Except for the shares of Company Capital Stock listed in Section 3.4(a) of the Company Disclosure Schedule and the Company Options listed in Section 3.4(b) of the Company Disclosure Schedule, there are no outstanding Company Securities. Except with respect to the rights of repurchase set forth in the Company Restricted Stock Agreements governing the Company Restricted Stock set forth in Section 3.4(b) of the Company Disclosure Schedule, there are no rights, agreements, arrangements or commitments of any kind or character, whether written or oral, to which the

Company is a party or by which it is bound obligating the Company to repurchase, redeem or otherwise acquire any Company Securities. There are no outstanding or authorized stock appreciation, phantom stock, profit participation, or other similar rights with respect to the Company. No bonds, debentures, notes or other Indebtedness of the Company having the right to vote on any matters on which stockholders may vote (or which is convertible into, or exchangeable for, securities having such right) are outstanding.

(d) Equity-Related Agreements. Section 3.4(d) of the Company Disclosure Schedule sets forth a complete and correct list of all Equity-Related Agreements. The Company has made available to Parent complete and correct copies of all Equity-Related Agreements.

3.5 No Conflict; Required Consents.

(a) The execution, delivery and performance by the Company of this Agreement and each of the Company Ancillary Agreements, and the consummation of the transactions contemplated hereby and thereby, do not and will not: (i) conflict with or violate the Charter Documents of the Company or any of its Subsidiaries, (ii) conflict with or violate any Laws or any judgment, decree or order to which the Company or any of its Subsidiaries is subject, or (iii) result (or would result, with or without notice or lapse of time, or both) in (A) any breach of or default under, (B) any Person's right to consent, notice, or right of termination, acceleration, cancellation, modification or amendment of, or right to any increased, additional, accelerated or guaranteed payment or performance under, (C) any Encumbrance on any properties or assets of the Company or any of its Subsidiaries pursuant to, or (D) any adverse effect to the rights or obligations of the Company or any of its Subsidiaries or loss of any benefit for the Company or any of its Subsidiaries under, any Contract or Governmental Permit.

(b) The Company and the Merger are not, and will not be, subject to a right of first negotiation, right of first offer or refusal, or any other similar right granted by the Company (or any of its Affiliates) that could affect or cause any delay in the consummation of the Merger.

(c) No consent, approval, order or authorization of, or registration, declaration or filing with, or notice to any Governmental Authority is necessary or required to be made or obtained by the Company to enable the Company to lawfully execute, deliver and perform this Agreement and each of the Company Ancillary Agreements and to consummate the transactions contemplated hereby and thereby, except for the filing of the Certificate of Merger with the Secretary of State of the State of Delaware.

3.6 Litigation. There is no, and during the past four (4) years there has not been any, Action pending or, to the Knowledge of the Company, threatened, against the Company or any of its Subsidiaries or against any officer, director, employee or agent of the Company or any of its Subsidiaries in his or her capacity as such, and to the Knowledge of the Company there is no valid basis for the commencement of any such Action. There is no judgment, decree, injunction, rule or order of any Governmental Authority, arbitrator or mediator binding on the Company or any of its Subsidiaries or any of their respective assets or properties. Neither the Company nor any of its Subsidiaries has any Actions pending against any Governmental Authority or any other Person, nor is there any reasonable basis therefor. Except as set forth on Section 3.6 of the Company Disclosure Schedule, the Company and each of its Subsidiaries and each of their respective employees and officers in their capacity as such, are not, and for the past four (4) years have not been, a party to any Action, nor, to the Knowledge of the Company, is there any material Action threatened, before any court or judicial or administrative agency or any Governmental Authority.

3.7 Taxes.

(a) The Company and each of its Subsidiaries has duly and timely filed all income and other material Tax Returns required to be filed under applicable Laws. All such Tax Returns are true, correct and complete in all material respects and were prepared in substantial compliance with all applicable Laws. All Taxes due and owing by the Company and each of its Subsidiaries (whether or not shown on any Tax Return) have been timely paid. No written claim has ever been made by a Governmental Authority in a jurisdiction where the Company or any of its Subsidiaries does not file Tax

Returns that the Company or any of its Subsidiaries is or may be subject to taxation by that jurisdiction. There are no Encumbrances for Taxes (other than Permitted Encumbrances) upon the assets of the Company or any of its Subsidiaries.

(b) The Company and each of its Subsidiaries has (i) complied with all applicable Laws relating to the withholding, collection, payment and reporting of Taxes and (ii) within the time and manner prescribed by Law, withheld and paid over to the appropriate Governmental Authority all Taxes required to have been withheld and paid in connection with any amounts paid or owing to any employee, independent contractor, creditor, stockholder, or other third party, and all IRS Form W-2 and 1099 or other applicable forms required with respect thereto have been properly completed and timely filed.

(c) No Tax audits or administrative or judicial Tax proceedings are pending or being conducted with respect to the Company or any of its Subsidiaries. Neither the Company nor any of its Subsidiaries has received from any Tax Authority (including jurisdictions where the Company or any of its Subsidiaries has not filed Tax Returns) any (i) notice indicating an intent to open an audit or other review, (ii) request for information related to Tax matters, or (iii) notice of deficiency or proposed adjustment for any amount of Tax proposed, asserted, or assessed by any Tax Authority against the Company or any of its Subsidiaries, in each case in writing. The Company and each of its Subsidiaries has delivered to Parent correct and complete copies of all U.S. federal and material state, local and non-U.S. income Tax Returns, examination reports, and statements of deficiencies assessed against or agreed to by Company and/or each of its Subsidiaries in connection with any taxable periods since January 1, 2019.

(d) Neither the Company nor any of its Subsidiaries has waived any statute of limitations in respect of Taxes nor agreed to, nor is subject to, any extension of time with respect to a Tax assessment or deficiency, in each case, that is currently in effect, in each case other than as a result of an extension to file a Tax Return that is automatically granted.

(e) Neither the Company nor any of its Subsidiaries is, nor has it ever been, a "distributing corporation" or a "controlled corporation" (within the meaning of Section 355(a)(1)(A) of the Code) (i) in a distribution of stock qualifying for tax-free treatment under Section 355 of the Code in the two (2) years prior to the Closing Date, or (ii) in a distribution that could otherwise constitute part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) in conjunction with the transactions contemplated by this Agreement.

(f) Neither the Company nor any of its Subsidiaries is or has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code. Neither the Company nor any of its Subsidiaries is a party to or bound by any Tax allocation or sharing agreement (other than any agreement the primary purpose of which is other than Taxes). Neither the Company nor any of its Subsidiaries has ever been a member of an affiliated group (within the meaning of Code Section 1504(a)), other than a group the common parent of which was the Company, filing a consolidated U.S. federal income Tax Return nor has any liability for the Taxes of any Person (other than the Company or its Subsidiaries) under Section 1.1502-6 of the Treasury Regulations (or any similar provision of state, local, or non-U.S. law), as a transferee or successor, by contract, or otherwise.

(g) The unpaid Taxes of the Company and each of its Subsidiaries did not, as of the Balance Sheet Date, exceed the reserve for actual Taxes (as opposed to any reserve for deferred Taxes established to reflect timing differences between book and Tax income) as shown on the Company Balance Sheet, and will not exceed such reserve as adjusted for the passage of time through the Closing

Date in accordance with the reasonable past custom and practices of the Company or applicable Subsidiary in filing Tax Returns. Neither the Company nor any of its Subsidiaries will incur any material liability for Taxes from the Balance Sheet Date through the Closing Date, other than in the ordinary course of business and consistent with reasonable past practices.

(h) Neither the Company nor any of its Subsidiaries has a permanent establishment or conducts business through any branch outside its respective country of incorporation, formation or organization, as applicable . Neither the Company nor any of its Subsidiaries is subject to Tax in any jurisdiction other than its respective country of incorporation, formation or organization, as applicable.

(i) Neither the Company nor any of its Subsidiaries will be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for a taxable period ending on or prior to the Closing Date; (ii) use of an improper method of accounting for a taxable period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any corresponding or similar provision of state, local, or non-U.S. income Tax law) executed prior to the Closing; (iv) installment sale or open transaction disposition made on or prior to the Closing; (v) prepaid amount or deferred revenue received on or prior to the Closing Date; or (vi) application of Section 952(c)(2) of the Code with respect to any interest held by the Company or any of its Subsidiaries in a "controlled foreign corporation" (as that term is defined in Section 957 of the Code) on or before the Closing Date pursuant to Sections 951, 951A or 965 of the Code..

(j) Neither the Company nor any of its Subsidiaries has any outstanding liability for Taxes under Section 965(h) of the Code (or any similar or corresponding provision of state or local law).

(k) Neither the Company nor any of its Subsidiaries is subject to any private letter ruling or closing agreement of the IRS or comparable rulings of any other Governmental Authority. Neither the Company nor any of its Subsidiaries has submitted a request for a private letter ruling, a request for administrative relief, a request for a change of any method of accounting, or any other written request that is pending with any Governmental Authority.

(l) Neither the Company nor any of its Subsidiaries is or has ever been a party to any "listed transaction," as defined in Section 6707A(c)(2) of the Code and Section 1.6011-4(b)(2) of the Treasury Regulations.

(m) There is no power of attorney given by or binding upon the Company or any of its Subsidiaries with respect to Taxes for any period for which the statute of limitations (including any waivers or extensions) has not yet expired that is currently in effect other than any customary power of attorney entered into with the Company's Tax preparer or payroll provider solely for the purpose of filing Tax Returns on behalf of the Company or any of its Subsidiaries.

(n) Neither the Company nor any of its Subsidiaries is a party to any joint venture, partnership or other arrangement or contract treated as a partnership for U.S. federal income tax purposes.

(o) For U.S. federal and applicable state and local income tax purposes, the Company and each of its Subsidiaries is and has always been properly classified as a C corporation.

(p) The Company and each of its Subsidiaries uses and has always used the accrual method of accounting for tax purposes.

(a) Neither the Company nor any of its Subsidiaries has utilized the employee retention credit relief provided under Section 2301 of the CARES Act or any related guidance, executive order or memorandum.

(q) Neither the Company nor any of its Subsidiaries owns any interest in any "controlled foreign corporation" or in any "passive foreign investment company" within the meaning of the Code.

(r) Each "nonqualified deferred compensation plan" under which the Company makes, is obligated to make or promises to make, payments subject to Section 409A of the Code, if any, has, since the inception of the Company, been operated and maintained in operational and documentary compliance with Section 409A of the Code, and the applicable Treasury Regulations and IRS guidance thereunder so as to avoid any Tax pursuant to Section 409A of the Code and the document or documents that evidence each such plan have, since the incorporation of the Company, conformed to the provisions of Section 409A of the Code and the Treasury Regulations thereunder. No payment pursuant to any arrangement between the Company and any "service provider" (as such term is defined in Section 409A of the Code and the Treasury Regulations thereunder) would subject any Person to a Tax pursuant to Section 409A of the Code, whether pursuant to the consummation of the transactions contemplated by this Agreement or otherwise. No Company Employee Plan or other Contract provides a gross-up, reimbursement or other indemnification for any Tax or related interest or penalty that may be imposed for failure to comply with the requirements of Section 409A of the Code.

(s) All Company Options have been authorized by the board of directors of the Company or an appropriate committee thereof, and, if required, approved by stockholders of the Company by the necessary number of votes or written consent, including approval of the option exercise price or the methodology for determining the Company Option exercise price and the substantive option terms. Each Company Option intended to qualify as an "incentive stock option" under Section 422 of the Code so qualifies. No Company Option has been retroactively granted, or the exercise price of any Company Option determined retroactively. No Company Option or other right to acquire Company Common Stock or other equity of the Company (A) has an exercise price that has been or may be less than the fair market value of a share of the underlying stock as of the date such Company Option or right was granted as determined in accordance with Section 409A of the Code, (B) has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such Company Option or right, or (C) has been granted with respect to any class of stock of the Company that is not "service recipient stock" (within the meaning of Section 409A of the Code and the Treasury Regulations thereunder).

(t) The Company has never entered into any Contract or maintained any Company Employee Plan (i) that could give rise to payments with respect to the performance of services that are nondeductible under Section 280G of the Code or subject to the excise Tax under Section 4999 of the Code or (ii) by which it is bound to compensate any employee of the Company or other service provider of the Company for any excise Tax or related interest or penalty paid pursuant to Section 4999 of the Code, and neither the execution of this Agreement nor the consummation of the transactions contemplated hereby could (either alone or upon occurrence of any additional event) result in, or cause the accelerated vesting, payment, funding or delivery of, or increase the amount or value of, any payment

or benefit to any employee, officer, director, consultant, independent contractor or other service provider of the Company or any of its ERISA Affiliates.

3.8 Related Party Transactions. There are no outstanding amounts payable to or receivable from, or advances by the Company or any of its Subsidiaries to, and neither the Company nor any of its Subsidiaries is otherwise a creditor or debtor to, or party to any Contract or transaction with, directly or indirectly, any Related Party, except (a) to the extent provided for by the terms and conditions of Company Employee Plans listed in Section 3.16(n) of the Company Disclosure Schedule and (b) transactions evidenced by the Equity-Related Agreements listed in Section 3.4(d) of the Company Disclosure Schedule. Neither the Company nor any of its Subsidiaries has ever, or has ever been deemed to have for purposes of any Law, in any transaction with any Related Party or, to the Knowledge of the Company, any of their respective Affiliates, (i) acquired or retained the use of property for proceeds greater than the fair market value thereof, (ii) received services or retained the use of property for consideration other than the fair market value thereof, or (iii) received interest or any other amount other than at a fair market value rate from any Person with whom it does not deal at arm's length within the meaning of applicable Tax Laws. Neither the Company nor any of its Subsidiaries has ever, or has ever been deemed to have for purposes of any Law, in a transaction with any Related Party or, to the Knowledge of the Company, any of their respective Affiliates, (A) disposed of property for proceeds less than the fair market value thereof, (B) performed services for consideration other than the fair market value thereof, or (C) paid interest or any other amount other than at a fair market value rate to any Person with whom it does not deal at arm's length within the meaning of applicable Tax Laws.

3.9 Company Financial Statements.

(a) Section 3.9(a) of the Company Disclosure Schedule sets forth the Company Financial Statements. The Company Financial Statements: (i) are derived from the Books and Records and are complete and correct, (ii) fairly present in all material respects the financial condition of the Company and its Subsidiaries on a consolidated basis at the dates therein indicated and the results of operations and cash flows of the Company and its Subsidiaries on a consolidated basis for the periods therein specified, and (iii) have been prepared in accordance with GAAP applied on a basis consistent with prior periods (except that the Company Financial Statements do not have notes and are subject to normal recurring year-end adjustments, the effect of which are not, individually or in the aggregate, material to the Company.

(b) All of the accounts receivable, whether billed or unbilled, of the Company and its Subsidiaries arose in the ordinary course of business, are carried at values determined in accordance with GAAP consistently applied, are not subject to any valid set-off or counterclaim, do not represent obligations for goods sold on consignment, on approval or on a sale-or-return basis or subject to any other repurchase or return arrangement, and are collectible except to the extent of reserves therefor set forth in the Company Balance Sheet or, for accounts receivable arising subsequent to the Balance Sheet Date, as reflected on the Books and Records of the Company and its Subsidiaries (which accounts receivable are recorded in accordance with GAAP consistently applied). No Person has any Encumbrance on any accounts receivable of the Company or its Subsidiaries and no request or agreement for deduction or discount has been made with respect to any accounts receivable of the Company or its Subsidiaries.

(c) Neither the Company nor any of its Subsidiaries has any material Liabilities, except for (i) those shown on the Company Balance Sheet or (ii) those that were incurred after the Balance Sheet Date in the Ordinary Course of Business (none of which relate to any breach of contract, breach of warranty, tort, infringement, or violation of Law, or any Action against the Company or any of its Subsidiaries, and which are included in the calculation of Closing Net Working Capital, Closing Indebtedness or Unpaid Transaction Expenses or are not individually or in the aggregate, material in amount). All reserves established by the Company that are set forth in or reflected in the Company Balance Sheet have been established in accordance with GAAP and are adequate. No bankruptcy, insolvency, winding up, or similar proceedings have occurred or are pending or, to the Knowledge of the Company, threatened against the Company or its Subsidiaries or any of the Company's or its Subsidiaries' respective properties or assets, and there is no basis therefor. The Company is, and will be as of immediately prior to the Closing, financially solvent in accordance with GAAP.

(d) Section 3.9(d) of the Company Disclosure Schedule sets forth a complete and correct list of each item of Indebtedness of the Company and its Subsidiaries as of the Agreement Date, identifying the name and address of the creditor thereto, all related Contracts, the amount of such Indebtedness as of the close of business on the Agreement Date, and any restriction or penalty upon the prepayment of any such Indebtedness. Except as set forth in Section 3.9(d) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries is or has ever been in default and no payments are past due with respect to any Indebtedness.

(e) The Company maintains Books and Records and a system of internal accounting controls reasonably designed to provide reasonable assurances (i) that transactions, receipts and expenditures of the Company and its Subsidiaries are being executed and made only in accordance with appropriate authorizations of management and the board of directors of the Company, (ii) that transactions are recorded as necessary (A) to permit preparation of financial statements in conformity with GAAP and (B) to maintain accountability for assets, (iii) regarding prevention or timely detection of unauthorized acquisition, use or disposition of the assets of the Company and its Subsidiaries and (iv) that the amount recorded for assets on the books and records of the Company and its Subsidiaries is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(f) Neither the Company nor any of its Representatives has received or otherwise obtained any written or, to the Knowledge of the Company, oral, complaint, allegation, assertion or claim regarding the accounting or auditing practices, procedures, methodologies or methods of the Company or its internal accounting controls, including any complaint, allegation, assertion or claim that the Company has engaged in questionable accounting or auditing practices. No member of the board of directors or any officer of the Company or any employee of the Company who has a significant role in the Company's internal control over financial reporting has committed fraud with respect to the Company's financial reporting.

3.10 Title to Properties. The Company and its Subsidiaries have good and marketable title to, or in the case of leased assets and properties, valid leasehold interests in, all of the material tangible assets and properties (including those shown on the Company Balance Sheet) used or held for use in, or necessary for, the operation of the Company Business, free and clear of all Encumbrances, other than Permitted Encumbrances. All machinery, vehicles, equipment and other material tangible personal property owned or leased by the Company or its Subsidiaries or used in the Company Business are in good operating condition and satisfactory repair, normal wear and tear excepted and are sufficient for the continued operation of the Company Business following the Closing. Section 3.10(a) of the Company Disclosure Schedule sets forth a complete and correct list of all leases or licenses with respect to material tangible personal property used by the Company or its Subsidiaries and lists the term of such lease, amounts payable, security deposit, maintenance and similar charges, and any advance payments thereunder. Section 3.10(b) of the Company Disclosure Schedule sets forth a complete and correct list of all real property leases or licenses to which the Company or any of its Subsidiaries is a party and lists the term of such lease, rent payable, security deposit, maintenance and similar charges, and any advance rent paid thereunder. All leases of real or personal property to which the Company or any of its Subsidiaries is a party are in full force and effect and afford the Company or its Subsidiary, as applicable, a valid leasehold interest in, or license to use, the real or personal property that is the subject of such lease or license. All rents, required deposits and additional rents which are due under the terms of such leases have been paid in full. Neither the Company nor any of its Subsidiaries has ever owned any real property.

3.11 Company Material Contracts.

(a) Section 3.11(a) of the Company Disclosure Schedule sets forth a list of each Contract of the following types to which the Company or any of its Subsidiaries is a party or to which the Company or any of its Subsidiaries or any of their respective assets or properties is bound, including the applicable subsection(s) to which such Contract is responsive:

(i) any Contract, other than Contracts concerning an at-will employment relationship that do not include a severance provision, providing for payments (whether fixed,

contingent or otherwise) by or to the Company or any of its Subsidiaries in an annual amount of One Hundred Thousand Dollars ($100,000) or more;

(ii) any dealer, distributor, reseller, OEM (original equipment manufacturer), VAR (value added reseller), sales representative or similar Contract under which any third party is authorized to sell, license, sublicense, lease, distribute, market or take orders for any Company Offering or Company Technology;

(iii) any Contract that (A) provides for the authorship, invention, creation, conception or other development of any Technology or Intellectual Property Rights (1) by the Company (or any of its Subsidiaries) for any other Person or (2) for the Company (or any of its Subsidiaries) by any other Person, including, in the case of each of clauses (1) and (2), any joint development, (B) provides for the assignment or other transfer of any ownership interest in Technology or Intellectual Property Rights (1) to the Company (or any of its Subsidiaries) from any other Person or (2) by the Company (or any of its Subsidiaries) to any other Person, (C) includes any grant of an Intellectual Property License to any other Person by the Company (or any of its Subsidiaries) (other than, with respect to this subsection (C) only, non-exclusive licenses granted to the Company's end users or customers in the Ordinary Course of Business pursuant to the Company's standard end user agreement(s), copies of which have been made available to Parent ("**Standard EULAs**")), or (D) includes any grant of an Intellectual Property License to the Company (or any of its Subsidiaries) by any other Person ("**Inbound Licenses**");

(iv) any Contract that relates to a partnership, joint venture, joint marketing, joint development or similar arrangement with any other Person;

(v) any Contract involving any Change of Control Payment or other Contract containing obligations of the Company or any of its Subsidiaries with any employee, advisor, or independent contractor or any former employee, advisor or independent contractor or otherwise involving commission or incentive pay, or non-discretionary bonus, retention, change in control, severance, Tax gross-up, relocation, repatriation or expatriation obligations. For the avoidance of doubt, the foregoing does not include obligations that are no longer in force and effect as of the Agreement Date;

(vi) any Contract under which the Company or any of its Subsidiaries has advanced or loaned any amount to any of its directors, officers, or employees (other than under the Company's 401(k) plan) or to any other Person;

(vii) any Contract relating to or evidencing any Indebtedness of the Company or any of its Subsidiaries or otherwise placing an Encumbrance (other than a Permitted Encumbrance) on any asset of the Company or any of its Subsidiaries;

(viii) any Contract (A) that restricts the Company or any of its Subsidiaries from, or following the Effective Time will restrict Parent or any of its Affiliates from (1) engaging in any aspect of its business, (2) participating or competing in any line of business, market or geographic area, (3) freely setting prices for its products, services or technologies (including most favored customer pricing provisions), (4) soliciting potential employees, independent contractors or other suppliers or customers (not including, with respect to this subsection (4) only, Contracts entered into between individual employees of the Company and their former employers which restricts the applicable individual employees of the Company from soliciting employees, independent contractors or other suppliers or customers of the former employers) or (B) under which the Company or any of its Subsidiaries grants or is bound by or, following the Effective Time, purports to have Parent or any of its Affiliates grant or be bound by, any exclusive rights, noncompetition rights, rights of refusal, rights of first negotiation or similar rights;

(ix) any Contract that is an Equity-Related Agreement;

(x) any Contract with any Union or any collective bargaining agreement or similar Contract with the Company's or any of its Subsidiaries' employees;

(xi) any Contract relating to the settlement or other resolution of any Action or threatened Action (including any agreement under which any employment-related claim is settled) executed by the Company or any of its Subsidiaries during the four (4) years preceding the Agreement Date;

(xii) any Contract with any Related Party;

(xiii) any Contract relating to the acquisition or disposition of a material portion of the assets of, or any equity interest in, any Person or business, whether by way of merger, consolidation, amalgamation, plan or scheme of arrangement, purchase or sale of stock or assets, license or otherwise;

(xiv) any Contract that contains an earn-out, escrow or other similar contingent payment or obligation;

(xv) any Contract between the Company or any of its Subsidiaries and any Governmental Authority or any university, college other educational institution or research center; or

(xvi) any Contract not otherwise listed above that is material to the Company or any of its Subsidiaries, or their respective business, operations, financial condition, properties or assets.

(b) All Company Material Contracts are in written form. The Company has made available to Parent correct and complete copies of each Company Material Contract, including all modifications, amendments, and supplements thereto. Each of the Company Material Contracts constitutes a valid and binding obligation of the Company (and any other party thereto), as applicable, enforceable in accordance with its terms, subject to the Enforceability Exceptions, and is in full force and effect in accordance with its terms. There has been no breach or default under any Company Material Contract by any party thereto, no event has occurred that (with or without notice or lapse of time, or both) would reasonably be expected to or would constitute a breach or default thereunder by any party thereto, and neither the Company nor any of its Subsidiaries, as applicable, has received (i) any claim of any such breach or default or (ii) written notice of cancellation or pending cancellation, or intention to reduce the level of business or scope of services under any such Company Material Contract or otherwise adversely affect the rights or obligations or business relationships of the parties under any such Company Material Contract by the other party to any Company Material Contract.

3.12 No Restrictions. Neither the Company nor any of its Subsidiaries is a party to, and no asset or property of the Company or any of its Subsidiaries is bound or affected by, any Contract, judgment, injunction, order or decree, that restricts or prohibits the Company or any of its Subsidiaries or, following the Merger, will restrict or prohibit Parent or any of its Affiliates, from freely engaging in the Company Business or from competing anywhere in the world (including any Contracts, judgments, injunctions, orders or decrees restricting the geographic area in which the Company or any of its Subsidiaries or, following the Merger, Parent or any of its Affiliates may sell, license, market, distribute or support any Company Offerings, Company Intellectual Property Rights or Company Technology or provide services or restricting the markets, customers or industries that the Company or any of its Subsidiaries or, following the Merger, Parent or any of its Affiliates may address in operating the Company Business or restricting the prices that the Company or any of its Subsidiaries or, following the Merger, Parent or any of its Affiliates may charge for Company Intellectual Property Rights, Company Technology or Company Offerings (including most favored customer pricing provisions)), or includes any grants by the Company or any of its Subsidiaries or, following the Merger, Parent or any of its Affiliates of exclusive rights or licenses, noncompetition rights, rights of refusal, rights of first negotiation or similar rights.

3.13 Intellectual Property.

(a) Section 3.13(a) of the Company Disclosure Schedule sets forth a complete and correct list of all (i) Registered Company Intellectual Property Rights, and (ii) material unregistered Marks owned or purported to be owned by, or exclusively licensed to, the Company or any of its Subsidiaries. For each item of Registered Company Intellectual Property Rights, Section 3.13(a) of the Company Disclosure Schedule lists (A) the record owner of such item, and, if different, the legal owner and beneficial owner of such item, (B) the jurisdiction in which such item is issued, registered or pending, (C) the issuance, registration or application date and number of such item, and (D) for each Domain Name registration, the applicable Domain Name registrar, the name of the registrant and the expiration date for the registration.

(b) All necessary fees and filings with respect to any Registered Company Intellectual Property Rights have been timely submitted to the relevant Governmental Authorities and Domain Name registrars to maintain such Registered Company Intellectual Property Rights in full force and effect. There are no renewals, annuities, payments, fees, responses to office actions or other filings required to be made and having a due date with respect to any Registered Company Intellectual Property Rights within one hundred-twenty (120) days after the Agreement Date. No issuance or registration obtained and no application filed by the Company or any of its Subsidiaries for any Intellectual Property Rights has been cancelled, abandoned, allowed to lapse or not renewed, except where the Company or its Subsidiary, as applicable, has, in its reasonable business judgment, decided to cancel, abandon, allow to lapse or not renew such issuance, registration or application. Neither the Company nor any of its Subsidiaries has claimed any status in the application for or registration of any Registered Company Intellectual Property Rights, including "small business status," that would not be applicable to Parent and/or the Surviving Corporation. The Registered Company Intellectual Property Rights are, and, as of and immediately following the Effective Time, will be valid, subsisting and enforceable, and there are no facts or circumstances that would render any Registered Company Intellectual Property Rights invalid or unenforceable.

(c) The Company or one of its Subsidiaries is the sole and exclusive owner of all right, title and interest in and to (i) all Registered Company Intellectual Property Rights and (ii) all other Company Intellectual Property Rights and Company Technology owned or purported to be owned by, or subject to an obligation to be assigned to, the Company and its Subsidiaries (clauses (i) and (ii) collectively, the "**Owned Company IP**"), free and clear of all Encumbrances. The Company or one of its Subsidiaries, as applicable, has the sole and exclusive right to bring a claim or suit against a third party for infringement or misappropriation of Owned Company IP. Neither the Company nor any of its Subsidiaries have (i) transferred to any Person ownership of, or granted any exclusive license with respect to, any Intellectual Property Rights that are or would have been, but for such transfer or grant, Company Intellectual Property Rights or (ii) permitted the rights of the Company or any of its Subsidiaries in any Intellectual Property Rights that are or were, at the time, Company Intellectual Property Rights to lapse or enter into the public domain. No Company Intellectual Property Rights or Company Technology are subject to any claim, proceeding or outstanding decree, order, judgment, stipulation (in each case against or binding on the Company) or Contract restricting in any manner, the use, transfer, or, (except for non-exclusive licenses granted pursuant to Intellectual Property Licenses listed in Section 3.11(a)(iii)(C) of the Company Disclosure Schedule and Standard EULAs in each case that would restrict the Company's or any of its Subsidiaries' ability to grant exclusive licenses) licensing thereof by the Company or any of its Subsidiaries, or which may affect the validity, use or enforceability of such Company Intellectual Property Rights or Company Technology. All Company Intellectual Property Rights and Company Technology that are not Owned Company IP ("**Licensed IP**") are validly licensed to the Company or its Subsidiaries pursuant to Intellectual Property Licenses contained in the Contracts listed in Section 3.11(a)(iv) of the Company Disclosure Schedule. The Company and its Subsidiaries, as applicable, have (and will continue to have immediately following the Effective Time) valid and continuing rights (under such Contracts) to use, sell, license and otherwise exploit, as the case may be, all Licensed IP as the same are currently used, sold, licensed and otherwise exploited by the Company and its Subsidiaries. The Company has not received any written notice of termination or cancellation under such Contracts, or received any written notice of breach or default under such Contracts, which breach has not been cured or waived. The Company is not in breach or default thereof in any material respect of such Contracts.

(d) All Owned Company IP is fully and freely transferable and assignable and may be transferred and assigned to Parent without restriction and without payment of any kind to any third Person. All Licensed IP is (or, upon Closing, will be) freely sublicensable to Parent, or the Company's or its Subsidiaries' rights in such Licensed IP may otherwise be extended to Parent, under the terms of the applicable Contracts listed in Section 3.13(d) of the Company Disclosure Schedule, without additional restriction and without payment of any kind to any third Person (other than license fees or similar fees that the Company would have had to pay in any event under the terms of the applicable Contracts).

(e) The Owned Company IP and the Licensed IP constitute all of the Intellectual Property Rights and Technology that are used in or are necessary, and are sufficient, to enable the Company and its Subsidiaries to conduct the Company Business as it currently is conducted and as currently proposed to be conducted, including the design, development, manufacture, use, marketing, import for resale, distribution, licensing out and sale of any Company Offering. The Company Intellectual Property Rights owned by or exclusively licensed to the Company and its Subsidiaries are valid and enforceable.

(f) None of the Registered Company Intellectual Property Rights have been or are subject to any proceeding in any patent or other government office contesting the validity, enforceability, claim construction, ownership or right to use, sell, offer for sale, license or dispose of any Registered Company Intellectual Property Rights. None of the Registered Company Intellectual Property Rights have been or are subject to any interference, derivation, reexamination (including ex parte reexamination, inter partes reexamination, inter partes review, post grant review or covered business method (CBM) review), cancellation, or opposition proceeding. The Company has not received any written notice asserting that any Registered Company Intellectual Property Rights or the proposed use, sale, offer for sale, license or disposition of products, methods or processes claimed or covered thereunder infringes or misappropriates or violates the rights of any third party or that the Company has otherwise infringed, misappropriated or otherwise violated the rights of any third party. None of the Registered Company Intellectual Property Rights is subject to any outstanding order of, judgment of, decree of or agreement with any government office that limits the ability of the Company to exploit any Registered Company Intellectual Property Rights.

(g) Section 3.13(g) of the Company Disclosure Schedule sets forth a complete and correct list of all Intellectual Property Licenses granted expressly under Patents (i) from another Person to the Company or any of its Subsidiaries, and (ii) from the Company or any of its Subsidiaries to another Person.

(h) Copies of the Company's and its Subsidiaries' standard form(s) of non-disclosure agreement, the Standard EULA, and any other of the Company's and its Subsidiaries' standard form(s), including attachments, of non-exclusive licenses of, or agreements to provide on a non-exclusive basis, Company Offerings to customers (collectively, the "**Standard Form Agreements**") have been made available to Parent.

(i) Neither the conduct of the Company Business as it is currently conducted or currently contemplated to be conducted by the Company and its Subsidiaries, nor any Company Offering (including the design, development, use, practice, offering, licensing, provision, import, branding, advertising, promotion, marketing, sale, distribution, making available, or other exploitation of any Company Offering), nor any manufacture marketing, sale, offering for sale, importation, use or intended use or other disposal of any product as currently sold or under development by the Company (i) has been or is violating any Contracts listed in Section 3.11(a)(iv) of the Company Disclosure Schedule; (ii) has been or is infringing, misappropriating (or resulting from the misappropriation of), diluting, using or disclosing without authorization, or otherwise violating (and, when conducted following the Closing in substantially the same manner, will not infringe, misappropriate, dilute, use or disclose without authorization, or otherwise violate) any Intellectual Property Rights of any third Person, (iii) has been or is contributing to or inducing (and, when conducted following the Closing in substantially the same manner, will not contribute to or induce) any infringement, misappropriation, or other violation of any Intellectual Property Rights of any third Person, or (iv) has been or is constituting (and, when conducted following the Closing in substantially the same manner, will not constitute) unfair competition or trade practices under the Laws of any relevant jurisdiction.

(j) Neither the Company nor any of its Subsidiaries has received any notice from any Person or is aware of any Person (i) alleging any infringement, misappropriation, misuse, dilution, violation, or unauthorized use or disclosure of any Intellectual Property Rights or Technology or unfair competition, (ii) inviting the Company or any of its Subsidiaries to take a license under any Intellectual Property Rights to any Company Offerings or the conduct of the Company Business or (iii) challenging the ownership, use, validity or enforceability of any Company Intellectual Property Rights or Company Technology. There is no basis for any Person to make any such allegation, invitation, or challenge. The Company has no reason to believe that any such claim under subsection (iii) is or may be forthcoming. Neither the Company nor any of its Subsidiaries is in violation of the terms of any Intellectual Property License.

(k) No Person is infringing, misappropriating, misusing, diluting or violating any Company Intellectual Property Rights, or Company Technology in each case owned by or exclusively licensed to the Company or any of its Subsidiaries, or Company Offering. Neither the Company or any of its Subsidiaries has made any written or unwritten claim against any Person alleging any infringement, misappropriation, misuse, dilution or violation of any Company Intellectual Property Rights, Company Technology owned or purported to be owned by or exclusively licensed to the Company or any of its Subsidiaries, or Company Offering.

(l) Neither the Company nor any of its Subsidiaries is restricted or limited from engaging in any line of business or from developing, using, making, selling, offering for sale any product, service or Technology or from hiring or soliciting potential employees or independent contractors. Neither this Agreement nor the transactions contemplated by this Agreement, including the assignment to Parent by operation of Law or otherwise of any Intellectual Property Licenses to which the Company or any of its Subsidiaries is a party, will result in: (i) Parent, the Company or any of their respective Affiliates granting to any third Person any right to or with respect to any Intellectual Property Rights owned by, or licensed to any of them (other than rights granted by the Company or its Subsidiaries on or prior to the Closing Date under Intellectual Property Rights held by the Company or its Subsidiaries as of the Closing Date) or being required to provide any source code for any Company Offering to any third Person, (ii) Parent, the Company or any of their respective Affiliates being bound by, or subject to, any non-compete or other restriction on its freedom to engage in, participate in, operate or compete in any line of business, or (iii) Parent, the Company or any of their respective Affiliates being obligated to pay any royalties or other license fees with respect to Intellectual Property Rights of any third Person in excess of those payable by the Company or its Subsidiaries in the absence of this Agreement or the transactions contemplated hereby.

(m) The Company and its Subsidiaries have taken commercially reasonable measures to protect all Proprietary Information of the Company and all Proprietary Information of any third Person in the Company's or any of its Subsidiaries' possession or control, or to which the Company or any of its Subsidiaries has access, with respect to which the Company or any of its Subsidiaries has a confidentiality obligation. No such Proprietary Information has been authorized to be disclosed in breach of a confidentiality obligation or has been actually disclosed in breach of a confidentiality obligation to any Person other than pursuant to a written confidentiality Contract restricting the disclosure and use of such Proprietary Information. Each current and former employee, director, consultants, and independent contractor of the Company and its Subsidiaries that has been involved in the authorship, invention, creation, conception or other development of any Company Technology has entered into an enforceable written non-disclosure and invention assignment Contract with the Company or such Subsidiary that effectively and validly assigns to the Company or such Subsidiary all Intellectual Property Rights and Technology authored, invented, created, conceived, or otherwise developed by such employee, consultant, independent contractor, or director in the scope of his, her or its employment or engagement with the Company or such Subsidiary (an "**Invention Assignment Agreement**") in a form made available to Parent prior to the Agreement Date. No current or former employee, consultant, independent contractor or director of the Company or any of its Subsidiaries has (i) excluded any Company Technology (or any Intellectual Property Rights in or to any Company Technology) authored, invented, created, conceived, or otherwise developed prior to his or her or its employment or engagement with the Company or any of its Subsidiaries from his or her or its assignment of inventions pursuant to such Person's Invention Assignment Agreement, (ii) failed to affirmatively indicate in such Invention Assignment Agreement that no Company Technology authored, invented, created, conceived, or

otherwise developed by him or her or it prior to his or her or its employment or engagement with the Company or any of its Subsidiaries exists, (iii) alleged, to the Company or any of its Subsidiaries or, to the Knowledge of the Company, any third Person, ownership or other exclusive rights by such employee, consultant, independent contractor or director, in any Technology authored, invented, created, conceived or otherwise developed by such employee, consultant, independent contractor or director in the scope of his, her or its employment or engagement with the Company or any of its Subsidiaries, or (iv) failed to effectively waive all moral rights held by such employee, consultant, independent contractor or director, in any Technology authored, invented, created, conceived or otherwise developed by such employee, consultant, independent contractor or director, in the scope of his, her or its employment or engagement with the Company or any of its Subsidiaries in favor of the Company or such Subsidiary, as applicable. Without limiting the foregoing, all rights in, to and under all Intellectual Property Rights and Technology created by the Company's founders for or on behalf of or in contemplation of the Company (or the Company's business) prior to their commencement of employment with the Company have been duly and validly assigned to the Company.

(n) (i) No government funding and no facilities of any university, college, other educational institution or research center were used in the development of any Owned Company IP or otherwise made available to the Company or any of its Subsidiaries for any other purpose, and (ii) no Governmental Authority or any university, college, other educational institution or research center owns, purports to own, has any other rights in or to (including through any Intellectual Property License), or has any option to obtain any rights in or to, any Owned Company IP. No employee of the Company or any of its Subsidiaries who has been involved in the creation or development of any Technology or Intellectual Property Rights for the Company or any of its Subsidiaries, or have had access to such Technology or Intellectual Property Rights, has performed services for the government, university, college, or other educational institution or research center during a period of time during which such employee, consultant or independent contractor was also performing services for the Company or any of its Subsidiaries. Without limiting the foregoing, there are no current or contingent usage rights, march-in rights, manufacturing restrictions or other rights of any governmental entity in or to any Company Intellectual Property Rights, or in or to any other Intellectual Property Rights that are either used by or for the Company or any of its Subsidiaries or that are otherwise necessary to conduct the business of the Company and its Subsidiaries as currently conducted and currently contemplated to be conducted.

(o) The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of any right of the Company or any of its Subsidiaries to own, use, practice or otherwise exploit any Company Intellectual Property Rights, Company Technology or Company Data in any material respect. Neither the execution, delivery and performance of this Agreement or any Company Ancillary Agreement, nor the consummation of the transactions contemplated by this Agreement or any Company Ancillary Agreement will, pursuant to any Contract to which the Company or any of its Subsidiaries is a party or otherwise bound, result (or purport to result) in the transfer or grant by the Company or Parent or any of their respective Affiliates to any Person (other than Parent and its Affiliates) of any ownership interest or Intellectual Property License with respect to any Company Intellectual Property Rights or Company Technology or any Intellectual Property Rights or Technology of Parent or any of its Affiliates.

(p) Neither the Company nor any of its Subsidiaries has incorporated any specifications, requirements, feedback or other contribution of any other Person in or to which the Company or its Subsidiaries does not have a right or license into any Intellectual Property Rights of the Company (or its Subsidiaries) or Company Offering. Neither the Company nor any of its Subsidiaries has undertaken any material joint development or similar activities with any other Person except as otherwise disclosed on the Company Disclosure Schedule.

3.14 Privacy and Data Protection.

(a) The Company has provided complete and correct disclosures with respect to its privacy policies and privacy and data handling practices including by providing all types of notice and obtaining all types of consent required by all applicable Privacy Requirements (as defined below). Such disclosures have not contained any material omissions related to the privacy policies and privacy and data practices of the Company and its Subsidiaries. None of the materials distributed or marketed by the

Company or any of its Subsidiaries, including privacy policies, have been inaccurate, misleading or deceptive such that the information or disclosure would violate any Privacy Requirements to which the Company or any of its Subsidiaries is subject.

(b) The Company and its Subsidiaries, its vendors, consultants, agents suppliers and/or subcontractors (such Persons acting in their capacity as service providers to the Company) ("**Company Service Providers**") who store, maintain, transmit or have routine access to Personal Information and User Data have at all times (i) complied in all respects with all applicable Privacy Laws, regulatory and self-regulatory guidelines and codes, published interpretations by Governmental Authorities of such Privacy Laws, guidelines and codes, and all similar consumer protection or privacy laws relating to the receipt, collection, compilation, use, storage, processing, sharing, safeguarding, security, disposal, destruction, disclosure, or transfer (including the transfer by or on behalf of the Company or any of its Subsidiaries of Personal Information or User Data from the European Economic Area to any jurisdiction in respect of which the European Commission has not issued an adequacy decision) of Personal Information (including employee data) or User Data; (ii) complied in all respects with all of the Company's and its Subsidiaries' policies regarding privacy and data security, including (A) all privacy policies and similar disclosures published on the Company Web Sites or otherwise communicated in writing to employees, users of any Company Web Site, Company Offering or Company Software and other third parties or otherwise communicated to the public, (B) any notice to or consent from the provider or subject of Personal Information or User Data, and (C) any contractual commitment made by the Company or its Subsidiaries with respect to such Personal Information, PHI and User Data and (iii) complied with all contractual obligations relating to the receipt, collection, compilation, use, storage, processing, sharing, safeguarding, security, disposal, destruction, disclosure, or transfer (including the transfer by or on behalf of the Company or any of its Subsidiaries of Personal Information or User Data (all of the foregoing, collectively, the "**Privacy Requirements**"). Neither the Company nor any of its Subsidiaries has received any claim or complaint regarding its or its agents' collection, use or disclosure of any data (including, without limitation, Personal Information, PHI and User Data) and/or failure to comply with any Privacy Requirements. Except as disclosed in Section 3.14(b) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries nor any of the Company Service Providers collects, stores, uses, accesses, discloses or transfers Personal Information, PHI or User Data outside of the United States of America.

(c) There have not been any actual or alleged incidents of, or claims or Actions related to, data security breaches, unauthorized access or use of any of the IT Systems, or unauthorized acquisition, destruction, damage, disclosure, loss, corruption, alteration, or use of any Personal Information or User Data or data owned by the Company or any of its Subsidiaries or provided by the Company's or any of its Subsidiaries' customers, whether held by the Company (or any of its Subsidiaries) or the Company Service Providers and there are no facts or circumstances which could reasonably serve as the basis for any such allegations or claims. Neither the Company nor any of its Subsidiaries has notified, or been required to notify, any Person of any information security breach or incident involving Personal Information or User Data. Neither the Company nor any of its Subsidiaries has received any correspondence relating to, or notice of any Actions, claims, investigations or alleged violations of, Laws with respect to Personal Information or User Data from any Person, there is no such ongoing Action, claim, investigation or allegation, and there are no facts or circumstances which could form the basis for any such Action, claim, investigation or allegation.

(d) No investigation, inspection, audit or other proceeding of any nature involving allegations of any violation of Privacy Laws is threatened, pending, or, to the Company's knowledge, contemplated by any Governmental Authority or other third party against the Company or any of its Subsidiaries or any Company Service Providers who store, maintain, transmit or have routine access to Personal Information or User Data.

(e) The Company and its Subsidiaries have implemented commercially reasonable, though in no event less than industry-standard organizational, physical, administrative and technical measures required by Privacy Requirements and in conformity with applicable industry standards to protect the integrity, security and operations of the Company's and its Subsidiaries' IT Systems, transactions executed thereby, and data owned by the Company or any of its Subsidiaries, including protecting against loss and against damage, accidental loss or destruction, unauthorized or unlawful

access, use, modification, disclosure or other misuse. The Company and its Subsidiaries have implemented industry standard policies and procedures to detect and respond to data security breaches and unauthorized access or use of the Company's or its Subsidiaries' IT Systems, Personal Information, and data owned or controlled by the Company or any of its Subsidiaries including by their respective employees and the Company Service Providers that have access to Personal Information. The Company and its Subsidiaries provide their respective employees and Company Service Providers with regular privacy and data security training in compliance with applicable Privacy Requirements. The Company and its Subsidiaries require all third parties to which it provides Personal Information and/or access thereto to maintain the privacy and security of such Personal Information, including where required by applicable Law by contractually obligating such third parties to protect such Personal Information from unauthorized access by and/or disclosure to any unauthorized third parties.

(f) The IT Systems are adequate and sufficient (including with respect to working condition and capacity) for the operations of the Company and its Subsidiaries. The Company and its Subsidiaries have continuously operated in a manner to preserve and maintain the performance, security and integrity of the IT Systems. The IT Systems are adequate and sufficient (including with respect to working condition and capacity) for the operations of the Company and its Subsidiaries, including having reasonable and appropriate back-up and disaster recovery procedures.

(g) The transfer of Personal Information and User Data in connection with the transactions contemplated by this Agreement will not violate any Privacy Requirements as they currently exist or as they existed at any time during which any of the Personal Information or User Data was collected or obtained. Neither the Company or any of its Subsidiaries is subject to any Privacy Requirements that, following the Closing, would prohibit the Company or any of its Subsidiaries or Parent from receiving or using Personal Information or User Data in the manner in which the Company and its Subsidiaries receive and use such Personal Information or User Data prior to the Closing.

(h) Except for disclosures of information required by Law, authorized by the provider of Personal Information or User Data, or provided for in the Contracts listed in Section 3.14(h) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries has shared, sold, rented or otherwise made available, and is sharing, selling, renting or otherwise making available, to third parties any Personal Information or User Data.

(i) In connection with each third-party servicing, outsourcing, processing, or otherwise using Personal Information or User Data collected, held, or controlled by or on behalf of the Company or its Subsidiaries, the Company has contractually obligated any such third party to (i) comply with applicable Privacy Laws with respect to Personal Information and User Data, (ii) act only in accordance with the instructions of the Company, (iii) take appropriate steps to protect and secure Personal Information and User Data from unauthorized disclosure, (iv) restrict use of Personal Information to those authorized or required under the servicing, outsourcing, processing, or similar arrangement, and (v) certify or guarantee the return or adequate disposal or destruction of Personal Information and User Data. The Company has disclosed all such data processing agreements to which it is a party.

(j) In connection with the processing of any Personal Information or User Data by the Company or any of its Subsidiaries on behalf of any third party, the Company has entered into valid, binding and enforceable written data processing agreements with any such party as required by the Privacy Laws. The Company has disclosed all such data processing agreements to which it is a party.

(k) The Company has all necessary and required rights to use, reproduce, modify, create derivative works of, license, sublicense, distribute and otherwise exploit the data contained in the Company Data in connection with the operation of the business of the Company and its Subsidiaries, and the Company has the right to transfer such rights as needed to effectuate the transactions contemplated by this Agreement.

(l) The Company has: (A) regularly conducted and regularly conducts commercially reasonable vulnerability testing, risk assessments, and external audits of, and tracks security incidents related to the Company's and its Subsidiaries' systems and products (collectively, "**Information Security**

Reviews"); (B) timely corrected any material exceptions or vulnerabilities identified in such Information Security Reviews; (C) made available complete and correct copies of all Information Security Reviews; and (D) timely installed software security patches and other fixes to identified technical information security vulnerabilities.

(m) Neither the Company nor any of its Subsidiaries has distributed or does distribute marketing communications to any Person, except in accordance with Privacy Laws, and opt-in consent has been obtained from all Persons in the European Union to marketing by electronic means in accordance with Privacy Laws. The Company and its Subsidiaries hold records evidencing all consents referred to under this Section 3.14(m).

(n) Neither the Company nor any of its Subsidiaries is currently using or has ever used the Credentials of any other Person to use or access any Third-Party Platform. Neither the Company nor any of its Subsidiaries has ever used web scraping, bots, spiders, indexing or similar methods or technology to collect data from the websites, online services or applications of any other Person. Neither the Company nor any of its Subsidiaries is, nor has the Company or any of its Subsidiaries received any notice that it is, in violation, breach or default of any Contract (including, without limitation, any website's terms of use or privacy policy) concerning the Company's or one of its Subsidiaries' collection of data or any of the websites from which Company or any of its Subsidiaries scrapes or otherwise obtains data, and there has not occurred any event that with the lapse of time or the giving of notice or both would constitute such a violation, breach or default.

(o) Except as otherwise disclosed in Section 3.14(o)(i) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries obtains any Usage Data from any other Person. The Company and each of its Subsidiaries uses its customers' personal data and usage data (whether aggregated, de-identified or otherwise modified) solely for the benefit of such customer that provided the data and, except as otherwise disclosed in Section 3.14(o)(ii) of the Company Disclosure Schedule, does not disclose its customers' data (whether aggregated, de-identified or otherwise modified) to any Person except for such customer's employees, subcontractors and agents, as requested by customer, or as otherwise explicitly set forth in the underlying Contract with such customer. Neither the Company nor any of its Subsidiaries has sold, transferred, licensed, disclosed, made available to the public or otherwise released for distribution any of its customer files and other customer information relating to the Company's or any of its Subsidiaries' current and former customers or agreed to do any of the foregoing. No Person other than the Company or its Subsidiaries, as applicable, possesses or has any claims or rights with respect to use of such customer files and other customer information. Neither the Company nor any of its Subsidiaries has disclosed, used, made available to the public, released for distribution or failed to protect or secure any confidential information or any system containing confidential information User Data or Personal Information in violation of any applicable Law or any Privacy Requirements.

3.15 Compliance with Laws.

(a) The Company and its Subsidiaries are, and at all times for the past six (6) years have been, in compliance in all material respects with all applicable Laws.

(b) The Company and its Subsidiaries hold all permits, licenses and approvals from, and have made all filings with, Governmental Authorities that are required to be held to conduct the Company Business in compliance with applicable Law and applicable Contracts ("**Governmental Permits**"), and all such Governmental Permits are valid and in full force and effect. Neither the Company nor any of its Subsidiaries have received in the past six (6) years any written notice or other written communication, or to the Knowledge of the Company, any oral notice or other oral communication, from any Governmental Authority regarding (i) any actual or possible violation of applicable Law or any Governmental Permit or any failure to comply with any term or requirement of any Governmental Permit or (ii) any actual or possible revocation, withdrawal, suspension, cancellation, termination or modification of any Governmental Permit.

(c) All materials, products and services distributed or marketed by the Company and its Subsidiaries have at all times made all material disclosures to users or customers required by Law, and

none of such disclosures made or contained in any such materials, products or services have been inaccurate, misleading or deceptive in any material respect.

3.16 Employees, ERISA and Other Compliance.

(a) Section 3.16(a)(i) of the Company Disclosure Schedule is a complete and correct list of all current employees of the Company and its Subsidiaries as of the Agreement Date, and for each such employee: (1) job position or title, (2) annualized base salary or hourly wage (as applicable), (3) annual commission opportunity and bonus potential, (4) classification as full-time, part-time, fixed-term, temporary or seasonal, (5) classification as exempt or non-exempt for purposes of wage and hour Laws, (6) whether a full-time or part-time employee, (7) accrued but unused vacation/paid time off balance and annual vacation/paid time off entitlement, (8) any visa or work permit status and the date of expiration, if applicable, (9) commencement date of employment with the Company or its Subsidiary, as applicable, (10) work location (country, state, city/town), (11) severance entitlements and notice required to terminate the relationship, if any, (12) active or inactive status (including anticipated return to work date for any inactive employee), and (13) the total amount of bonus, severance, retention, change in control and/or other amounts to be paid to such employee at the Closing or otherwise in connection with the transactions contemplated hereby. Section 3.16(a)(ii) of the Company Disclosure Schedule is a complete and correct list of all independent contractors, consultants, agency or leased workers or other agents used by the Company and its Subsidiaries and classified by the Company and its Subsidiaries as other than employees, or compensated other than through wages paid by the Company through the Company's payroll ("**Contingent Workers**") as of the Agreement Date, and for each such individual: (1) fee or compensation arrangements, (2) commencement date with the Company, Subsidiaries or any other Affiliate of the Company, (3) service location (country, state); (4) description of services provided; (5) approximate average hours worked per week; (6) notice required to terminate the relationship, and (7) confirmation as to whether a written independent contractor agreement exists.

(b) The Company and its Subsidiaries currently correctly classify and pay, and have for the four (4) years preceding the Agreement Date correctly classified and paid, employees as exempt employees and nonexempt employees under the Fair Labor Standards Act, the National Minimum Wage Act 1998 (in relation to employees and workers in the United Kingdom) and other Laws, and the Company and its Subsidiaries is and has been in compliance with such Laws for the four (4) years preceding the Agreement Date. All employees of the Company and its Subsidiaries are, and have been since their respective start of employment by the Company or its Subsidiary, as applicable, legally permitted to be employed by the Company in the jurisdiction in which such employee is employed in their current job capacities for the maximum period permitted by Law. All independent contractors providing services to the Company or its Subsidiaries are and, for the three (3) years preceding the Agreement Date, have been properly classified, treated and paid as independent contractors for purposes of federal and applicable state Tax Laws, Laws applicable to employee benefits and other Laws. Except as set forth on Section 3.16(b)(i) of the Company Disclosure Schedule, all employees of the Company and its Subsidiaries are employed at-will and no employee is subject to any employment contract with the Company or its Subsidiary, whether oral or written. Except as set forth on Section 3.16(b)(ii) of the Company Disclosure Schedule, neither the Company nor any of its Subsidiaries have any employment Contracts currently in effect that are not terminable at will (other than agreements with the sole purpose of providing for the confidentiality of Proprietary Information or assignment of inventions).

(c) The Company and each of its Affiliates: (i) are, and, at all times during the four (4) years preceding the Agreement Date, have been, in compliance in all material respects with all applicable Laws respecting employment, including fair employment practices, terms and conditions of employment, restrictive covenants, discrimination, harassment, victimization, retaliation, workplace health and safety, pay equity, pay transparency, background checks, wages and hours, overtime pay, payroll documents and wage statements, equal employment opportunity, work authorization and immigration compliance, termination, dismissal or discharge, plant closing, mass layoff and redundancy requirements, affirmative action, workers' compensation, disability, unemployment compensation, whistleblowers, labor relations and collective bargaining, the proper classification and treatment of employees as exempt or non-exempt and the proper classification and treatment of independent contractors, health care continuation requirements of COBRA, employee leave including the requirements of the Family and Medical Leave Act of 1993, as amended (to the extent applicable), the requirements of

the Health Insurance Portability and Accountability Act of 1996, as amended, the Transfer of Undertakings (Protection of Employment) Regulations 2006 and any similar provisions of state Law and no liability for any failure to comply with any such obligation or requirement has been transferred to the Company or any of its Subsidiaries by virtue of the Transfer of Undertakings (Protection of Employment) Regulations 2006, (ii) have withheld, paid and reported all amounts required by Law with respect to compensation, wages, salaries, commissions, bonuses, fees, and other payments to employees or Contingent Workers of the Company and its Subsidiaries, (iii) are not liable for any arrears of wages or any Taxes or any penalty for failure to comply with any Law, (iv) are not liable for any employment taxes or any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Authority with respect to unemployment compensation benefits, social security or any other applicable social insurance, or other benefits or obligations for employees of the Company and its Subsidiaries (other than routine payments to be made in the Ordinary Course of Business), and (v) are not delinquent in any payments to any employee or Contingent Worker for any compensation, wages, salaries, commissions, bonuses, fees, vacation pay or other payments due with respect to any services performed for it or amounts required to be reimbursed to such employees or Contingent Workers. There are no pending or, to the Knowledge of the Company, threatened Actions against the Company or any of its Affiliates under any worker's compensation policy or long-term disability policy. No employee or Contingent Worker of the Company or any of its Subsidiaries is eligible to earn commission, incentive compensation, or other post-employment or post-engagement compensation payments after the end of their employment or engagement pursuant to applicable Contracts.

(d) Neither the Company nor any of its Subsidiaries is a party to or currently negotiating or is in receipt of an outstanding application or request for the (voluntary or involuntary) recognition or derecognition of any collective bargaining or similar agreement, work rules or practices with any labor organization, staff association, works council union or other person purporting to act as exclusive bargaining representative ("**Union**") of any employees or Contingent Workers, and neither the Company nor any of its Subsidiaries have a duty to bargain with any Union, nor are any organized groups of its employees represented by any labor union. There is no, and in the past three (3) years there has been no pending, or to the Company's Knowledge, threatened, labor dispute, picketing of any nature, organizational campaigns, work slowdown, work stoppage, strike, or any other concerted interference with normal operations, involving the Company or any of its Subsidiaries. To the Knowledge of the Company, neither the Company nor any of its Subsidiaries has engaged in any unfair labor practice. To the Knowledge of the Company, no employee or Contingent Worker of the Company or any of its Subsidiaries currently intends to terminate his or her employment or service arrangement with the Company or its Subsidiary, as applicable, and to the Knowledge of the Company no employee or Contingent Worker of the Company or any of its Subsidiaries has received an offer to join a business that may be competitive with the Company Business.

(e) The Company and its Subsidiaries are in compliance with the requirements of the Immigration Reform Control Act of 1986 and have a complete and correct copy of U.S. Citizenship and Immigration Services Form I-9 for each of its employees and are in compliance with all local Laws respecting immigration and right to work requirements.

(f) Except as set forth on Schedule 3.16(f) of the Company Disclosure Schedule, currently and within the four (4) years preceding the Agreement Date, the Company and its Subsidiaries are not, have not been subject to, and have not received any threat of any form of litigation, governmental audit, governmental investigation, administrative agency proceeding, private dispute resolution procedure, or internal or external investigation of alleged employee misconduct, in each case with respect to employment or labor matters (including but not limited to allegations related to dismissal, equal employment opportunity, discrimination, retaliation, victimization, immigration, unpaid compensation, pay equity, noncompliance with wage and hour laws, classification of employees as exempt from overtime or minimum wage Laws, the misclassification of independent contractors, benefits, collective bargaining, redundancy, the payment of social security and similar Taxes, workplace safety and health, whistleblowers, and/or privacy rights of employees violation of restrictive covenants, sexual harassment, other unlawful harassment or unfair labor practices).

(g) During the three (3) year period preceding the Agreement Date, the Company and each of its Subsidiaries have paid and continue to pay each of its employees in a manner that

complies with the requirements of the Equal Pay Act, the Massachusetts Equal Pay Law, and any other federal, state, or local Laws pertaining to the equal pay of employees.

(h) Neither the Company nor any of its Subsidiaries have experienced a collective redundancy (requiring consultation with appropriate representatives as defined in section 188 of the Trade Union and Labour Relations (Consolidation) Act 1992 and/or the issue of a form HR1) at any time or a "mass layoff," or "plant closing" or similar group "employment loss" as defined by the WARN Act or any other equivalent Law in respect of the Company or its Subsidiaries and neither the Company nor any of its Subsidiaries has been affected by any transaction or engaged in any lay-offs, employment terminations or other employment actions sufficient in number to trigger the application of any such Law. During the one hundred and eighty (180) day period preceding the Agreement Date, neither the Company nor any of its Subsidiaries have had one hundred (100) or more employees.

(i) No furlough, temporary layoff, material work schedule change or reduction in hours, or reduction in salary or wages, or other material workforce changes affecting employees or independent contractors of the Company or any of its Subsidiaries has occurred within the twelve months prior to the date hereof, or, as of the date hereof, is contemplated, planned or announced, including as a result of COVID-19 or any Law, Order, directive, guidelines or recommendations by any Governmental Authority in connection with or in response to COVID-19. Neither the Company nor its Subsidiaries has otherwise experienced material employment-related liability with respect to COVID-19 Measures and no group of employees or independent contractors of the Company and its Subsidiaries is unable to perform his or her duties to the Company and its Subsidiaries due to COVID-19. The Company and its Subsidiaries are in compliance with (including records, training, notices, and other requirements) all Law, Order, directive, guidelines or recommendations by any Governmental Authority in connection with or in response to COVID-19.

(j) Neither the Company nor any of its Subsidiaries is subject to any affirmative action obligations under any Law, including, without limitation, Executive Order 11246, nor is the Company or any of its Subsidiaries a government contractor or subcontractor for purposes of any Law with respect to the terms and conditions of employment, including, without limitation, the Service Contracts Act or prevailing wage Laws.

(k) To the Company's Knowledge, no employee or Contingent Worker of the Company or any of its Subsidiaries is in violation of any term of any Contract or any restrictive covenant relating to the right of any such employee or Contingent Worker to be employed by or to render services to the Company or any of its Subsidiaries or to use Proprietary Information of others. To the Company's Knowledge, the employment of any employee or engagement of any Contingent Worker by the Company or its Subsidiaries, as applicable, does not subject them to Liability to any third party.

(l) At all times during the four (4) years preceding the Agreement Date, the Company and each of its Subsidiaries have maintained policies (1) prohibiting employment discrimination on all grounds constituting unlawful discrimination, (2) prohibiting sexual harassment and all other forms of discriminatory harassment, and (3) providing complaint and investigation procedures with respect to (1) and (2). At all times during the four (4) years preceding the Agreement Date, any and all such policies have conformed with applicable legal requirements, including, as applicable, with respect to independent contractors. At all times during the four (4) years preceding the Agreement Date, the Company and each of its Subsidiaries has complied in all material respects with any applicable legal requirements with respect to training concerning prevention of discrimination, harassment, retaliation, victimization and/or abusive conduct. Except as set forth on Section 3.16(l)(i) of the Company Disclosure Schedule, to the Knowledge of the Company at no time during the four (4) years preceding the Agreement Date have any allegations been made within or outside the Company alleging conduct that, if confirmed, would constitute violations of any of the policies referenced in (1) and/or (2). Except as set forth on Section 3.16(l)(ii) of the Company Disclosure Schedule, at no time during the three (3) years preceding the Agreement Date has the Company received a complaint within the scope of (3) or conducted an investigation of allegations of any alleged violation of (1) or (2). To the Knowledge of the Company, there are no facts that could reasonably be expected to give rise to a claim of sexual harassment or other discriminatory harassment against or involving the Company, any of its Subsidiaries, or any employee, director or Contingent Worker of the Company or any of its Subsidiaries.

(m) The Company and each of its Subsidiaries is and at all relevant times has been in compliance with COVID-19 related safety and health standards and regulations issued and enforced by the Occupational Safety and Health Administration (OSHA) and any applicable OSHA-approved state plan or the equivalent local Law. The Company and each of its Subsidiaries is and has at all relevant times been in compliance with the paid and unpaid leave requirements of the Families First Coronavirus Response Act, and, to the extent the Company or any of its Subsidiaries has granted employees paid sick leave or paid family leave under the Families First Coronavirus Act, the Company or its Subsidiary, as applicable, has obtained and retained all required documentation required to substantiate eligibility for sick leave or family leave tax credits.

(n) Except as set forth on Section 3.16(n) of the Company Disclosure Schedule, in the past twelve (12) months (i) no officer or senior executive's employment with the Company or any of its Subsidiaries has been terminated for any reason; and (ii) to the Knowledge of the Company, no officer or senior executive, or group of employees or Contingent Workers, has expressed any plans to terminate his, her, its, or their employment or service arrangement with the Company or any of its Subsidiaries, as applicable; and (iii) no officer or senior executive of the Company or any of its Subsidiaries has been absent (other than on vacation) for a period of more than four weeks owing to sickness or injury.

(o) Except as set forth on Section 3.16(o) of the Company Disclosure Schedule, the consummation of the transactions contemplated in this Agreement will not (i) entitle any employee or Contingent Worker of the Company to severance pay, unemployment compensation, bonus payment or any other payment, (ii) accelerate the time of payment for vesting of, or increase the amount of compensation due to, any such employee, or (iii) entitle any such employee to terminate, shorten or otherwise change the terms of his employment.

(p) Neither the Company nor any of its Subsidiaries has been party to a "relevant transfer" (as defined by the Transfer of Undertakings (Protection of Employment) Regulations 2006) at any time.

(q) Section 3.16(q) of the Company Disclosure Schedule sets forth a true, complete and correct list of every Company Employee Plan and each agreement with a Company Employee (each, a "**Company Employee Plan**" and collectively, the "**Company Employee Plans**").

(r) True, complete and correct copies of the following documents, with respect to each Company Employee Plan, where applicable, have been made available to Parent (i) all documents embodying or governing such Company Employee Plan (or for unwritten Company Employee Plan a written description of the material terms of such arrangement) and any funding medium for the Company Employee Plan, (ii) the most recent IRS determination or opinion letter; (iii) the filed IRS Form 5500s for the last three years; (iv) the most recent actuarial valuation report; (v) the most recent summary plan description (or other descriptions provided to employees) and all modifications thereto; (vi) all non-routine correspondence to and from any state or federal agency related to such Company Employee Plan; and (vii) the last three years of non-discrimination testing results.

(s) Each Company Employee Plan that is intended to qualify under Section 401(a) of the Code is so qualified and has received a favorable determination or approval letter from the IRS with respect to such qualification, or may rely on an opinion letter issued by the IRS with respect to a prototype plan adopted in accordance with the requirements for such reliance, or has time remaining for application to the IRS for a determination of the qualified status of such Company Employee Plan for any period for which such Company Employee Plan would not otherwise be covered by an IRS determination and, to the Knowledge of the Company, no event or omission has occurred that would cause any Company Employee Plan to lose such qualification or require corrective action to the IRS or Employee Plans Compliance Resolution System to maintain such qualification.

(t) Each Company Employee Plan is and has been established, operated and administered in all material respects in accordance with applicable Laws and regulations and with its terms including without limitation ERISA, the Code, and the Affordable Care Act. No Company Employee Plan is, or within the past six years has been, the subject of an application or filing under a government sponsored amnesty, voluntary compliance, or similar program, or been the subject of any

self-correction under any such program No litigation or governmental administrative proceeding, audit or other proceeding or Action (other than those relating to routine claims for benefits) is pending or, to the Knowledge of the Company, threatened with respect to any Company Employee Plan or any fiduciary or service provider thereof, and, to the Knowledge of the Company, there is no reasonable basis for any such litigation or proceeding. All payments and/or contributions required to have been timely made with respect to all Company Employee Plans either have been made or have been accrued in accordance with the terms of the applicable Company Employee Plan and applicable Law. Each Company Employee Plan satisfies in all material respects the minimum coverage, affordability and non-discrimination requirements under the Code.

(u) Neither the Company nor any ERISA Affiliate has ever maintained, contributed to, or been required to contribute to or had any Liability with respect to, including on account of any ERISA Affiliate (whether contingent or otherwise), to (i) any employee benefit plan that is or was subject to Title IV of ERISA, Section 412 of the Code, Section 302 of ERISA, (ii) a Multiemployer Plan, (iii) any funded welfare benefit plan within the meaning of Section 419 of the Code, (iv) any "multiple employer plan" (within the meaning of Section 210 of ERISA or Section 413(c) of the Code), (v) any "multiple employer welfare arrangement" (as such term is defined in Section 3(40) of ERISA), and neither the Company nor any ERISA Affiliate has ever incurred any Liability under Title IV of ERISA that has not been paid in full, or (vi) any obligation to provide health care or any other non-pension benefits to any employees or other service providers after their employment or service is terminated (other than as required by Part 6 of Subtitle B of Title I of ERISA or similar state law) and neither the Company nor any ERISA Affiliate have ever promised to provide such post-termination benefits.

(v) Each Company Employee Plan may be amended, terminated or otherwise modified (including cessation of participation) by the Company to the greatest extent permitted by applicable Law, including the elimination of any and all future benefit accruals thereunder and no employee communications or provision of any Company Employee Plan has failed to effectively reserve the right of the Company or the ERISA Affiliate to so amend, terminate or otherwise modify such Company Employee Plan.

(w) No Company Employee Plan is subject to the laws of any jurisdiction outside the United States.

(x) Any transfer of property which was subject to a substantial risk of forfeiture and which would otherwise have been subject to taxation under Section 83(a) of the Code is covered by a valid and timely filed election under Section 83(b) of the Code, and a copy of such election has been provided to the Company.

3.17 Books and Records. The Company has made available to Parent complete and correct copies of the minute books, share transfer ledgers, and other similar corporate records, each as amended to date, of the Company and its Subsidiaries. The minute books of the Company and each of its Subsidiaries accurately reflect all corporate actions of the Company or such Subsidiary, as appliable, which are required by Law, the Charter Documents of the Company or such Subsidiary, as applicable, or any applicable Contract to be passed upon by the stockholders or the board of directors (or any committee thereof) of the Company or such Subsidiary, as applicable, as well as all other actions previously taken by the stockholders, the board of directors and the committees of the board of directors of the Company or such Subsidiary, as applicable. The Company and each of its Subsidiaries has maintained Books and Records that are complete and correct in all material respects and accurately and fairly reflect, in all material respects, the business activities of the Company or such Subsidiary, as applicable. Neither the Company nor any of its Subsidiaries have engaged in any material transaction, maintained any bank account or used any corporate funds except as reflected in its Books and Records. At the Closing, the minute books and other Books and Records of the Company and each of its Subsidiaries will be in the possession of the Company. Section 3.17 of the Company Disclosure Schedule sets forth a list as of the Agreement Date of all of the current officers and directors of the Company (including, for each such individual, the position held).

3.18 Insurance. The Company and its Subsidiaries maintain the policies of insurance and bonds set forth in Section 3.18 of the Company Disclosure Schedule (the "**Insurance Policies**"), which

include all legally required workers' compensation and other coverage in such amounts that cover such risks as are in accordance with normal industry practice for companies engaged in businesses similar to that of the Company and its Subsidiaries. Complete and correct copies of the Insurance Policies have been made available to Parent. Section 3.18 of the Company Disclosure Schedule sets forth (a) the name of the insured and the insurer under each such Insurance Policy, the type of Insurance Policy, policy number and the term and amount of coverage thereunder, and (b) all claims made under such Insurance Policy, or any other policy, within the prior five (5) years. To the Company's Knowledge, there is no claim pending under any of such Insurance Policy as to which coverage has been questioned, denied or disputed by the underwriters of such policy or bond or for which its total value (inclusive of defense expenses) would reasonably be expected to exceed the applicable policy limits. All premiums due and payable under all such Insurance Policies and bonds have been timely paid, and the Company and its Subsidiaries are otherwise in compliance in all material respects with the terms of such policies and bonds. All such Insurance Policies remain, and will remain immediately following the Closing, in full force and effect, and, to the Company's Knowledge, no insurance provider has threatened to terminate or increase the premium with respect to, any of such Insurance Policies. Neither the Company nor any of its Subsidiaries has named any additional insureds under its Insurance Policies and is not required to do so under any Contract. Except as set forth in Section 3.18 of the Company Disclosure Schedule, all Insurance Policies are occurrence-based. Neither the Company nor any of its Subsidiaries have any self-insurance or co-insurance programs. Other than the Insurance Policies, neither the Company nor any of its Subsidiaries is bound by, a beneficiary of, an obligor under or a party to, any other insurance policy. To the Knowledge of the Company, no insurer plans to raise the premiums for, or materially alter the coverage under, any such Insurance Policy.

3.19 Environmental Matters. The Company, its Subsidiaries and each of their respective predecessors have at all times been in material compliance with all Environmental Laws which compliance includes the possession of all Governmental Permits and other governmental authorizations required under Environmental Laws and material compliance with the terms and conditions thereof. Neither the Company nor any of its Subsidiaries has received any written notice or other written communication, whether from a Governmental Authority, citizens groups, employee or otherwise, that alleges that the Company or any of its Subsidiaries is not in compliance with any Environmental Law, and to the Knowledge of the Company, there are no circumstances that may prevent or interfere with the compliance by the Company or any of its Subsidiaries with any current Environmental Law in the future. To the Knowledge of the Company, no current or prior owner of any real property leased or possessed by the Company or any of its Subsidiaries has received any written notice or other written communication, whether from a Governmental Authority, citizens group, employee or otherwise, that alleges that such current or prior owner or the Company or any of its Subsidiaries is not in compliance with any Environmental Law.

3.20 Suppliers. Section 3.20 of the Company Disclosure Schedule sets forth the top ten (10) vendors and suppliers of products and services to the Company and its Subsidiaries based on amounts paid or payable by the Company and its Subsidiaries to such vendors and suppliers during each of (i) the twelve-month period ending on December 31, 2023 and (ii) the year-to-date period ending on the last day of the calendar month immediately preceding the Agreement Date (each, a "**Significant Supplier**"). The Company and each of the Subsidiaries, as applicable, is current in its payments consistent with the payment schedule for such Significant Supplier established and agreed in the Ordinary Course of Business to all Significant Suppliers and neither the Company nor any of its Subsidiaries have, and since January 1, 2024 has had, any material dispute concerning Contracts with, or products and/or services provided by, any Significant Supplier that arose or remain unresolved. Neither the Company nor any of its Subsidiaries has received any written or oral notice from any Significant Supplier that such supplier shall not continue as a supplier to the Company or any of its Subsidiaries or, following the Effective Time, Parent or any of its Affiliates or that such supplier intends to terminate, breach or not renew existing Contracts with the Company or any of its Subsidiaries or, following the Effective Time, Parent or any of its Affiliates.

3.21 Anti-Money Laundering Laws. The Company and its Subsidiaries are, and have always been, in material compliance with the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, the United Kingdom Proceeds of Crime Act 2002 and all other applicable anti-money laundering and counter terrorist financing Laws.

3.22 Anti-Corruption and Anti-Bribery Laws.

(a) None of the Company or any of its Subsidiaries or, to the Company's Knowledge, any of their respective directors, officers, agents, employees, independent contractors or other representatives, or any other Person associated with or acting for or on behalf of the Company or any of its Subsidiaries, has, directly or indirectly, in connection with the conduct of any activity of the Company or any of its Subsidiaries: (i) made, offered or promised to make or offer any payment, loan or transfer of anything of value, including any reward, advantage or benefit of any kind, to or for the benefit of any Foreign Government Official, candidate for public office, political party or political campaign, or any official of such party or campaign, for the purpose of (A) influencing any act or decision of such Foreign Government Official, candidate, party or campaign or any official of such party or campaign, (B) inducing such Foreign Government Official, candidate, party or campaign or any official of such party or campaign to do or omit to do any act in violation of a lawful duty, (C) obtaining or retaining business for or with any Person, (D) expediting or securing the performance of official acts of a routine nature, or (E) otherwise securing any improper advantage; (ii) paid, offered or agreed or promised to make or offer any bribe, payoff, influence payment, kickback, unlawful rebate or other similar unlawful payment of any nature; (iii) made, offered or agreed or promised to make or offer any unlawful contributions, gifts, entertainment or other unlawful expenditures; (iv) established or maintained any unlawful fund of corporate monies or other properties; (v) created or caused the creation of any false or inaccurate books and records related to any of the foregoing; or (vi) otherwise violated any provision of the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§78dd-1, et seq. ("**FCPA**"), the United Kingdom Bribery Act of 2010 (the "**Bribery Act**") or any other applicable anti-corruption or anti-bribery Law.

(b) The Company and its Subsidiaries have established and maintain written policies, procedures and internal controls designed to ensure compliance with the FCPA, the Bribery Act and all other applicable anti-corruption and/or anti-bribery Laws and to ensure that all books and records of the Company and its subsidiaries accurately and fairly reflect, in reasonable detail, all transactions and dispositions of funds and assets.

(c) Neither the Company nor any of its Subsidiaries has undergone or is undergoing any audit, review, inspection, investigation, survey or examination by a Governmental Authority relating to the compliance of the Company or any of its Subsidiaries with the FCPA, the Bribery Act, anti-corruption, or anti-kickback activity. To the Knowledge of the Company, there are no threatened Actions, nor presently existing facts or circumstances that would constitute a reasonable basis for any future Actions, with respect to the compliance of the Company or any of its Subsidiaries or any of their respective directors, officers, agents, employees, independent contractors or other representatives with the FCPA or the Bribery Act, or any anti-corruption or anti-kickback activity by the Company or any of its Subsidiaries.

3.23 Trade Compliance.

(a) The Company and its Subsidiaries have at all times conducted their export, import and related transactions in accordance with (i) all applicable U.S. export, re-export, import, anti-boycott, and economic sanctions Laws and regulations, including the Export Administration Regulations, the Arms Export Control Act, the International Traffic in Arms Regulations, the trade and economic sanctions regulations administered by the U.S. Department of Treasury's Office of Foreign Assets Control, and (ii) all other applicable import and export control Laws and regulations in the other countries in which the Company or its Subsidiaries conducts business (the "**Trade Laws**"). The Company and its Subsidiaries have obtained, and are in material compliance with, all import and export licenses and other required consents, authorizations, waivers, approvals, and orders, and have made or filed any and all necessary notices, registrations, declarations and filings with any Governmental Authority, and have met the requirements of any license exceptions or exemptions, as required in connection with (i) the import, export and re-export of products, services, Software or other Technology, and (ii) releases of technical data, Software or other Technology to foreign nationals located in the United States and abroad ("**Trade Approvals**"). The Company and its Subsidiaries are in material compliance with the terms of all applicable Trade Approvals. There are no pending or, to the Knowledge of the Company, threatened inquiries, investigations, enforcement actions, voluntary disclosures or other claims against the Company or any of its Subsidiaries with respect to Trade Laws or Trade Approvals. There are no actions, conditions

or circumstances pertaining to the Company's and any of its Subsidiaries' export, import and related transactions that would reasonably be expected to give rise to any future inquiries, investigations, enforcement actions, voluntary disclosures or other claims. No Trade Approvals for the transfer of export licenses used in the Company Business to Parent or any of its Affiliates are required, or such Trade Approvals can be obtained expeditiously without material cost. Neither the Company nor any of its Subsidiaries have exported or re-exported to any countries subject to U.S. embargo or trade sanctions or to entities identified on any U.S. governmental export exclusion lists, including the Denied Persons List, Entity List, Unverified List, Specially Designated Nationals List, and any other applicable lists maintained by the U.S. Departments of Treasury, State, or Commerce. None of the Company or any of its Subsidiaries or any of their respective officers, directors, employees, advisors, agents, representatives, independent contractors or any other Person associated with or acting for or on behalf of the Company or any of its Subsidiaries (i) is a Person with whom transactions are prohibited or limited under any economic sanctions Laws, including those administered by any U.S. Governmental Authority (including the Office of Foreign Assets Control), the United Nations Security Council, the European Union or Her Majesty's Treasury, or (ii) within the last five (5) years, has violated any economic sanctions Laws. Neither the Company nor any of its Subsidiaries has, within the last five (5) years, made any voluntary disclosures to U.S. Governmental Authorities under U.S. economic sanctions Laws, been the subject of any governmental investigation or inquiry regarding compliance with such Laws or been assessed any fine or penalty under such Laws.

3.24 Healthcare Laws.

(a) The Company and its Subsidiaries hold all material permits, franchises, variances, registrations, exemptions and other governmental authorizations, approvals, and clearances, consents, approvals, and clearances, and have submitted all applicable notices to, all Governmental Authorities, including all authorizations as required under the Federal Food, Drug and Cosmetic Act of 1938, as amended (the "**FDCA**"), the Public Health Service Act of 1944, as amended (the "**PHSA**"), the regulations of the U.S. Food and Drug Administration (the "**FDA**") promulgated thereunder, the regulations of the Drug Enforcement Agency ("**DEA**"), and any other Governmental Authority that regulates the design, development, testing, quality, identity, strength, purity, safety, efficacy, labeling, manufacturing, storage, distribution, import, export, marketing, promotion, advertising, detailing, or sale of the Company Offerings, including any premarket clearance or approval, the practice of medicine, or billing to a federal health care program (any such Governmental Authority, a "**Regulatory Authority**") necessary for the lawful operation of the businesses of the Company or any of its Subsidiaries as currently conducted (the "**Company Permits**"), and all such Company Permits are valid and in full force and effect. Since January 1, 2020, there has not occurred any material violation of, default under, or event giving to others, including any Governmental Authority, any right of termination, revocation, amendment, non-renewal, cancellation, or material adverse modification of, with or without notice or lapse of time or both, any Company Permit. The Company and each of its Subsidiaries are in compliance in all material respects with the terms of all Company Permits, and no event has occurred that, to the Knowledge of the Company, would reasonably be expected to result in the termination, revocation, cancellation, non-renewal or material adverse modification of any Company Permit. Neither the Company nor any of its Subsidiaries has (i) received written notice of any pending or threatened Action from the FDA or other Regulatory Authority or Governmental Authority alleging, or (ii) made any material voluntary or involuntary disclosure to a Governmental Authority stating that any operation or activity of the Company or any of its Subsidiaries is in violation in any material respect of any applicable Healthcare Law.

(b) All of the Company Offerings have been designed, manufactured, imported, exported, processed, developed, labeled, stored, tested, marketed, promoted, advertised, detailed, distributed and sold by the Company or any of its Subsidiaries in all material respects in compliance with all applicable requirements under any Company Permit or Healthcare Law, including applicable statutes and implementing regulations administered or enforced by the FDA or other Regulatory Authority. To the Company's Knowledge, all applications, submissions, notifications and information required to be submitted by the Company or its Subsidiaries in connection with, any and all requests for Company Permits relating to the Company or any of its Subsidiaries when submitted to the FDA or other Regulatory Authority, were true, complete and correct in all material respects as of the date of submission, and any updates, changes, corrections or modification to such applications, submissions,

notifications and information required under applicable Healthcare Laws have been submitted to the FDA or other applicable Regulatory Authority.

(c) Neither the Company nor its Subsidiaries nor, to the Company's Knowledge, any of their respective officers, directors, employees or agents (acting on behalf of the business of the Company and its Subsidiaries), have committed any act, made any statement or failed to make any statement in each case, related to the business of the Company and its Subsidiaries and which, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA or any other Regulatory Authority to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," or other similar Laws. Neither the Company nor or any of its Subsidiaries nor, to the Knowledge of the Company, any of their respective officers, directors, employees or agents (acting on behalf of the business of the Company and its Subsidiaries) has been subject to any kind of consent decree, individual integrity agreement, deferred prosecution agreement, or other similar form of agreement with any Governmental Authority or convicted of any crime or engaged in any conduct that has resulted, or would reasonably be expected to result, in a debarment, exclusion, disqualification, or ineligibility under applicable Law, including, without limitation, 21 U.S.C. Section 335a and 42 U.S.C. Section 1320a-7, and no Actions that would reasonably be expected to result in such a debarment, exclusion, disqualification, or ineligibility are pending, or to the Knowledge of the Company, threatened against the Company or any of its Subsidiaries, or to the Knowledge of the Company, any of their respective officers, directors, employees or agents (acting on behalf of the business of the Company and its Subsidiaries). To the Knowledge of the Company, neither the Company nor any of its Subsidiaries has received notice from the FDA or any other Governmental Authority that it is being investigated for data or healthcare program fraud.

(d) The manufacture of Products by or on behalf of the Company and its Subsidiaries has been and is being conducted in compliance in all material respects with all applicable Laws including current Good Manufacturing Practices and current Good Tissue Practices, as applicable. Neither the Company nor its Subsidiaries nor, to the Knowledge of the Company, any of their respective employees or independent contractors, has received any FDA Form 483, warning letter, untitled letter, or other similar correspondence or written notice from the FDA or any other Regulatory Authority alleging or asserting material noncompliance with any applicable Laws or Company Permits with respect to any Product of the Company or its Subsidiaries. No manufacturing site owned by the Company, its Subsidiaries, or to the Company's Knowledge, any of their respective contractors is or has been subject to a shutdown or import or export prohibition imposed or requested by FDA or other Regulatory Authority. To the Knowledge of the Company, no event has occurred which would reasonably be expected to lead to any Action by any Regulatory Authority or any FDA Form 483, warning letter, untitled letter, or other similar correspondence.

(e) All studies, tests and preclinical and clinical trials being conducted by, or on behalf of, the Company or its Subsidiaries, have been and are being conducted in compliance in all material respects with applicable Healthcare Laws, including the applicable requirements of Good Laboratory Practices and Good Clinical Practices, if any. The Company and its Subsidiaries have not received any written notices, correspondence or other communication from any institutional review board, the FDA or any other Regulatory Authority, recommending or requiring the termination, suspension, or material modification of any ongoing or planned clinical trials conducted by, or on behalf of, the Company or its Subsidiaries. To the Knowledge of Company, no event has occurred which would reasonably be expected to lead to the termination, suspension, or material modification of any ongoing or planned clinical trials conducted by, or on behalf of, the Company or its Subsidiaries.

(f) The Company and its Subsidiaries have not either voluntarily or involuntarily, initiated, conducted or issued, or caused to be initiated, conducted or issued, any recall, field notification, field correction, market withdrawal, or replacement, safety alert, warning, "dear doctor" letter, investigator notice, or other notice or action, in each case relating to an alleged lack of safety, efficacy or regulatory compliance of any Product or Product candidate ("**Company Safety Notices**"). To the Knowledge of the Company, no facts would reasonably be expected to cause (i) a Company Safety Notice with respect to any Company Offering sold or intended to be sold by the Company or its Subsidiaries; (ii) a material change in the marketing classification or a material change in labeling of any such Company

Offering; or (iii) a termination, suspension or material modification of marketing or testing of any such Company Offering.

(g) The Company, its Subsidiaries, and to the Knowledge of the Company, their respective officers, directors, employees and agents (acting on behalf of the business of the Company and its Subsidiaries) are, and at all times have been, in compliance in all material respects with all applicable Healthcare Laws. There is no civil, criminal, administrative, or other Actions pending, received by or filed or threatened in writing against the Company or any of its Subsidiaries, or, to the Knowledge of the Company, any of their respective officers, directors, employees or agents (acting on behalf of the business of the Company and its Subsidiaries) alleging any material violation by the Company or its Subsidiaries of any applicable Healthcare Laws.

(h) Each of the Company and its Subsidiaries has distributed, documented, and reported Company Offering samples in all material respects in accordance with applicable Healthcare Laws.

(i) Neither the Company nor its Subsidiaries nor, to the Knowledge of the Company, any of their respective directors, officers or employees has received written notice that it is subject to any pending or threatened investigation, claim, or enforcement Action by the FDA, the DEA, U.S. Department of Health and Human Services-Office of Inspector General ("**HHS-OIG**"), private whistleblowers, or Centers for Medicare & Medicaid ("**CMS**"), U.S. Department of Veterans Affairs ("**VA**") VA Office of Inspector General ("**VA OIG**"), or U.S. Department of Justice ("**DOJ**,"), or any other state or non-U.S. equivalent Governmental Authorities pursuant to any Healthcare Laws in connection with the business of the Company and its Subsidiaries.

3.25 Product Defects.

(a) Since January 1, 2020, all Company Offerings have been provided in material conformity with the Company's and the Company's Subsidiaries' applicable contractual commitments, warranties and specifications.

(b) Since January 1, 2020, the Company has not received or otherwise been made aware of any written notices, citations or decisions by any Governmental Authority that any of the Company Offerings are defective or fail to meet any applicable standards promulgated by any such Governmental Authority. The Company has obtained, in all countries where it is marketing or has marketed any Company Offerings, all applicable licenses, registrations, approvals, clearances and authorizations required by local, state or federal agencies in such countries regulating the safety, effectiveness and market clearance of such Company Offerings currently marketed by the company in such countries. No recall, withdrawal, field correction or other action to recover possession of the Company Offerings has occurred.

3.26 Brokers' Fees

. No investment banker, broker, finder or similar party is or shall be entitled to any payment of any fees of expenses in connection with the origin, negotiation or execution of this Agreement or in connection with the Merger or any other transaction contemplated by this Agreement based upon arrangements made by or on behalf of the Company or any of its Affiliates at or prior to the Effective Time.

3.27 Information Statement. None of the information included in the Information Statement, or any amendments or supplements thereto, in each case in the form delivered to the Company Stockholders will contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein not misleading. The Information Statement will comply with the requirements of the DGCL.

3.28 Disclosure. No representation or warranty or other statement made by the Company or any of the Company's Representatives in this Agreement, the Company Disclosure Schedule, the certificates delivered pursuant to this Agreement or the Company Ancillary Agreements contains or,

when delivered to the Parent, will contain any untrue statement of a material fact or omits, or when delivered to Parent, will omit, to state any material fact necessary in order to make the statements contained herein and therein, in light of the circumstances under which such statements were made, not misleading. The Company has made available complete and correct and, where applicable, executed copies of each document that has been requested by Parent and that is in the Company's possession or control or that is listed (or required to be listed) in the Company Disclosure Schedule.

Article 4

REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Parent and Merger Sub represent and warrant to the Company as follows as of the date hereof:

4.1 Organization and Good Standing. Parent is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware and has the corporate power and authority to own, operate and lease its properties and to carry on its business as now conducted. Merger Sub is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. Each of Parent and Merger Sub is duly qualified or licensed to do business, and is in good standing, in each jurisdiction where the character of the properties owned, leased or operated by it or the nature of its activities makes such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on Parent's or Merger Sub's ability to consummate the Merger or to perform their respective obligations under this Agreement, the Parent Ancillary Agreements and the Merger Sub Ancillary Agreements.

4.2 Power, Authorization and Validity.

(a) Power and Authority. Parent has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement and each of the Parent Ancillary Agreements and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance by Parent of this Agreement and each of the Parent Ancillary Agreements and the consummation by Parent and Merger Sub of the transactions contemplated hereby or thereby have been duly and validly approved and authorized by all necessary corporate action on the part of Parent. Merger Sub has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement and each of the Merger Sub Ancillary Agreements to which it is to be party and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance by Merger Sub of this Agreement and each of the Merger Sub Ancillary Agreements to which it is to be party and the consummation of the transactions contemplated hereby or thereby have been duly and validly approved and authorized by all necessary corporate action on the part of Merger Sub.

(b) Enforceability. This Agreement has been duly executed and delivered by Parent and Merger Sub. This Agreement and each of the Parent Ancillary Agreements are, or when executed by Parent shall be, assuming the due authorization, execution and delivery by the Company and the other Persons party hereto or thereto, valid and binding obligations of Parent, enforceable against Parent in accordance with their respective terms, subject to the Enforceability Exceptions. This Agreement and each of the Merger Sub Ancillary Agreements to be entered into by Merger Sub are, or when executed by Merger Sub shall be, assuming the due authorization, execution and delivery by the Company and the other Persons party hereto or thereto, valid and binding obligations of Merger Sub, enforceable against Merger Sub in accordance with their respective terms, subject to the Enforceability Exceptions.

4.3 No Conflict; Required Consents and Approvals.

(a) The execution, delivery and performance by Parent and Merger Sub of this Agreement and each of the Parent Ancillary Agreements (in the case of Parent) and Merger Sub Ancillary Agreements (in the case of Merger Sub), and the consummation of the transactions contemplated hereby

and thereby, do not and will not: (i) conflict with or violate the Charter Documents of Parent or Merger Sub or (ii) conflict with or violate any Laws or any judgment, decree or order to which Parent or Merger Sub are subject, except in the case of clause (ii) where such conflict or violation would not reasonably be expected to result in a material adverse effect on Parent's or Merger Sub's ability to consummate the Merger or to perform their respective obligations under this Agreement, the Parent Ancillary Agreements or the Merger Sub Ancillary Agreements.

(b) No consent, approval, order or authorization of, or registration, declaration or filing with, any Governmental Authority is necessary or required to be made or obtained by Parent or Merger Sub to enable Parent and Merger Sub to lawfully execute, deliver and perform this Agreement, each of the Parent Ancillary Agreements (as to Parent) and the Merger Sub Ancillary Agreements to be entered into by Merger Sub (as to Merger Sub) or to consummate the transactions contemplated hereby or thereby, except for (i) such consents, approvals, orders, authorizations, registrations, declarations and filings, if any, that if not made or obtained by Parent or Merger Sub would not reasonably be expected to result in a material adverse effect on Parent's or Merger Sub's ability to consummate the Merger or to perform their respective obligations under this Agreement, the Parent Ancillary Agreements (as to Parent) and the Merger Sub Ancillary Agreements (as to Merger Sub), (ii) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware, and (iii) any filings required under applicable securities Laws.

4.4 Merger Sub. Parent is the sole stockholder of Merger Sub. Merger Sub was formed solely for the purpose of engaging in the transactions contemplated by this Agreement, has engaged in no other business activities and has conducted its operations only as contemplated by this Agreement.

Article 5

COVENANTS

5.1 Information Statement.

(a) Prior to the Effective Time, the Company shall, with the assistance of Parent, prepare an information statement (together with any amendments thereof or supplements thereto, the "**Information Statement**") to be used in connection with soliciting stockholder approval of the matters set forth in the Written Consent in order to consummate the Merger and the other transactions contemplated hereby. The Information Statement shall include, among other things, a description of the terms of this Agreement, certain Company Ancillary Agreements and the transactions contemplated hereby and thereby, the requisite notice of appraisal rights under the DGCL, and the unanimous recommendation of the board of directors of the Company to the Company Stockholders to vote in favor of the approval and adoption of this Agreement and the Merger, the other transactions contemplated hereby and the other matters set forth in the Written Consent. Prior to the Effective Time, the Company will send the Information Statement to each Company Stockholder in connection with soliciting such approval in accordance with applicable Law. The parties hereto shall cooperate with each other in connection with the preparation of the Information Statement, including by providing information reasonably necessary for the preparation of the Information Statement, and by accepting all reasonable comments suggested in connection therewith. No amendment or supplement to the Information Statement will be made by the Company without the approval of Parent, not to be unreasonably withheld, conditioned or delayed.

5.2 Data Room. Within two (2) Business Days following the Closing Date, the Company will deliver to Parent a digital copy of all documents and other information that was included in the Virtual Data Room on or prior to the Closing Date.

5.3 Termination of Certain Company Employee Plans. Unless Parent requests otherwise in writing, the Company shall, on the Closing Date, terminate any plan that is intended to meet the requirements of Section 401(k) of the Code, and which is sponsored, or contributed to, by the Company or any of its ERISA Affiliates (the "**401(k) Plan**") and no further contributions shall be made to the 401(k) Plan. On the Closing Date, the Company shall provide to Parent executed resolutions of the board of directors of the Company authorizing such termination.

5.4 Repayment of Indebtedness and Transaction Expenses.

(a) On or prior to the Closing Date, the Company shall obtain in connection with each Company Secured Note, in each case in form and substance satisfactory to Parent, in addition to the Note Cancellation Agreements (i) a UCC-3 termination statement or authorization of the Company or one of its Subsidiaries to file a UCC-3 termination statement terminating the security interests of each Person holding a security interest in the assets of the Company or its Subsidiaries, (ii) forms of notices of termination for any account control agreements entered into in connection with such Company Secured Note, (iii) forms of terminations for any intellectual property security agreements filed with the United States Patent and Trademark Office or United States Copyright Office in connection with such Company Secured Note, (v) an IRS Form W-9 or Form W-8, as applicable, from each holder of such Company Secured Note.

(b) Prior to the Closing Date, if requested by Parent or the Paying Agent, the Company shall obtain, an IRS Form W-9 or Form W-8, as applicable, from each legal counsel, advisor, service provider, accountant and other Person who is entitled to a fee in connection with Closing which constitutes a Transaction Expense, as set forth in the Initial Payment Allocation Schedule.

5.5 Company Securityholders Notices. Prior to or concurrently with the Closing, the Company shall have timely provided to the Company Securityholders all advance notices required to be given to such Company Securityholders in connection with this Agreement, the Merger and the transactions contemplated by this Agreement under the Charter Documents, the Company Stock Plan or other applicable Contracts and under Law, or obtain waivers of the same, in each case in form and substance satisfactory to Parent.

5.6 Tail Policy and Indemnification.

(a) Prior to the Effective Time, the Company shall purchase tail insurance coverage for the Company's directors and officers, in form and substance satisfactory to Parent, which shall provide such directors and officers and the Company, respectively, with coverage for six (6) years following the Effective Time with respect to claims arising out of acts or omissions occurring at or prior to the Effective Time ("**Tail Policy**").

(b) For a period of six (6) years from and after the Closing Date, Parent shall cause the Surviving Corporation to indemnify (including advancement of expenses) and hold harmless all past and present officers and directors of the Company to the same extent such Persons are permitted to be indemnified by the Company as of the date of this Agreement pursuant to the Charter Documents of the Company or under applicable Law for acts or omissions which occurred at or prior to the Effective Time.

5.7 Terminated Agreements. The Company shall, and, as applicable, shall cause its Subsidiaries to, use reasonable best efforts to cause each of the agreements listed on Section 3.4(d) of the Company Disclosure Schedule (the "**Terminated Agreements**") to be terminated, in each case effective prior to or as of the Effective Time, including sending all required notices, such that each Terminated Agreement shall be of no further force or effect prior to or as of the Effective Time.

5.8 [***]

. Following the Closing Date, Parent may determine, in its sole discretion, acting reasonably, [***] (the "**Unused Product Assets**") (such determination, an "**Unused Product Asset Determination**"). An Unused Product Asset Determination may be made by Parent (a) at any time in Parent's sole discretion, or (b) following receipt of a written request from the Securityholder Representative with respect to such Unused Product Asset, which written request shall not be delivered by the Securityholder Representative prior to the [***] anniversary of the Closing Date, and in no event may the Securityholder Representative make a request with respect to the Unused Product Asset more than [***]. If Parent makes an Unused Product Asset Determination pursuant to the preceding sentence with respect to the Unused Product Assets, the Securityholder Representative shall have thirty (30) days from the date the Securityholder

Representative receives notice of such determination to request to negotiate a license with respect thereto. If the Securityholder Representative notifies Parent of its intent to take a license, thereafter Parent and the Securityholder Representative shall negotiate in good faith with respect to the terms of a non-exclusive license for Securityholder Representative to use such Unused Product Asset, pursuant to which the Securityholder Representative shall pay to Parent an amount in cash equal to [***] percent [***] of the Net Sales of such Unused Product Asset for a period of ten (10) years from the launch of such Unused Product Asset in the applicable jurisdiction, which royalty shall be payable to Parent in accordance with the terms set forth in Section 2.12(c)(ii). [***].

5.9 Closing Deliverables. As of the Closing, Parent shall have received the following documents, each of which shall be in full force and effect:

(a) Paying Agent Agreement. The Paying Agent shall have executed and delivered to Parent the Paying Agent Agreement.

(b) Resignations of Directors and Officers; Releases. Each of the directors and officers of the Company and each of its Subsidiaries in office immediately prior to the Effective Time shall have executed and delivered to Parent a resignation letter and release in form and substance satisfactory to Parent.

(c) Secretary's Certificate. Parent shall have received a certificate dated as of the Closing Date, signed by the secretary of the Company, certifying as to (i) an attached copy of the Charter Documents of the Company and stating that the Charter Documents have not been amended, modified, revoked or rescinded, (ii) an attached copy of the resolutions of the board of directors of the Company evidencing the Board Approval, and stating that such resolutions have not been amended, modified, revoked or rescinded, (iii) an attached copy of the Written Consents received from Company Stockholders, and stating that such Written Consents constitute the Stockholder Approval and that the resolutions set forth therein have not been amended, modified, revoked or rescinded, and (iv) the names and signatures of the officers of the Company authorized to sign this Agreement, the Company Ancillary Agreements and the other documents to be delivered by the Company hereunder and thereunder.

(d) FIRPTA. Parent shall have received a properly executed statement, issued by the Company pursuant to Treasury Regulations Sections 1.897-2(h) and 1.1445-2(c)(3) dated as of the Closing Date and signed by an officer of the Company, certifying that interests in the Company, including shares of Company Capital Stock, do not constitute "United States real property interests" under Section 897(c) of the Code, together with the notice to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), in the form attached here to as Exhibit F.

(e) [***].

(f) Evidence that [***] has been paid according to the Lease Termination Agreement.

(g) Evidence that all Equity-Related Agreements referred to in Section 3.4(d) of the Company Disclosure Schedule have been terminated.

Article 6

SURVIVAL; INDEMNIFICATION

6.1 Survival. If the Merger is consummated, (a) the General Representations, and the right of any Indemnified Party to bring a General Representation Claim, shall survive the Closing until the date that is eighteen (18) months following the Closing Date (the "**Expiration Date**"), and (b) the Fundamental Representations, and the right of any Indemnified Party to bring a Fundamental Representation Claim, shall survive the Closing until the 60th day following the expiration of the applicable statute of limitations (as such statute of limitations pertains to the subject matter of such

Fundamental Representation, or to the ability of Parent or any third party to make a claim relating to the subject matter of such Fundamental Representation or certification or to the failure of such Fundamental Representation or certification to be true and correct, as the case may be, whichever is later); *provided, however*, that (i) no right to indemnification, compensation and reimbursement pursuant to this Article 6 in respect of any Claim based upon any failure of a representation or warranty to be true and correct that is set forth in a Claim Notice delivered prior to the applicable expiration date of such representation or warranty shall be affected by the expiration of such representation or warranty and (ii) no such expiration shall affect the rights of any Indemnified Party, under this Article 6 or otherwise, to seek recovery of Losses arising out of any claim for Fraud, which rights will survive until the 60th day following the expiration of the statute of limitations applicable to such claim for Fraud. Each covenant or agreement contained in this Agreement shall survive the Closing and remain in full force and effect until such covenant or agreement has been fully performed or fulfilled in accordance with its terms.

6.2 Indemnification of Parent and Indemnified Parties. Each Indemnifying Securityholder shall severally (based on each such Indemnifying Securityholder's Pro Rata Share), and not jointly, indemnify and hold harmless each of Parent and its Affiliates and its and their respective stockholders and Representatives (each hereinafter referred to individually as a "**Parent Indemnified Party**" and collectively as the "**Parent Indemnified Parties**") from and against, and compensate and reimburse each of the Parent Indemnified Parties for, any and all Losses incurred by a Parent Indemnified Party, directly or indirectly, and whether arising out of a third party claim or a direct claim, arising out of, resulting from or in connection with:

(a) any inaccuracy in or breach of a representation or warranty made by the Company in Article 3 of this Agreement;

(b) any inaccuracy in the calculation of Closing Cash, Closing Indebtedness and the Closing Net Working Capital and/or the Net Working Capital Deficit;

(c) any breach of, or failure to perform or comply with, any of the covenants of or agreements made by the Company in this Agreement;

(d) any Pre-Closing Taxes;

(e) any Stakeholder Claim; and

(f) any matter referred to in Schedule 8.2(g) hereto.

6.3 Indemnification by Parent. Parent shall indemnify and hold harmless each Indemnifying Securityholder and their respective Affiliates and Representatives (each hereinafter referred to individually as a "**Stockholder Indemnified Party**" and collectively as the "**Stockholder Indemnified Parties**") from and against, and compensate and reimburse each of the Stockholder Indemnified Parties for, any and all Losses incurred by such Stockholder Indemnified Party, directly or indirectly, and whether arising out of a third party claim or a direct claim, arising out of, resulting from or in connection with:

(a) any inaccuracy in or breach of a representation or warranty made by Parent or Merger Sub in Article 4 of this Agreement; and

(b) any breach of, or failure to perform or comply with, any of the covenants of or agreements made by Parent or Merger Sub in this Agreement.

6.4 Limitations.

(a) The Parent Indemnified Parties will not be entitled to indemnification, compensation and reimbursement with respect to any General Representation Claim pursuant to Section 6.2(a) unless the Parent Indemnified Parties have incurred, as to all General Representation Claims,

Losses in excess of [***]in the aggregate (the "**Basket**"), after which the Parent Indemnified Parties shall be entitled to be indemnified for Losses from the first dollar.

(b) Subject to Sections 6.4(a) and 6.4(e), in the case of any General Representation Claim, each Indemnifying Securityholder shall be severally and not jointly liable for such Indemnifying Securityholder's Pro Rata Share of any Losses resulting therefrom, *provided* that the aggregate liability for the Indemnifying Securityholders for all General Representation Claims shall be capped at [***] (the "**General Representation Cap**"). The Basket and the General Representation Cap shall not apply to Claims or Losses under any Special Matters, or any Claims or Losses for Fraud.

(c) The Stockholder Indemnified Parties will not be entitled to indemnification, compensation pursuant to Section 6.3(a) unless and until the aggregate of all Losses for which the Stockholder Indemnified Parties would, but for this Section 6.4(c) be entitled to indemnification hereunder exceeds the Basket, after which the Stockholder Indemnified Parties shall be entitled to be indemnified for Losses in excess of such amount, up to the General Representation Cap.

(d) In no event will the aggregate amount of Losses for which the Stockholder Indemnified Parties will be indemnified and held harmless and entitled to recover under Section 6.3(b) exceed $[***] provided, further, that notwithstanding anything herein to the contrary, no Stockholder Indemnified Party shall have the right to be indemnified for any Losses to the extent they are in the nature of (a) consequential or special damages or (b) punitive or exemplary damages.

(e) Notwithstanding anything herein to the contrary, there shall be no maximum liability for any Indemnifying Securityholder in the case of any claim for Fraud. Furthermore, in no event will any Indemnifying Securityholder be liable for (i) any other Indemnifying Securityholder's Fraud or (ii) breach of any other Company Securityholders' covenants or agreements contained in this Agreement, any Joinder Agreement or any other agreement entered into in connection with the transaction contemplated hereby.

(f) In determining whether there is an inaccuracy in or breach of a representation or warranty, or the amount of any Losses in respect of any such inaccuracy or breach, any materiality, Material Adverse Effect or similar qualification limiting the scope of such representation or warranty shall be disregarded.

(g) The representations, warranties, covenants, and agreements of the parties contained in this Agreement, and the rights and remedies that the Indemnified Parties are entitled to hereunder, shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation (or right thereto or opportunity thereof) made by, or by virtue of the knowledge of, any Indemnified Party or any of their respective Representatives of the affairs of the Company or any of its Subsidiaries or any Indemnifying Securityholder or Parent or Merger Sub, as applicable, or any inaccuracy in or breach of any representation, warranty, covenant or agreement of the Company, whether such knowledge arose before or after the Agreement Date. No Indemnified Party shall be required to show reliance on any representation, warranty, covenant or agreement in order for such Indemnified Party to be entitled to indemnification, compensation and reimbursement hereunder.

(h) Any liability for indemnification under this Article 6 will be determined without duplication of recovery for the same Losses by reason of the state of facts giving rise to such liability.

(i) Notwithstanding anything to the contrary in this Article VI or otherwise in this Agreement, the Indemnifying Securityholders shall not be liable under Article VI or otherwise in this Agreement with respect to (and Parent shall pay or cause to be paid) (i) any Taxes that were taken into account in the calculation of Indebtedness, Net Working Capital, Transaction Expenses or otherwise taken into account in the calculation of the Initial Merger Consideration as finally determined pursuant to Section 2.12(f), (ii) Taxes incurred by the Surviving Corporation, Parent or any of their respective Affiliates as a result of actions outside the ordinary course of business taken after the Closing on the Closing Date, (iii) any Taxes arising as a result of a breach by Parent, the Surviving Corporation or any of their Affiliates of Article VII, or (z) Taxes of the Company incurred after the Closing Date (other than

Taxes arising directly as a result of a breach of a representation contained in Section 3.7(f), (i), (k), (l), (q), (p) or (s)).

6.5 Claim Notice. If any Indemnified Party, wishes to assert a Claim, the Indemnified Party shall deliver written notice thereof, executed by a Representative of such Indemnified Party (a "**Claim Notice**"), to the Securityholder Representative or Parent, as applicable. The Claim Notice shall set forth: (a) that an Indemnified Party has directly or indirectly incurred, paid or accrued or reasonably believes it may have to directly or indirectly incur, pay or accrue, Losses; (b) the actual or estimated amount of such Losses to the extent known or reasonably estimable (which, in the case of Losses not yet incurred, paid or accrued, may be the maximum amount reasonably anticipated by Parent to be incurred, paid or accrued or may be the amount of Losses claimed by a third party in a Third-Party Claim); and (c) a brief description, in reasonable detail (to the extent reasonably available to such Indemnified Party), of the facts, circumstances or events giving rise to the alleged Losses based on such Indemnified Party's belief thereof. A Claim Notice may be updated and amended from time to time by the Indemnified Party by delivering an updated or amended Claim Notice to the Securityholder Representative or Parent, as applicable, so long as such update or amendment only asserts bases for Losses reasonably related to the underlying facts and circumstances specifically set forth in such original Claim Notice. All Claims properly set forth in an original Claim Notice or any update or amendment thereto shall remain outstanding until such Claims for Losses have been finally resolved or satisfied.

6.6 Defense and Settlement of Third-Party Claims.

(a) In the event an Indemnified Party becomes aware of a claim by a third party (a "**Third-Party Claim**") that such Indemnified Party in good faith believes may result in a Claim by or on behalf of an Indemnified Party, such Indemnified Party shall have the right in its sole discretion to conduct the defense of and to settle or resolve such Third-Party Claim. The applicable Indemnified Party shall notify the Securityholder Representative or Parent, as applicable, of any such Third-Party Claim, and the Securityholder Representative (on behalf of the Indemnifying Securityholders) or Parent, as applicable, shall be entitled, at their expense, to participate in, but not to determine or conduct, the defense of such Third-Party Claim. The Securityholder Representative or Parent, as applicable, shall have the right to receive copies of all pleadings, notices and communications with respect to the Third-Party Claim to the extent that receipt of such documents does not affect any privilege relating to Parent or any Indemnified Party and subject to execution of a standard non-disclosure agreement to the extent that such materials contain confidential or proprietary information. The reasonable costs and expenses incurred or paid by any Indemnified Party in connection with the defense (including reasonable attorneys' fees, other professionals' and experts' fees, costs of investigation and court or arbitration costs) of any such Third-Party Claim, and the reasonable amounts paid or incurred in the settlement or other resolution of any such Third-Party Claim, are recoverable by the Indemnified Party as Losses pursuant to this Article 6 regardless of the outcome of such Third-Party Claim, subject to the limitations on recovery in Section 6.4. Any amounts required to be paid or incurred by an Indemnified Party pursuant to the final determination of a Governmental Authority presiding over any such Third-Party Claim shall be deemed reasonable for purposes of this Section 6.6.

(b) Notwithstanding anything contained herein to the contrary, if (A) the Securityholder Representative or Parent, as applicable, fails to notify the Indemnified Party within ten (10) Business Days after receipt of any Claim Notice of a Third-Party Claim that the Securityholder Representative or Parent, as applicable, elects to defend the Indemnified Party pursuant to the terms hereunder, (B) the Securityholder Representative or Parent, as applicable, elects to defend the Indemnified Party pursuant to the terms hereunder but, upon petition by the Indemnified Party, a court of competent jurisdiction rules that the Securityholder Representative or Parent, as applicable, has failed to diligently prosecute or settle the Third-Party Claim, (C) such Third-Party Claim seeks an injunction or other equitable relief against the Indemnified Party or alleges a criminal violation, (D) the Indemnified Party is advised by counsel that if Indemnified Party and the Securityholder Representative or Parent, as applicable, are represented by the same counsel, it would result in a conflict of interest for such counsel or prejudice the prosecution of the defenses available to the Indemnified Party, (E) the amount in dispute exceeds the maximum amount for which an Indemnifying Securityholder could be liable pursuant to this Article 6 in light of the limitations on indemnification herein, (F) the Securityholder Representative or Parent, as applicable, does not agree in writing that the Securityholder Representative or Parent, as

applicable, is obligated to pay for any Losses arising from or related to such Third-Party Claim (subject to the limitations on indemnification set forth in Section 6.4), or (G) the Third-Party Claim involves a customer, supplier or other material business relationship of the Company, then the Indemnified Party shall have the right to defend, subject to the indemnification obligations of the Securityholder Representative or Parent, as applicable, the Third-Party Claim by all appropriate proceedings, which proceedings shall be prosecuted by the Indemnified Party to a final conclusion or settled, subject to the limitations on settlement by the Indemnified Party set forth in this Agreement and subject to the other terms, conditions and limitations of the indemnification obligations of the Securityholder Representative or Parent, as applicable, under this Agreement.

6.7 Payment of Claims. If any Losses are determined, agreed or deemed agreed to be owed to any Indemnified Party in accordance with this Article 6 (such amount, the "**Owed Amount**"), then any Indemnified Party may seek recovery from any source available to such Indemnified Party pursuant to this Article 6, provided that, with respect to an Owed Amount pursuant to a claim arising under Section 6.2, a Parent Indemnified Party must, subject to the limitations contained in Section 6.4, offset the Owed Amount from any Contingent Consideration that has been finally determined to be earned and payable to the Company Securityholders pursuant to Section 2.12, and such offset against Contingent Consideration will be the sole source of recovery of Owed Amounts pursuant to any claim arising under Section 6.2.

6.8 Tax Consequences of Indemnification Payments. All payments (if any) made to an Indemnified Party pursuant to any indemnification, compensation or reimbursement obligations under this Article 6 or Article 7 will be treated as adjustments to the Total Merger Consideration for Tax purposes and such agreed treatment will govern for purposes of this Agreement, unless otherwise required by Law.

6.9 Exclusive Remedy. Following the Closing, except for (a) claims for Fraud and (b) claims for equitable relief, the rights to indemnification, compensation and reimbursement under this Article 6 shall be the sole and exclusive remedy of the Indemnified Parties against the Indemnifying Securityholders or Parent, as applicable, with respect to breaches of the representations, warranties, covenants and agreements set forth in this Agreement, any Joinder Agreement or any other agreement entered into in connection with the transactions contemplated by this Agreement.

6.10 Appointment of Securityholder Representative.

(a) By voting in favor of the adoption of this Agreement, executing and delivering a Joinder Agreement or participating in the Merger and receiving the benefits thereof, each Indemnifying Securityholder shall be deemed to have approved the designation of and hereby designates the Securityholder Representative as the representative of the Company Securityholders and as the attorney-in-fact and agent for and on behalf of each Indemnifying Securityholder with respect to Claims under this Article 6 and the taking by the Securityholder Representative of any and all actions and the making of any decisions required or permitted to be taken by the Securityholder Representative under this Agreement, including the exercise of the power to: (i) give and receive notices and communications (on behalf of itself or any other Indemnifying Securityholder) relating to this Agreement or any of the transactions and other matters contemplated hereby, (ii) authorize Parent and any other applicable Indemnified Party to be indemnified, compensated or reimbursed for Losses in satisfaction of Claims by Parent or any other Parent Indemnified Party pursuant to this Article 6 (including by not objecting to such Claims), (iii) agree to, object to, negotiate, resolve, enter into settlements and compromises of, demand litigation of, and comply with orders of courts with respect to (A) Claims by Parent or any other Indemnified Party pursuant to this Article 6 or (B) any dispute between any Parent Indemnified Party and any such Company Securityholder, in each case, relating to this Agreement or any of the transactions or other matters contemplated hereby and (iv) take all actions necessary or appropriate in the judgment of the Securityholder Representative for the accomplishment of the foregoing. The Securityholder Representative shall have authority and power to act on behalf of each Company Securityholder with respect to the disposition, settlement or other handling of all Claims under this Article 6 and all rights or obligations arising under this Article 6. The Company Securityholders (including each of the Indemnifying Securityholders) and their respective successors, heirs, estates and assigns shall be bound by all actions taken and documents executed by the Securityholder Representative in connection with this Article 6, and Parent and the other Parent Indemnified Parties shall be entitled to rely on any action or decision of the Securityholder Representative. The Indemnifying Securityholders recognize and intend

that the power of attorney granted in this Section 6.10(a) and the powers, immunities and rights to indemnification granted to the Securityholder Representative hereunder: (1) are coupled with an interest and are irrevocable; (2) may be delegated by the Securityholder Representative; and (3) shall survive the death, incapacity, dissolution, liquidation, bankruptcy or winding up of each of the Company Securityholders (including each of the Indemnifying Securityholders) and shall be binding on any successor thereto. Each Company Securityholder (x) agrees that all actions taken by the Securityholder Representative under this Agreement shall be binding upon such Company Securityholder and such Company Securityholder's successors as if expressly confirmed and ratified in writing by such Company Securityholder and (y) waives any and all defenses which may be available to contest, negate or disaffirm the action of the Securityholder Representative taken in good faith under this Agreement. The Securityholder Representative shall only have the duties expressly stated in this Agreement and shall have no other duty, express or implied. The Securityholder Representative may engage attorneys, accountants and other professionals and experts. The Securityholder Representative may in good faith rely conclusively upon information, reports, statements and opinions prepared or presented by such professionals, and any action taken by the Securityholder Representative based on such reliance shall be deemed conclusively to have been taken in good faith. Parent may conclusively rely, without independent verification or investigation, upon any action of the Securityholder Representative as being the binding decision or action of the Indemnifying Securityholders, and Parent shall not be liable to any Company Securityholder or any other Person for any actions taken or omitted from being taken by them or by Parent in accordance with or reliance upon any decision or action of the Securityholder Representative. The Person serving as the Securityholder Representative may be replaced from time to time by the holders of a majority in interest of the Total Merger Consideration payable to the Company Securityholders. No bond shall be required of the Securityholder Representative, and the Securityholder Representative shall receive no compensation for his, her or its services. Notices or communications to or from the Securityholder Representative shall constitute notice to or from each of the Company Stockholders.

(b) In performing the functions specified in this Agreement, the Securityholder Representative shall not be liable to any Company Securityholder in the absence of gross negligence or willful breach on the part of the Securityholder Representative. Each Company Securityholder shall severally (based on each such Company Securityholder's respective Pro Rata Share), and not jointly, indemnify and hold harmless the Securityholder Representative from and against any loss, liability or expense incurred without gross negligence or willful breach on the part of the Securityholder Representative and arising out of or in connection with the acceptance or administration of its duties hereunder, including any out-of-pocket costs and expenses and legal fees and other legal costs reasonably incurred by the Securityholder Representative.

(c) The Securityholder Representative represents and warrants to Parent and Merger Sub as of the Agreement Date and as of the Closing Date as follows: (i) the Securityholder Representative has all requisite power and authority to execute and deliver this Agreement and any other applicable Contract, instrument or document contemplated hereby and to perform his obligations hereunder and thereunder, (ii) this Agreement and any other applicable Contract, instrument or document contemplated hereby has been duly executed and delivered by the Securityholder Representative and constitutes a valid and binding obligation of the Securityholder Representative, enforceable in accordance with its terms and (iii) neither the execution, delivery or performance of this Agreement or any other applicable Contract, instrument or document contemplated hereby by the Securityholder Representative nor the consummation of the Merger will conflict with, or result in a termination, breach, impairment or violation of any applicable Law or Contract to which the Securityholder Representative is bound.

Article 7

TAX MATTERS

7.1 Tax Returns. Parent shall cause the Company and its Subsidiaries to prepare and timely file all Tax Returns for a Pre-Closing Tax Period or Straddle Period that are due after the Closing Date (the "**Parent Prepared Returns**"). Each Parent Prepared Return that is an income Tax Return or other Tax Return, in each case which shows an amount of Taxes due and payable for which the Parent would be entitled to indemnification pursuant to Article VI shall be submitted to Securityholder Representative for

its review and comment at least fifteen (15) days prior to the due date of such Parent Prepared Return (taking into account applicable extensions). Parent shall incorporate any reasonable and timely made comments made by the Securityholder Representative to such Parent Prepared Return prior to such due date to the extent such comments are sustainable on a "more-likely-than-not" basis. In the event the Securityholder Representative and Parent cannot resolve a dispute with respect to this Section 7.1, the dispute shall be referred to the Independent Accountants in a manner consistent with the procedures set forth in Section 2.12(d).

7.2 Tax Contests. Each party hereto shall notify each other after acquiring knowledge of any inquiry, claim, audit, assessment, proceeding or similar event with respect to any Taxes of the Company or any of its Subsidiaries for a Pre-Closing Tax Period (any such inquiry, claim, audit, assessment, proceeding or similar event, a "**Tax Contest**"). Any failure to so notify the Securityholder Representative of any Tax Contest shall not relieve the Company Stockholders of any liability with respect to such Tax Contest except to the extent that such failure shall have materially prejudiced the defense of such Tax Contest. Parent shall control any Tax Contest; provided, however, that, with respect to any Tax Contest that would be reasonably expected to result in material Pre-Closing Taxes for which the Company Securityholders are liable, (i) Parent shall keep the Securityholder Representative reasonably informed of the progress of such Tax Contest, (ii) the Securityholder Representative shall be permitted to fully participate in any such Tax Contest at the Company Stockholders' expense and (iii) Parent shall not settle, compromise or abandon such Tax Contest without the Securityholder Representative's prior written consent (not to be unreasonably withheld, conditioned or delayed). In the event of a conflict between this Section 7.2 and Section 6.6, this Section 7.2 shall control.

7.3 Cooperation. Parent and the Securityholder Representative agree to furnish or cause to be furnished to the other, upon request, as promptly as practicable, such information and assistance relating to Taxes, including access to books and records, as is reasonably necessary for the filing of all Tax Returns by Parent or the Securityholder Representative, the making of any election relating to Taxes, the preparation for any audit by any Tax Authority and the prosecution or defense of any claim, suit or proceeding relating to any Tax. Parent, the Company and the Securityholder Representative shall each retain all books and records in their possession with respect to Taxes of the Company and its Subsidiaries for a period of at least seven (7) years following the Closing Date. Notwithstanding the foregoing or any other provision herein to the contrary, in no event shall the Securityholder Representative be entitled to review or otherwise have access to any Tax Return, or information related thereto, of Parent or its Affiliates (other than Tax Returns of the Company for Pre-Closing Tax Periods, including pro forma Tax Returns with respect to the portion of the Straddle Period ending on and including the Closing Date).

7.4 Straddle Period. In the case of any Taxes of the Company or any of its Subsidiaries that relate to a Straddle Period, (i) the amount of any Taxes based on or measured by income or receipts, sales or use Taxes, employment Taxes, or withholding Taxes relating to the portion of the Straddle Period ending on and including the Closing Date shall be determined based on an interim closing of the books as of the close of business on the Closing Date (and for such purpose, the taxable period of any partnership, other pass through entity or any non-U.S. entity owned by the Company or any of its Subsidiaries shall be deemed to terminate at such time), provided, that exemptions, allowances or deductions that are calculated on an annual basis (such as the deductions for depreciation and real estate taxes) will be apportioned between the Pre-Closing Tax Period and the post-Closing Tax period in a manner consistent with the methodology described in clause (ii) of this Section 7.4 and (ii) the amount of any other Taxes for a Straddle Period that relates to the portion of the Straddle Period ending on and including the Closing Date shall be deemed to be the amount of such Tax for the entire taxable period multiplied by a fraction the numerator of which is the number of days in the taxable period ending on and including the Closing Date and the denominator of which is the number of days in such Straddle Period.

7.5 Transfer Taxes. Any transfer, stamp, documentary, sales, use, registration, VAT and other similar Taxes (including all applicable real estate transfer Taxes) incurred in connection with this Agreement and the transactions contemplated hereby ("**Transfer Taxes**") will be borne fifty percent (50%) by the Company Stockholders and fifty percent (50%) by Parent. The party required by Law to file any Tax Return shall prepare and timely file all necessary documentation and Tax Returns required to be filed with respect to such Transfer Taxes (with the cooperation of the other party) and shall promptly provide the other party with copies of any such documentation and Tax Returns..

7.6 Post-Closing Tax Actions. Without the prior written consent of the Securityholder Representative (which consent shall not be unreasonably withheld, conditioned or delayed), Parent and its Affiliates shall not, and shall not permit the Surviving Corporation to, take any of the following actions unless the failure to take or omission of any of the following actions would result in a violation of applicable Law: (i) file or amend or otherwise modify any Tax Return relating to a Pre-Closing Tax Period (except in accordance with Section 7.1), (ii) make, change or revoke any Tax election (including any election under Section 338 of the Code or comparable election under any other applicable Law) that has retroactive effect to any Pre-Closing Tax Period, or (iii) voluntarily approach any Tax Authority or initiate any "voluntary disclosure" or similar proceeding with respect to any Tax matter for a Pre-Closing Tax Period; provided, that the foregoing limitations shall only apply to the extent such action could reasonably be expected to create or increase the indemnification obligations of the Company Stockholders under Article VI.

Article 8

MISCELLANEOUS

8.1 Governing Law; Jurisdiction; Venue. This Agreement shall be governed and construed in accordance with the internal Laws of the State of Delaware, irrespective of its conflicts of law principles and any other Law that would cause the application of the Laws (including the statute of limitations) of any jurisdiction other than the State of Delaware. The parties hereto hereby irrevocably submit to the exclusive jurisdiction of the Court of Chancery of the State of Delaware (unless the Federal courts have exclusive jurisdiction over the matter, in which case the United States District Court for the District of Delaware) for any action, suit or proceeding arising out of or relating to this Agreement and of any of the documents referred to in this Agreement, and in respect of the transactions contemplated hereby and thereby, and hereby irrevocably waive, and agree not to assert, as a defense in any action, suit or proceeding arising out of or relating to this Agreement and of any of the documents referred to in this Agreement, and in respect of the transactions contemplated hereby and thereby, that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in said courts or that the venue thereof may not be appropriate or that this Agreement or any such document may not be enforced in or by such courts, and the parties hereto irrevocably agree that all claims with respect to such action, suit or proceeding shall be heard and determined in the Court of Chancery of the State of Delaware or the United States District Court for the District of Delaware; *provided* that a judgment rendered by such court may be enforced in any court having competent jurisdiction. The parties hereby consent to and grant any such court jurisdiction over the Person of such parties and over the subject matter of such dispute and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 8.8 or in such other manner as may be permitted by Law, shall be valid and sufficient service thereof. With respect to any particular action, suit or proceeding, venue shall lie solely in the courts of the State of Delaware in accordance with this Section 8.1, and the parties hereby agrees to waive any objection to such venue of any action, suit or proceeding arising out of or relating to this Agreement and of any of the documents referred to in this Agreement, and in respect of the transactions contemplated hereby and thereby.

8.2 Assignment. Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated, in whole or in part, by operation of law or otherwise by any of the parties hereto without the prior written consent of the other parties hereto, and any such assignment without such prior written consent shall be null and void, except that Parent may assign this Agreement to any direct or indirect wholly owned Subsidiary of Parent or to any Person who acquires all or substantially all of the assets of Parent or a majority of the outstanding voting securities of Parent (whether by merger, consolidation, share purchase or otherwise) without the prior consent of any other party hereto.

8.3 Severability. If any provision of this Agreement, or the application thereof, shall for any reason and to any extent be declared invalid, illegal or unenforceable, then the remainder of this Agreement shall remain in full force and effect and the application of such provision to other persons or circumstances shall be interpreted so as reasonably to effect the intent of the parties hereto. The parties further agree to replace such void or unenforceable provision of this Agreement with a valid and

enforceable provision that shall achieve, to the maximum extent permitted by Law, the original economic, business and other purposes of the void or unenforceable provision.

8.4 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original as regards any party whose signature appears thereon and all of which together shall constitute one and the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of all parties reflected hereon as signatories.

8.5 Other Remedies. Except as otherwise expressly provided herein, any and all remedies herein expressly conferred upon a party hereunder shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by Law or equity on such party, and the exercise of any one remedy shall not preclude the exercise of any other. The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached, and that money damages would not be an adequate remedy for any such damage. The parties hereto agree that the parties shall be entitled to equitable relief by way of an injunction or injunctions, specific performance or otherwise (without posting a bond or other security) to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of the United States or any State having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity.

8.6 Amendments and Waivers.

(a) This Agreement may be amended by the parties hereto by an instrument in writing signed on behalf of each of the parties hereto at any time before or after any approval hereof by the stockholders of the Company and Merger Sub; *provided*, *however*, that after the receipt of Written Consents constituting the Stockholder Approval, no amendment shall be made that requires further approval by the Company Stockholders under the DGCL without obtaining such requisite approval.

(b) At any time prior to the Effective Time, the Company (in the case of Parent or Merger Sub) or Parent (in the case of the Company), and at any time after the Effective Time, the Securityholder Representative (in the case of Parent or the Surviving Corporation) or Parent (in the case of the Securityholder Representative), may, to the extent not legally prohibited, (i) extend the time for the performance of any of the obligations or other acts of the other party hereunder, (ii) waive any inaccuracies in the representations and warranties of the other party contained herein or in any document delivered pursuant hereto and (iii) waive compliance by the other party with any of the agreements or conditions contained herein. Any agreement on the part of a party hereto to any such extension or waiver shall be valid only if set forth in a written instrument signed on behalf of the party against which such waiver or extension is to be enforced. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement. No single or partial exercise by a party hereto of its rights under this Agreement will be deemed to preclude any other or further exercise of such party's rights under this Agreement.

8.7 Expenses. Except as otherwise expressly provided herein, whether or not the Merger is successfully consummated, each party shall bear its own respective legal, accounting, and financial advisory fees and other expenses incurred with respect to this Agreement, the Merger and the transactions contemplated hereby.

8.8 Notices. All notices and other communications required or permitted under this Agreement shall be in writing and shall be either hand delivered in person, sent by facsimile, sent by electronic mail, sent by certified or registered first-class mail, postage pre-paid, or sent by nationally recognized express overnight service. Such notices and other communications shall be effective and be deemed delivered and received (a) upon receipt if hand delivered, (b) on the date of transmission if

transmitted by facsimile or electronic mail by 5:00 p.m. (Pacific time) on a Business Day, otherwise on the next Business Day after transmission, (c) three (3) Business Days after mailing if sent by mail, and (d) one (1) Business Day after dispatch if sent by overnight courier, to the following addresses, or such other addresses as any party may notify the other parties in accordance with this Section 8.8:

If to Parent or Merger Sub:

Parent
Orasure Technologies, Inc.
220 East First Street
Bethlehem, Pennsylvania 18015

Attention: Carrie Eglinton Manner
E-Mail: [***]

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
3025 John F. Kennedy Boulevard, 8th Floor
Philadelphia, PA 19104

Attention: Rachael Bushey, and Allison Nicklin
E-Mail: [***]

If to the Company:

Sherlock Biosciences, Inc.
115 Cedar Street N3
Milford, MA 01757
Attention: [***]
E-Mail: [***]

with a copy (which shall not constitute notice) to:

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
One Marina Park Drive #900
Boston, MA 02210
Attention: Timothy H. Ehrlich
E-mail: [***]

If to the Securityholder Representative:

Mr. Paul Meister
[***]

8.9 WAIVER OF JURY TRIAL. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH SUCH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION

DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH PARTY HERETO CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) SUCH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.9.

8.10 Interpretation; Rules of Construction. The terms "hereof," "herein" and similar terms refer to this Agreement as a whole (including the Company Disclosure Schedule and the Annexes, Exhibits and Schedules hereto), and when a reference is made in this Agreement to Annexes, Exhibits, Schedules, Sections or Articles, such reference shall be to an Annex, Exhibit or Schedule to, or Section or Article of, this Agreement, respectively, unless otherwise indicated. The words "include," "includes" and "including" when used herein shall be deemed in each case to be followed by the words "without limitation." The words "asset" or "property" shall be construed as having the same meaning and effect and to refer to any and all assets and properties, real and personal, tangible and intangible. When a reference is made to a specific law, act or statute, such reference shall include any regulations promulgated thereunder. Any agreement, instrument or statute defined or referred to herein means such agreement, instrument, or statute, in each case, as from time to time amended, modified or supplemented (in the case of agreements or instruments, if permitted under this Agreement), including in the case of statutes by succession or comparable successor statutes; *provided* that any reference to any agreement or instrument on the Company Disclosure Schedule or on any Schedule to this Agreement shall not refer to any amendment, modification or supplement thereto unless expressly set forth in the Company Disclosure Schedule or such other Schedule. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. The terms defined herein have the meanings assigned to them in this Agreement and include plural as well as the singular. Accounting terms not otherwise defined have the meaning assigned to them in accordance with GAAP. Pronouns of either gender or neuter shall include, as appropriate, the other pronoun forms. Unless stated otherwise, the terms "dollars" and "$" shall mean United States dollars. Any action required by the terms hereof to be taken on a specific day that is not a Business Day shall instead be required to be taken on the next succeeding Business Day, and if the last day of a time period specified herein is a non-Business Day, such period shall be deemed to end on the next succeeding Business Day. Any reference to any document or information having been "made available" by the Company shall only include any such document or information that has been posted in the Virtual Data Room and as to which Parent and its Representatives have been provided written notice and full access by 5:00 p.m. Eastern Time on the third (3rd) Business Day prior to the execution of this Agreement and that has remained available to Parent and its Representatives through the Closing.

8.11 Agreement Binding on the Parties; Third-Party Beneficiary Rights. This Agreement shall be binding upon and inure solely to the benefit of each party hereto and its successors and permitted assigns and nothing in this Agreement is intended to or shall confer upon any other Person (other than the Indemnified Parties) any legal or equitable rights, benefits, or remedies of any nature whatsoever under or by reason of this Agreement.

8.12 Public Announcement. Parent may issue such press releases, and make such other public announcements and disclosures relating to this Agreement, the Merger or the other transactions contemplated hereby as it determines are required under applicable securities Laws or regulatory or stock exchange rules or as it deems otherwise appropriate Neither the Company nor the Securityholder Representative shall, and each shall cause its respective Affiliates and representatives not to, issue any press releases or make any public announcements or disclosures relating to this Agreement, the Merger or the other transactions contemplated hereby without Parent's prior written consent.

8.13 Confidentiality.

(a) The parties acknowledge that the Company and Parent previously have executed the Confidentiality Agreement, which will continue in full force and effect in accordance with its terms

until the Effective Time, at which time, and without further action by any party hereto, it shall terminate and be of no further force and effect; *provided* that nothing in the Confidentiality Agreement shall be deemed to restrict Parent's rights under Section 8.12. If this Agreement is, for any reason, terminated prior to the Closing, the Confidentiality Agreement shall continue in full force and effect in accordance with its terms.

(b) The Securityholder Representative hereby agrees to hold this Agreement and the transactions contemplated hereby, and all information received by the Securityholder Representative with respect hereto or thereto or in connection herewith (including any information obtained with respect to any Claims), in confidence and not disclose the existence or terms hereof or any such information to any third party (other than the Indemnifying Securityholders or legal counsel engaged by the Securityholder Representative, in each case solely to the extent necessary to perform its obligations hereunder and only if such Persons are subject to an obligation to keep such information confidential).

8.14 Entire Agreement. This Agreement, the Exhibits and Schedules hereto, the Company Ancillary Agreements, the Company Disclosure Schedule, the Parent Ancillary Agreements, the Confidentiality Agreement and the Merger Sub Ancillary Agreements constitute the entire understanding and agreement of the parties hereto with respect to the subject matter hereof and supersede all prior and contemporaneous agreements or understandings, inducements or conditions, express or implied, written or oral, between the parties with respect hereto or thereto. The express terms hereof control and supersede any course of performance or usage of the trade inconsistent with any of the terms hereof.

[**Signature Pages Follow**]

In Witness Whereof, the parties hereto have executed this Agreement as of the date first above written.

PARENT

ORASURE TECHNOLOGIES, INC.

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

MERGER SUB

PROJECT WATSON MERGER SUB, INC.

By: /s/ Carrie Eglinton Manner
Name: Carrie Eglinton Manner
Title: President

In Witness Whereof, the parties hereto have executed this Agreement as of the date first above written.

COMPANY

SHERLOCK BIOSCIENCES, INC.

By: /s/ Bryan Dechairo
Name: Bryan Dechairo
Title: Chief Executive Officer

In Witness Whereof, the parties hereto have executed this Agreement as of the date first above written.

SECURITYHOLDER REPRESENTATIVE

By: /s/ Paul Meister
Name: Paul Meister

ORASURE TECHNOLOGIES, INC.

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

(Effective as of May 2, 2023)

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 with which the Company or any of its subsidiaries has a 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.

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.

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 and executive officers (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.

5. 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
Sherlock Securities Corporation	Massachusetts
221B Foundation	Delaware
Sense Biodetection Limited	England and Wales
Sense Biodetection Inc	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-262633) on Form S-3 and registration statements (Nos. 333-281500, 333-270863, 333-270861, 333-248424, 333-220148, 333-198237, 333-176315, 333-151077, 333-138814, 333-118385, 333-102235, 333-50340) on Form S-8 of our report dated March 11, 2024, except for Note 13, 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 7, 2025

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 7, 2025, 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, 2024. We consent to the incorporation by reference of said reports in the Registration Statements of OraSure Technologies, Inc. on Form S-3 (File No. 333-262633) and on Forms S-8 (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, and File No. 333-50340).

/s/ GRANT THORNTON LLP

Philadelphia, Pennsylvania
March 7, 2025

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, 2024, 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 28, 2024.

/s/ Mara G. Aspinall
Signature

Mara G. Aspinall
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2024, 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 28, 2024.

/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, 2024, 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 28, 2024.

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

Nancy J. Gagliano, M.D.
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2024, 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 28, 2024.

/s/ Lelio Marmora
Signature

Lelio Marmora
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2024, 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 28, 2024.

/s/ Robert W. McMahon
Signature

Robert W. McMahon
Print Name

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that the undersigned constitutes and appoints **Michele Anthony and Stefano Taucer,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2024, 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 28, 2024.

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

David J. Shulkin, M.D.
Print Name

Exhibit 31.1

Certification

I, Carrie Eglinton Manner., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 7, 2025

/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 7, 2025

/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, 2024 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 7, 2025

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, 2024 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 7, 2025